ıtes
ıntal Protection
bstances

Office of Toxic Substances
Washington, DC 20460

EPA-560/3-86-002
March 1986

EPA New Chemical Review

Process Manual

EPA-560/3-86-002
March 1986

Office of Toxic Substances
U.S. Environmental Protection Agency

Contents

Introduction

The purpose of this manual is to provide an introduction to the new chemical review process as it takes place in the Office of Toxic Substances (OTS). Organized chronologically, the manual presents the process in terms of component procedures and meetings. The description of each meeting includes a discussion of objectives, participants, preparation, and accomplishments (decisions and written output). Divisions and branches that participate in the process are described in Appendix A, Functions of Divisions and Branches in the New Chemical Review Process. A flow diagram of the new chemical review process may aid understanding of the text; the New Chemical Review Process Diagram can be found in Appendix C. Reports are discussed in the context of preparation for a meeting or as written output resulting from a meeting. The manual also presents EPA's statutory authority and options for action under §5 of the Toxic Substances Control Act (TSCA).

New chemical review is mandated by TSCA. Any person who intends to manufacture or import a new chemical substance is required to provide to EPA available data on the chemical structure, production, use, release, exposure, and health and environmental effects. The submitter of new chemical information may claim that any part of the data supplied to EPA is entitled to confidential treatment. Confidentiality procedures have been developed to protect such information (see Appendix E). In reviewing and regulating new chemicals, EPA utilizes an integrated approach that draws on knowledge and experience across disciplinary and organizational lines to identify and evaluate concerns regarding health and environmental effects, exposure and release, and economic impacts.

Submissions that activate new chemical review may be either a Premanufacture Notice (PMN), a polymer or low volume exemption notice, or test marketing exemption application. Exemption applications and notices take certain production or chemical parameters into account that, if verified to meet requirements, exempt the manufacturer of the substance from being subject to an entire PMN review process.

The manual contains seven chapters as follows:

- Chapter I, "Pre-Notice," describes procedures that take place up to the time that the submission is received by EPA;
- Chapter II, "Pre-Notice/Receipt to Focus Meeting," describes procedures and meetings that take place up through the Focus Meeting, which is the first point in the process at which a regulatory decision is made;
- Chapter III, "Focus to Division Directors' Meeting," describes the process that guides development of cases that remain in review after Focus;
- Chapter IV, "Action," describes EPA's options for actions under §5 of TSCA and circumstances under which EPA will litigate to regulate under §5;
- Chapter V, "Exemptions," describes submitter requirements and EPA procedures regarding exemption applications and notices;
- Chapter VI, "Follow-Up Review," describes activities to evaluate possible new uses of chemicals referred by new chemical review and to assess the hazard potential of such chemicals under changed conditions;
- Chapter VII, "Post-Review," describes procedures for Notice of Commencement, substantiation of confidentiality claims, and generic name development.

Appendices A through G, the Glossary of terms and abbreviations used in the manual, and the Bibliography, provide additional information pertaining to new chemical review in OTS. Appendix A is a table, "Functions of Divisions and Branches in the New Chemical Review Process." Appendix B is an OTS organizational chart, Appendix C is a flow diagram of the new chemical review process, and Appendix D is a meeting schedule. Appendix E discusses confidential business information, Appendix F provides a list of major databases searched, and Appendix G is the form that submitters complete for new chemical review. The Bibliography provides citations for background materials regarding legal authority and regulatory development of new chemical review.

I. Pre-Notice

A. Pre-Notice Searches of the Inventory

Prior to the manufacture or import of a new chemical substance, a person may wish to ascertain if the substance is already on the unpublished, non-confidential, or confidential sections of the Toxic Substances Control Act Chemical Substance Inventory (TSCA Inventory). Non-confidential search requests for adequately defined chemical substances may be submitted to the Inventory Inquiry Service at Chemical Abstracts Service. Non-confidential search requests of a more complex nature (e.g., tradename products) may be sent to the Chemical Inventory Section (CIS) of the Confidential Data Branch/Information Management Division (CDB/IMD) at EPA.

A manufacturer may also request a search of the confidential section of the TSCA Inventory by submitting a statement of bona fide intent to manufacture a substance (a bona fide) to EPA (see 40 CFR 710.7 (g) and 720.25). The bona fide is received by the Confidential Document and Systems Control Section (CDSCS) of the Confidential Data Branch (CDB/IMD), which logs and tracks the submission into the Document and Personnel Security System (DAPSS) before routing it to CIS for processing. See Receipt Section for a description of DAPSS. The general information contained in the bona fide is reviewed by a CIS staff member to render a judgment of complete or incomplete according to prescribed requirements. Substance identity information is evaluated by a chemist in CIS to determine if the chemical name and structure provided by the submitter are adequate to perform an accurate search of the TSCA Inventory. The following information must be contained in a bona fide:

1) Specific chemical identity of the substance,
2) A signed statement of intent,
3) An elemental analysis,
4) Intended use,
5) Analytical data (i.e., infrared spectral analysis), and
6) A description of research and development activities conducted to date on the substance.

CIS coordinates the search of the TSCA Inventory for the substance with the Inventory contractor, Chemical Abstracts Service (CAS). A CIS chemist assures that the CAS search results are accurate and in keeping with Agency policy concerning Inventory listings. The CIS chemist also contacts submitters of bona fide notices as necessary to resolve problems of chemical nomenclature and chemical structure. Following this search, CIS prepares a response to the submitter including the CAS-preferred name and CAS Registry Number or TSCA Inventory accession number. The submitter is thus given the correct name for use in a future PMN or in future reports to EPA for on-Inventory chemicals. The response letter is returned along with the bona fide submission to CDSCS, which logs results of the search into DAPSS.

The time required to process a complete bona fide is normally 30 days; however, review time can be extremely variable for bona fides determined to be incomplete. If the bona fide substance is on the TSCA Inventory, a PMN or exemption application or notice is not required. If the substance is not on the TSCA Inventory, manufacturers and importers may consider submitting a PMN, polymer or low volume exemption notice, or application for a test market exemption if appropriate. Otherwise, the manufacturer or importer must complete the PMN form for any intended uses of the chemical subject to new chemical review under §5 of TSCA. See Receipt section for a description of the information content and processing of the PMN form.

B. Pre-Notice Communications

The Pre-Notice Communications Coordinator in the Premanufacture Notice Management Branch of the Chemical Control Division (PNMB/CCD) assists persons preparing a notice or considering the submission of a notice. Pre-Notice inquiries may pertain to the scope of TSCA and Premanufacture Notification requirements. Questions on subjects such as information requirements for a submission, §5 exemptions, premanufacture testing, confidentiality, bona fides, generic name development,

consolidated notices, joint submissions, and notice review procedures are asked of the Pre-Notice Communications Coordinator. The Pre-Notice Communications Coordinator:

1) Responds to telephone inquiries and letters providing guidance on technical, regulatory, and procedural issues,
2) Coordinates conferences at the request of industry persons prior to submissions,
3) Serves as an interface between the Agency and persons seeking approval for consolidated PMN submissions and generic chemical names, and
4) Interacts with other OTS offices (including the Industrial Chemistry Branch of the Economics and Technology Division (ICB/ETD), Chemical Engineering Branch of the Economics and Technology Division (CEB/ETD), Confidential Data Branch of the Information Management Division (CDB/IMD), and Regulatory Program Development Branch of the Chemical Control Division (RPDB/CCD)) to ensure consistency of technical and regulatory response.

ICB/ETD and CDB/IMD interact with the Pre-Notice Communications Coordinator in responding to inquiries regarding technical aspects of reporting requirements, when appropriate.

C. Receipt

On the day of receipt, the PMN or exemption application or notice is reviewed by the Confidential Document and Systems Control Section of CDB/IMD for completeness. In cases where the submission is incomplete, the submitter is notified by telephone followed by a formal notice by registered mail. Day 1 of the review period is then delayed pending submitter response. CDSCS/IMD also acknowledges receipt of completed submissions through formal letters. A completed PMN form includes the following information on the new chemical substance:

1) Submitter identity and plant site information,
2) Chemical identity,
3) Production, import, and use data,
4) Human exposure and environmental release data,
5) Test data, e.g., fate, mammalian toxicity, aquatic toxicity, and
6) Sanitized version if any information is claimed confidential.

Following the review for completeness, CDSCS/IMD then reviews the submission for confidentiality claims. If the submission is judged to be complete, the notice period begins. An ICB/ETD chemist then reviews the chemical identity and other technical information in PMN submissions and exemption applications and notices for conformance with §5 rules and policies, generic name development, and clarification of proposed uses. PMNs must be reviewed within 90 days of receipt, unless the Agency, for good cause, extends the review period for up to an additional 90 days. Polymer exemption notices and low volume exemption applications must be reviewed within 21 days of receipt, unless EPA extends the review period. The Agency can at any time grant a suspension of the review period upon request by a submitter, for example, to develop additional data or review options. Test market exemption applications must be reviewed within 45 days.

On the day that a completed PMN or exemption application or notice is received, tracking procedures are initiated by the Confidential Document and Systems Control Section of CDB/IMD. CDB/IMD attaches a green cover to the CBI submission, assigns a document control number (appropriate to the type of submission) and a case number, and logs the document into several information systems. DAPSS, the Document and Personnel Security System, records and monitors the receipt, tracking, and archiving of all TSCA documents. Every report generated by the new chemical review process is tracked through DAPSS as well as all submitter input. DAPSS also maintains the TSCA CBI Access List, which contains clearance information for Federal employees and contractors. The Management Information Tracking System, MITS, a non-confidential system, serves many functions throughout the review period including generation of weekly case status reports, review schedules, and support for reviewers through programmed information retrieval.

Submission data is entered by CDSCS into PENTA, a confidential information system that stores scientific and regulatory information from all cases submitted under §5 of TSCA and from most reports generated by new chemical review. One primary use of PENTA is to identify structural, functional, and/or use analogues. Each submission has a pre-review search by CDSCS in PENTA,

to locate exact matches or analogues. CIS/CDB/IMD searches the TSCA Inventory to gather background information (see Inventory Procedures, page II-1). The results of the IMD searches for related cases are passed on to the Premanufacture Notice Management Branch/Chemical Control Division (PNMB/CCD), the Industrial Chemistry Branch/Economics and Technology Division (ICB/ETD), and to the Exposure Assessment Branch/Exposure Evaluation Division (EAB/EED). Together these branches narrow the list of possible analogues to those most relevant. PNMB/CCD then begins preparation of a related case summary for the Focus meeting.

The Confidential Document and Systems Control Section of IMD routes a confidential version of each submission to the Confidential Business Information Center (CBIC) of OTS for reproduction and makes submissions available to case reviewers. CDSCS routes a non-confidential version of each submission (prepared by the submitter or CDSCS) to the OTS public information office and prepares a Federal Register notice from the non-CBI submission.

A. Inventory Procedures

Concurrent with acknowledgment to the submitter of receipt of a bona fide, PMN, or exemption application or notice and data entry procedures within IMD, the public and confidential portions of the TSCA Inventory are searched for the substance by the Chemical Abstracts Service (CAS). Information from CAS is reviewed by chemists in the Chemical Inventory Section (CDB/IMD), who use this information to verify whether the substance is on the TSCA Inventory. CIS chemists assure that the Inventory search results are in keeping with Agency policy concerning Inventory listings and chemical nomenclature. CIS chemists interact with ICB chemists as needed when performing this review; in addition, CIS chemists contact submitters, in coordination with PNMB, as necessary to resolve problems of chemical nomenclature and chemical structure. If the substance is on the TSCA Inventory, the PMN, low volume exemption notice, or test market exemption application number assigned to the substance is retained and a disposition code is assigned. The submitter is notified of the results of the Inventory search, and no further review work is conducted on the submission.

CIS ensures that chemical names assigned to non-confidential as well as confidential chemicals entering the Inventory at the end of new chemical review are accurate and appropriate descriptions of substances. CIS also develops generic names for the confidential portion of the TSCA Inventory in cooperation with the submitter.

Chemical names assigned to new substances that have been received under polymer exemptions are added to the Inventory along with descriptive information about structure (e.g., molecular weight composition, residual monomer levels). Chemicals that are subjects of test market exemptions are not added to the Inventory. Substances that have been approved under low volume exemption are automatically added to a searchable file, which is not a part of the TSCA Inventory. Test market and low volume exemptions require no notice of commencement (NOC).

B. Chemistry Review and Search Strategy (CRSS) Meeting

At the CRSS meeting, chemical information is evaluated for all submissions accepted pursuant to §5 of TSCA. Chemical nomenclature, structure, physical and chemical properties, reactions, technical aspects of use, and other relevant information is reviewed for completeness, consistency, and accuracy. Determinations are made as to conformance with technical aspects of §5 rules and policies. The development of further chemical data, analogous substances, and ambiguous information is discussed. This meeting occurs between day 8 and day 12 in the review process.

CRSS is led by a senior staff person from the Industrial Chemistry Branch/Economics and Technology Division (ICB/ETD). The ICB/ETD provides industrial chemistry and related technical evaluations to all OTS Divisions to support both risk assessments and non-regulatory decisionmaking. Attending the CRSS meeting are all ICB chemists and the Section Chief of the New Chemicals Section of ICB.

Prior to the CRSS meeting, an ICB chemist responsible for making assignments will review copies of PMNs, low volume exemption notices, and test market exemption applications received by IMD. Specific cases are linked to expedite review. Preliminary estimates of required chemistry effort are made for each case and group of related cases and the cases are assigned. In addition, the generic chemical names for substances that have confidential chemical identities are evaluated for acceptability for publication in the §5(d)(2) Federal Register Notice. The published CRSS meeting agenda is coordinated with CEB and PNMB assignments to help expedite the evaluation of related substances.

Two to three working days before the CRSS meeting, chemists begin to: evaluate the chemistry and related data; seek clarification from submitters; solve any §5(d)(2) generic name problems; provide technical support to and coordinate with CIS/IMD on TSCA Inventory searches, and initiate search requests on unusual, associated substances; review routine PENTA searches for analogues and matches; conduct manual and computer-assisted literature searches; calculate properties using estimation methods; and prepare draft chemistry reports including large structural representations used as visual aids in review process meetings.

At the meeting, chemists review chemical nomenclature including the generic name, structure,

critical physical properties such as vapor pressure and solubility in water, chemical properties such as hydrolysis rates and extent of dissociation, the practical applications intended, and related data for the substances under review. The review of some PMNs and exemption notices and applications may be terminated based on established criteria and professional judgment.

The written output of the CRSS meeting is a partially completed Chemistry report that reflects CRSS discussions and further information development. The report represents validated chemical data including the ICB's chemical indexing of the identity for PENTA. A CRSS drop form is completed for those submissions whose reviews have been terminated.

C. Structure-Activity Team (SAT) Meeting

The structure-activity team (SAT) predicts hazard potential for new chemicals based on such things as physical/chemical properties, data on analogous chemicals, knowledge of chemical reactivity, and, occasionally, on data on the new chemical itself. The SAT meeting occurs between day 9 and 13 (on the day following the CRSS meeting).

The team is chaired by the SAT coordinator from the Toxic Effects Branch/Health and Environmental Review Division (TEB/HERD). The coordinator, or a HERD senior staff member, presides at the SAT meeting and is responsible for recording the deliberations of the team. Members of the SAT are drawn largely from the branches of HERD, but also include representatives from ICB/ETD, the Exposure Assessment Branch/Exposure Evaluation Division (EAB/EED), and the Chemical Screening Branch/Existing Chemical Assessment Division (CSB/ECAD).

For each chemical considered at the SAT meeting, a representative from ICB/ETD presents findings from the CRSS meeting and clarifies chemistry questions raised by the SAT. An environmental fate profile is presented by a representative from EAB/EED. The SAT chair presents information on related chemicals from PMN files, PENTA searches, and from published literature. Following presentation of background data, the team discusses absorption, metabolic fate, and potential health effects. A representative from the Environmental Effects Branch (EEB/HERD) delivers the ecotoxicity report.

Based on information presented by meeting participants, the SAT assigns a hazard concern rating to the substance for potential health and ecological hazards.

The written output produced as a result of the SAT meeting is a SAT report. The discussions and evaluations of the SAT meeting are summarized in this report. In addition to the meeting summary, a complete SAT report includes listing of physical/chemical properties, discussion of chemical fate in wastewater treatment and in the environment, toxicity test data summaries, and basis for Quantitative Structure-Activity Relationships (QSARs).

D. Exposure Assessment Meeting (EXAM)

EXAM establishes a preliminary profile of exposure and release for new chemicals that are not under the polymer or low volume exemptions or CRSS drops. Consumer and worker exposure, environmental release, and environmental fate and possible treatments are evaluated. This meeting takes place between day 12 and 16.

EXAM is co-chaired by members of the Exposure Assessment Branch/Exposure Evaluation Division (EAB/EED) and by the Chemical Engineering Branch/Economics and Technology Division (CEB/ETD). EAB/EED has the responsibility to estimate physical/chemical properties; evaluate the fate of the chemical in wastewater treatment, surface water, ground water, soil, sediment, and air; and estimate all potential human exposures to the chemical except occupational exposure and all exposures of environmental biota. CEB/ETD reviews PMNs and exemption notices and applications to determine sources of environmental release, release rate estimates, production technologies, controls to limit releases and exposures, and occupational exposure. Also attending the EXAM meeting is a representative from ICB/ETD. Representatives from the Design and Development Branch/Exposure Evaluation Division (DDB/EED) may also be assigned to cases serving as EED exposure assessors.

Prior to the meeting, EXAM participants review the draft Chemistry report and a brief summary of the SAT report. The CEB engineer prepares information on worker exposure and environmental release and controls likely to be used. The EED assessor prepares exposure information that may pertain to consumer, environmental biota, drinking water, or other exposures. ICB/ETD provides a brief version of their report to EXAM members.

At the EXAM meeting, chemistry is presented by a senior ICB/ETD representative. Following this, a brief statement on health and ecotoxicity concerns is presented from the SAT report. The CEB engineer presents findings on worker exposure, environmental release, personal protective equipment, and engineering control options. The EED assessor presents findings on physical/chemical properties; predictions of environmental fate in wastewater treatment, surface water, septic tanks, soil and landfills; environmental releases resulting from the use of consumer goods; human exposures to the chemical (except occupational exposure); and all exposures of environmental biota.

Two written outputs are produced as a result of the EXAM meeting: an EXAM report covering the EED assessment, and an Engineering report covering the CEB assessment.

E. Focus Meeting

The Focus meeting examines the results of the CRSS, SAT, and EXAM meetings to decide which issues need further investigation. The Focus meeting is the first point in the process at which a regulatory decision is made based on both hazard and exposure. If no further investigation is warranted, the reviewers may decide to drop the case from further review at Focus. This meeting takes place between day 15 and 19.

Focus is led by the Branch Chief of the Premanufacture Notice Management Branch/Chemical Control Division (PNMB/CCD). PNMB is responsible for overseeing and managing the evaluation and disposition of PMNs and exemption notices and applications within the regulatory time frame and assigns a Program Manager to coordinate the PMN review. Representatives from the CRSS, SAT, and EXAM meetings attend Focus to present their findings. Also attending the Focus meeting are senior staff and managers from EED, HERD, and ETD. The Program Manager may attend but is not required to be present.

Prior to the Focus meeting, a Focus schedule is prepared. PNMB prepares a regulatory history of selected analogues (from the PENTA search and the SAT summary). A Regulatory Impacts Branch/ Economics and Technology Division (RIB/ETD) economist does a preliminary assessment of the case. HERD holds an informal meeting where TEB, the Oncology Branch (OB), and the Chemical Review and Evaluation Branch (CREB) review the SAT report and information on related cases. EAB/EED prepares SAT and Initial EXAM Chemical Fate reports on low volume exemptions.

At the meeting, ICB presents chemistry, and HERD presents human and environmental toxicity evaluations (a SAT meeting summary). The engineer from CEB and exposure assessor from EAB summarize the Engineering report and the EXAM report, respectively. Based on a preliminary assessment for some cases (criterion is based on SAT evaluations), a RIB/ETD representative may recommend that the substance be referred to the Follow-up program if there is evidence indicating that uses other than those cited in the submissions are possible and/or production volume is likely to increase.

Based on a consensus of meeting attendees, the Focus meeting leader decides whether to proceed with further evaluation, or to drop the case. If concerns are identified at the Focus meeting, the case enters Standard Review. If no concerns are identified, the case is dropped. When appropriate, cases (whether dropped or continuing in review) may be referred to Follow-up. The case enters Follow-up Review to investigate potential other uses or increased volumes that would lead to increased exposures if concerns are identified either at Focus or during the review, but are mitigated by low volume and/or low exposure.

Two written outputs are produced as a result of the Focus meeting: a set of Focus notes and an Assignment sheet (for those chemicals continuing in review). Focus notes highlight the Focus meeting and contain results of SAT and EXAM meetings. Case review team members assigned by support branches and scheduled meetings are listed on a MITS-generated Assignment sheet, which is distributed by the Program Manager.

A. Workplan Meeting

At the Workplan meeting, the objectives of the Standard Review process for each PMN that is not dropped at Focus are clarified, and assignments and scheduling are discussed. This is the first time that the case review team meets to address decisions made at the Focus meeting. This meeting is held between day 23 and 27.

Workplan is led by the PNMB/CCD Program Manager and is always attended by a Technical Integrator (TI) from CREB/HERD, the Chemical Review and Evaluation Branch of HERD. The TI assigned by CREB on the day following the Focus meeting has the primary lead for technical discussions at the Workplan meeting. The TI is responsible for technical oversight and integration of hazard and exposure information to produce risk assessments. The case chemist, economist, chemical engineer, hazard and exposure assessors, and Information Services Section (ISS) representative also attend the Workplan meeting.

Prior to the meeting, Focus notes are prepared and all documentation and reports prepared prior to the Workplan meeting are available for review by Workplan meeting attendees. The Program Manager is responsible for knowing Focus decisions and issues raised for special attention.

At the meeting, the Program Manager transmits information concerning Focus decisions and issues of concern to case reviewers. The TI is responsible for developing questions to resolve hazard and exposure issues raised at the Workplan meeting. When necessary, ISS is asked to perform literature searches.

Following the Workplan meeting, the TI distributes the results of literature searches to case reviewers. The TI works to resolve technical issues with hazard reviewers, exposure assessors, the engineer, and the chemist. The TI briefs the Program Manager on progress of the technical components of the case. The Program Manager maintains contact with the TI, exposure assessor, economist, attorney and PMN submitter during Standard Review, and is responsible for informing the submitter that the case has entered Standard Review. ISS may retrieve hard copies of the literature for case review.

Written output is produced within two days of the Workplan meeting; the TI provides to the Program Manager a list of questions developed from the Workplan meeting. The Program Manager reviews and distributes questions to the relevant case reviewer. Draft reports are due approximately 15 days after the Workplan meeting.

B. Mid-course Meeting

The Mid-course meeting assesses the progress of the case and integrates submitted reports. The meeting is held to discuss whether the PMN is ready for CCD Disposition and, if not, how much more work is required. The Program Manager may decide to recommend discontinuing the review of the case or may choose to continue the review if more in-depth work is needed. This meeting is held three to four weeks after the Workplan meeting (approximately day 44-48).

Mid-course is led by the Program Manager. The TI, as well as the case reviewers, attends the Mid-course meeting.

Prior to the Mid-course meeting, each reviewer is required to submit a draft that contains all information known up to that point and identifies data gaps. Hazard reports are reviewed and integrated by the TI. Exposure, release, chemistry, and economic reports are submitted to the Program Manager. The Program Manager is responsible for notifying the TI of receipt of these reports and their contents.

At the meeting, the Program Manager and the TI decide what remains to be done and how much time is required. The Program Manager may decide to drop the case (or a portion of the case) at CCD Disposition because of assessments discussed at Mid-course.

Based on information presented at Mid-course, recommendations are made to determine whether (1) concerns are adequately addressed, (2) concerns require additional resources to be addressed, or (3) evaluation of issues identified at Focus indicates that regulation should not be pursued. ISS may conduct more searches to meet the needs for continued case review.

No formal written output results from the Mid-course meeting. However, if a case is continued, draft reports are revised in response to recommendations made at Mid-course.

C. CCD Disposition Meeting

The CCD Disposition meeting resolves questions on the need for further review of cases. The CCD Disposition participants may drop cases or concerns from review if data gaps or inconsistencies can be resolved. A CCD Disposition meeting (and drop) can occur any time after the Mid-course meeting.

The CCD Disposition meeting is led by the Branch Chief of PNMB. Senior staff persons from CCD, HERD, ETD, EED, and each supporting branch attend. This meeting is also attended by the Program Manager and TI.

Prior to the CCD Disposition meeting, the Program Manager prepares an Analysis of Disposition Options report based on all of the reports and decisions developed up to this point.

At the meeting, cases may be dropped from further review if issues can be resolved. In some cases, additional resources will be assigned to a case in order to address concerns.

Written output produced as a result of a CCD Disposition meeting is a Final Disposition Summary that is written by the Program Manager for cases dropped as a result of decisions made at CCD Disposition. If a case is dropped at a CCD Disposition meeting, then draft reports become final reports. Concerns and decision rationales will be reported for those cases that remain in the review process following CCD Disposition.

D. ETD Disposition Meeting

The ETD Disposition meeting provides an opportunity for ETD management to review assessments in areas of chemistry, engineering and economics, and prepares the Director of ETD for the Division Directors' meeting. The ETD Disposition meeting is held between day 57 and 65.

The meeting is chaired by the ETD Director and attended by the Branch Chiefs, Section Chiefs, and individual case reviewers from CEB, ICB, and RIB. The Program Manager and TI may attend.

Prior to the ETD Disposition meeting, the first drafts of reports prepared by ICB, RIB, and CEB are revised as new information on the case surfaces and comments are received from the Program Manager and TI.

At the ETD Disposition meeting, the chemist assigned from ICB presents chemistry review results; the engineer from CEB presents worker exposure, environmental release results, and control alternatives; and the economist from RIB presents findings on available substitutes and socioeconomic analyses.

The written output produced as a result of the ETD Disposition meeting is the ETD Disposition Meeting Summary. This summary covers the conclusion of the ETD review and serves as the ETD Director's briefing material for the Division Directors' meeting.

E. HERD Disposition Meeting

At the HERD Disposition meeting, the TI briefs HERD management on the case. The outcome of the meeting is a decision on whether the new chemical in review presents a potential health or ecological hazard and, if so, whether there is sufficient exposure to the chemical to pose a potentially significant risk. Recommendations for appropriate tests to address data gaps are also made at the meeting. The meeting ordinarily falls between day 57 and 65 of the review process.

The HERD Disposition meeting is chaired by the Deputy Director of HERD and is attended by HERD managers and senior scientists, case reviewers from HERD, the Program Manager, and the TI.

Prior to the meeting, the TI prepares a support document consisting of final assessments from HERD reviewers, together with a risk assessment summary written by the TI. The summary consists of background information on the chemical, brief descriptions of potential toxic effects and exposures, conclusions about potential risk, and testing recommendations. Following the HERD Disposition meeting, the support document is logged into the CBIC.

The written output produced as a result of this meeting is a HERD Disposition Meeting summary, which contains issues that bear on determination of potential risk, disposition decisions, and testing recommendations.

F. PNMB Options Meeting

At the PNMB Options meeting, the Program Manager presents the PMN case, with recommended options, to the Branch Chief and Section Chiefs of PNMB. Regulatory recommendations are assess-

ed for feasibility from a legal standpoint. This meeting occurs on about day 72 to 75 (shortly before the Division Directors' Briefing).

The PNMB Options meeting is chaired by the Branch Chief of PNMB. Attending the meeting are the Program Manager, the Branch Chief of PNMB, PNMB Section Chiefs, and an attorney from PNMB.

Written output produced as a result of the Options meeting is the Division Directors' Briefing Paper, which is prepared by the Program Manager. This briefing paper characterizes the potential toxicity of the PMN substance and identifies issues of concern regarding the substance.

G. Division Directors' Briefing

The Division Directors' Briefing is held 1) to brief the Division Directors of CCD, EED, ETD, and HERD, and the Deputy Director of OTS on PMN cases; and 2) to determine what action will be taken on PMN substances. The meeting takes place between day 79 and 82.

The meeting is chaired by the Deputy Director of OTS and is attended by Directors of CCD, EED, ETD, HERD, the Program Manager, and the Technical Integrator. Other Branch Chiefs involved in the review and a representative from the Office of General Counsel (OGC) also attend. The Program Manager or the TI also requests that certain case reviewers attend the Division Directors' Briefing.

Prior to the meeting, the Division Directors' Briefing paper is made available for review. In the event that RIB/ETD identifies (a) substitute(s), HERD makes a relative hazard finding of the new chemical as compared with the substitute(s).

At the meeting, the Program Manager briefs the Division Directors and recommends regulatory action regarding a PMN substance. Following discussion, the Division Directors decide what the final action (if any) will be.

As a result of the briefing, the Directors will either 1) initiate a Consent or Unilateral §5(e)/5(f) order or rule to control, limit, or ban manufacture, processing, distribution in commerce, use, or disposal of the substance (see Action, page IV-1); 2) enter into a voluntary (or informal) agreement with the submitter (e.g., upfront testing); 3) refer the case for Follow-up; 4) drop the PMN from further consideration; or 5) request further case review and revisit at a later Division Directors' Briefing.

Written output from this meeting is a Division Directors' Briefing Summary that is prepared by PNMB. The report records all salient points of discussion, the final disposition of the PMN, and includes rationale and logic for decisions and supporting documentation.

At the end of the PMN review period, EPA has the authority under TSCA §5 to issue a limitation or ban on a new chemical substance if the Agency can demonstrate that the manufacture, processing, use, distribution in commerce, or disposal of the substance may present an unreasonable risk of injury to health or the environment and/or the substance may be manufactured in substantial quantities and either enters the environment in substantial quantities or there may be significant human exposure to the substance. Section 5(c) of TSCA authorizes certain extensions in the PMN review period, §5(h)(1) allows exemption of manufacturers and importers of new chemical substances for test marketing from PMN requirements under new chemical review, and §5(h)(4) also allows manufacturers/importers of some polymers, low volume chemicals, and other applicable substances to apply for exemptions. EPA's options for actions under §5 are explained in the following sections.

A. §5(c) Extension Notice

The §5(c) Notice is the vehicle by which the new chemical review period can be extended up to 90 additional days. The additional time allows EPA to complete its review, to assess the merits of the case, and to determine whether a §5(e) Order or §5(f) action is appropriate. (For polymer exemption notices, which have a 21-day review period, EPA can extend the review back to 90 days and use §5(c) to add up to an additional 90 days.)

B. §5(e) Order

At the end of the review period for a PMN submission, EPA may issue a proposed order prohibiting or limiting the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance. EPA may take this action if it is determined that:

Available information on the substance is insufficient to determine its health and/or environmental effects, and

a) the manufacture, processing, distribution in commerce, use, or disposal of the substance may present an unreasonable risk, or

b) the substance is or will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure.

A §5(e) Order may be issued as a "Consent Order" where EPA and the manufacturer or importer agree to certain conditions, or as a "unilateral order" in which the company does not enter into agreement on the conditions of the EPA order. These conditions may include testing requirements, use of protective equipment by workplace employees, or monitoring for exposure and release.

A decision to issue a §5(e) Order is based on an assessment of the hazards and exposure information detailed in the documents prepared up to and through the Division Directors' meeting. The Program Manager, PNMB attorney, case reviewers, and OGC are on the workgroup to participate in drafting a §5(e) Order which, if adversarial, must be served on the submitter no less than 45 days before the close of the review period. An abbreviated Red Border review asks for concurrence of OGC and the Office of Program Planning and Evaluating (OPPE). The Assistant Administrator for the Office of Pesticides and Toxic Substances must approve and sign the §5(e) Order unless irreconcilable objections have been raised by OGC or OPPE. (In this case, the EPA Administrator makes the final decision to issue the §5(e) Order.)

C. §5(f) Action

Under §5(f), EPA has the authority to issue an order banning or a rule limiting the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance based on a finding that the manufacture, processing, distribution in commerce, use, or disposal of the substance will present an unreasonable risk of injury to human health or the environment before a TSCA §6 rule could be issued to prevent such risk.

The participants and background materials required to process a §5(f) action are the same as those for a §5(e) Order. However, a §5(f) action must be approved by the EPA Administrator. Thus, there must be a Red Border review (Agency-wide review procedure).

D. Litigation

If the submitter files objections to a unilateral §5(e) or §5(f) proposed Order within 30 days after it is issued, the Order does not go into effect. Once objections to the §5(e) Order are received, it is assumed that litigation will take place unless the objections change EPA's conclusion that restrictions are necessary. EPA's OGC must go to a U.S. District Court to ask for an injunction to put the Order into effect. OGC works with the Department of Justice, which assigns an attorney to help litigate the case. OGC's potential involvement in litigation requires OGC attorneys to be in a position to evaluate objections to proposed §5(e) and §5(f) Orders. An OGC representative usually attends the Division Directors' meetings to contribute to decisions regarding possible §5(e) and §5(f) actions, and OGC reviews all §5(e) and §5(f) Orders that result from the new chemical review process.

OGC begins to organize the preparation of affidavits and other materials to support a §5(e) or §5(f) injunctive action. The following documents may be prepared depending on the nature of the objections to the §5(e) or §5(f) Order:

1) An affidavit concerning exposure/release potential as well as economic analysis (prepared by EED and ETD),
2) An affidavit on potential human health and/or environmental effects/toxicity (prepared by HERD),
3) An affidavit from CCD explaining how the PMN program works and how the PMN was reviewed, and
4) A revised risk assessment that addresses any new information received in the objections (prepared by HERD).

OGC assists the OTS divisions in the preparation of the affidavits needed for the injunctive action, if necessary.

A. Test Market Exemption

A company that wants to assess the marketability of a new chemical substance may apply for a test market exemption (TME) under TSCA §5(h)(1). TME applications are responded to within 45 days and are processed in the same manner as PMNs from receipt to the Focus meeting. During the 45-day period, the test market application is evaluated for the potential to cause an unreasonable health or environmental risk. If no such finding is made, a decision to grant the test market exemption is made at the Focus meeting.

There is no maximum production volume limitation for applicability, but the submitter must identify the chemical substance and define persons who will obtain the substance during the test market period. A TME is issued for a specified time period; this time varies but is always specified. Certain enforceable restrictions (such as mandatory worker protective equipment) may be stipulated as part of the exemption.

Receipt of TME applications and EPA's decision to grant or deny TMEs are published in the Federal Register. TMEs are effective upon signature by the Director of the Office of Toxic Substances. If a TME application is denied, the manufacturer or importer can submit a PMN.

B. Polymer Exemption

A manufacturer or importer of certain new polymers may submit a notice under the polymer exemption, which provides for 21-day EPA review (40 CFR 723.250). The submitter must complete applicable portions of the PMN form (EPA Form 7710-25). A chemist in ICB/ETD determines whether the composition of the polymer qualifies it for the polymer exemption. Polymer exemptions are effective after day 21 unless the company has been notified by telephone, followed by written notification, that the substance is ineligible for exemption.

C. Low Volume Exemption

New chemical substances to be manufactured or imported at an annual volume of 1,000 kg or less may be exempt from PMN review under TSCA (40 CFR 723.50). Manufacturers or importers of low volume substances may provide a notice to EPA with information on the chemical's structure and intended uses. The notice, which does not have to be completed on the PMN form, is reviewed within 21 days. Possible health risk concerns from exposure to the chemical are evaluated based on information gathered on analogues. The submitter is free to manufacture or import after 21 days unless EPA notifies the submitter by telephone, followed by written notification, that it may not.

The volume for the substance cannot exceed 1,000 kg. Certain stipulations, such as requirements for worker protection equipment, may be included as part of the notice to EPA and are binding. Only one company may manufacture or import a specific substance under the low volume exemption.

Chemicals are referred to the Existing Chemical Control Branch/Chemical Control Division (ECCB/CCD) for Follow-up by the Premanufacture Notice Management Branch/Chemical Control Division (PNMB/CCD) because (1) a hazard concern has been identified during PMN review and (2) exposures/releases different from the PMN exposures/releases are suspected. Referrals to Follow-up are generally made at the Focus, CCD Disposition, or Division Directors' meeting. ECCB is responsible for managing Follow-up technical and regulatory evaluations and implementing regulatory decisions. These evaluations may include a more detailed toxicology review, a new use and exposure analysis, and technical integration report. Based on the findings of the technical review, ECCB has the responsibility of determining the appropriate course of regulatory action.

The Follow-up program has several regulatory options available. One is to issue a Significant New Use Rule (SNUR) pursuant to §5(a)(2) of TSCA. A SNUR is designed to limit or prohibit certain activities associated with the substance(s) (e.g., release to water) without prior notice to EPA. A second option is for OTS to issue a §8(a) rule that requires a manufacturer or processor of a specified substance to notify the Agency when a certain activity or event has occurred (e.g., production volume has reached a certain volume). A third approach is for ECCB to refer a chemical to another OTS program that can more appropriately evaluate and regulate, if necessary, the substance. For instance, if the risk case is well defined and considered to be significant the substance could be referred to §6; a substance may be submitted to Test Rules Development Branch (TRDB) for data development consideration, or if the chemical is defined as an existing chemical (chemical on original TSCA Inventory) the substance will be referred to the Existing Chemical Assessment Division (ECAD). (ECAD manages the Follow-up process for existing chemicals. Follow-up for existing chemicals is analogous to Follow-up for new chemicals.) Substances for which a §5(e) Consent Order has been written may also be subject to a SNUR authored by PNMB.

The current Follow-up process is undergoing re-evaluation. A more detailed description of the Follow-up program will be added to a later date.

A. Notice of Commencement

When the review period expires, the submitter may commence manufacture/import of a new substance if EPA or a Federal court has not banned these activities. The manufacturer/importer of a new substance must submit a notice of commencement (NOC) of manufacture or import to the Confidential Document and Systems Control Section on or after the first day of manufacture or import up to 30 days after manufacture or import commences. No specific form is required to be submitted for a notice of commencement of manufacture or import. However, the submitter is required to provide the specific chemical identity, case number, and the exact date of commencement.

After reviewing the notice of commencement, CDSDS tracks the document through DAPSS and enters the NOC date into PENTA and MITS. A CIS chemist obtains the NOC and copies of the original CIS Inventory search results, PMN, ICB chemistry report and any relevant telephone logs from the CBIC files. Based on this review the CIS chemist determines the most accurate nomenclature to reflect the chemical substance as reviewed by OTS, and notifies the Chemical Abstracts Service to add this substance to the Inventory. Thereafter, any person may produce the substance without giving notice to the Agency. CDSCS compiles a list of NOC's for monthly publication in the Federal Register.

If the substance is an exempt polymer, the CIS chemist performs a similar review and provides CAS with the absolute molecular weight and residual monomer values. This information, along with the chemical name and an exemption flag comprise the Inventory listing for the substance.

In the case of an exempt low volume substance that has not been denied, the chemist performs a similar review as soon as the 21 day review period has expired and the required documents have been turned in to the CBIC by ICB/ETD and PNMB/CCD. The chemist then notifies CAS to add this substance to the low volume exemption list. Although these substances are not technically on the Inventory they are maintained on the TSCA Inventory with an "L" flag indicating their special status.

B. CBI Substantiation

Chemical substances whose specific identity is claimed as confidential during new chemical review do not automatically remain confidential when entered onto the TSCA Inventory after a NOC is received from the manufacturer or importer. The submitter must substantiate any claim of confidentiality for the chemical identity in the NOC, reporting to EPA information such as harmful effects resulting from disclosure of chemical identity and measures already taken to prevent disclosure. Substantiation of claims must accompany the NOC and are evaluated by CDB attorneys and CDSCS upon receipt. ETD personnel will aid IMD if IMD requires technical assistance in reviewing substantiations, preparing letters to companies, making further inquiries, or researching issues pertinent to substantiation review. Submitters should contact a CDB attorney to find out what constitutes an approved or denied substantiation. A complete list of questions that must be answered in order to substantiate chemical identity claims is found in the Federal Register published on May 13, 1983, 48 FR 21752.

C. Generic Name Development

Chemical substances whose identities are claimed as confidential prior to new chemical review are assigned generic names by the submitter. These generic names or generic names that have been negotiated by ICB/ETD are used for identification purposes in §5(d)(2) notices. When the substance is placed on the TSCA Inventory, a CIS representative reviews the generic name originally used for 5(d)(2) purposes in light of the chemical identity and the unique features of the molecule that contribute to its confidential nature. Unless the 5(d)(2) generic name meets Inventory standards, a more revealing Inventory generic name is negotiated with the submitter.
After CIS receives written confirmation of the submitter's agreement to this name, the CIS staff sends the approved generic name to CAS for subsequent publication on the TSCA Inventory.

Appendix A

Functions of Divisions and Branches in the New Chemical Review Process

Functions of Divisions and Branches in the New Chemical Review Process

Chemical Control Division (CCD)
Manages the regulatory evaluation and decisionmaking process for substances subject to manufacturing or process notices under §5 of TSCA.

- Premanufacture Notice Management Branch of the Chemical Control Division (PNMB/CCD)

  Oversees and manages the evaluation and disposition of PMNs and exemption applications within the regulatory time frame. Communicates with the submitter (through a Program Manager) to acquire information or to clarify Notice data.

- Existing Chemical Control Branch of the Chemical Control Division (ECCB/CCD)

  Manages the Follow-up evaluation of substances referred by new chemical review. Develops Significant New Use Rules (SNURs) to restrict or prohibit specified new uses of a substance.

Economics and Technology Division (ETD)
Provides chemistry, economics, and engineering support for the evaluation of PMNs and other exemption applications required under §5 of TSCA.

- Industrial Chemistry Branch of the Economics and Technology Division (ICB/ETD)

  Provides industrial chemistry and related technical evaluations to all OTS Divisions to support both risk assessments and non-regulatory decisionmaking for all new chemicals reported pursuant to §5 of TSCA.

- Chemical Engineering Branch of the Economics and Technology Division (CEB/ETD)

  Reviews PMNs and exemption requests to characterize industrial activities and determine sources of environmental release, release rate estimates, protective clothing, personal protective equipment, engineering control options, production technologies, and occupational exposure.

- Regulatory Impacts Branch of the Economics and Technology Division (RIB/ETD)

  Provides economic, marketing, and socioeconomic analyses in support of PMN and exemption review. Reviews submissions for availability and cost/performance analyses of substitutes, potential uses and benefits of the new chemical, and market trends.

Exposure Evaluation Division (EED)
Provides scientific assessments of human and environmental exposure for substances subject to manufacturing or process notices under §5 of TSCA.

- Exposure Assessment Branch of the Exposure Evaluation Division (EAB/EED)

  Estimates physical/chemical properties; evaluates chemical fate in wastewater treatment, surface water, ground water, soil, sediment, and air; and estimates all potential exposures to the chemical except occupational exposure and all exposures of environmental biota for all substances evaluated under §5 of TSCA.

- Design and Development Branch of the Exposure Evaluation Division (DDB/EED)

  May serve as EED exposure assessors in estimating non-occupational exposures and assessing chemical fate for substances evaluated under §5 of TSCA.

Health and Environmental Review Division (HERD)
Provides expertise for health and ecological effects considered in the scientific evaluation of a PMN or other exemption application required under §5 of TSCA.

- Chemical Review and Evaluation Branch of the Health and Environmental Review Division (CREB/HERD)

  Manages the technical and scientific evaluations of PMNs.

- Oncology Branch of the Health and Environmental Review Division (OB/HERD)

  Assesses the chronic human toxicity and oncogenicity of PMN substances.

- Toxic Effects Branch of the Health and Environmental Review Division (TEB/HERD)

  Assesses the human toxicity of PMN substances with the exception of chronic toxicity and oncogenicity.

- Environmental Effects Branch of the Health and Environmental Review Division (EEB/HERD)

  Assesses environmental impact of PMN substances.

Information Management Division (IMD)
Ensures security and control of documents (or other forms of information) that contain CBI. Coordinates CBI and non-CBI information searches for new chemical review and provides systems development and support operations. Investigates persons applying for TSCA CBI Clearance.

- Chemical Information Branch of the Information Management Division (CIB/IMD)

  Performs literature searching and retrieval in support of identification, evaluation, and naming of submissions requiring new chemical review under §5 of TSCA.

- Confidential Data Branch of the Information Management Division (CDB/IMD)

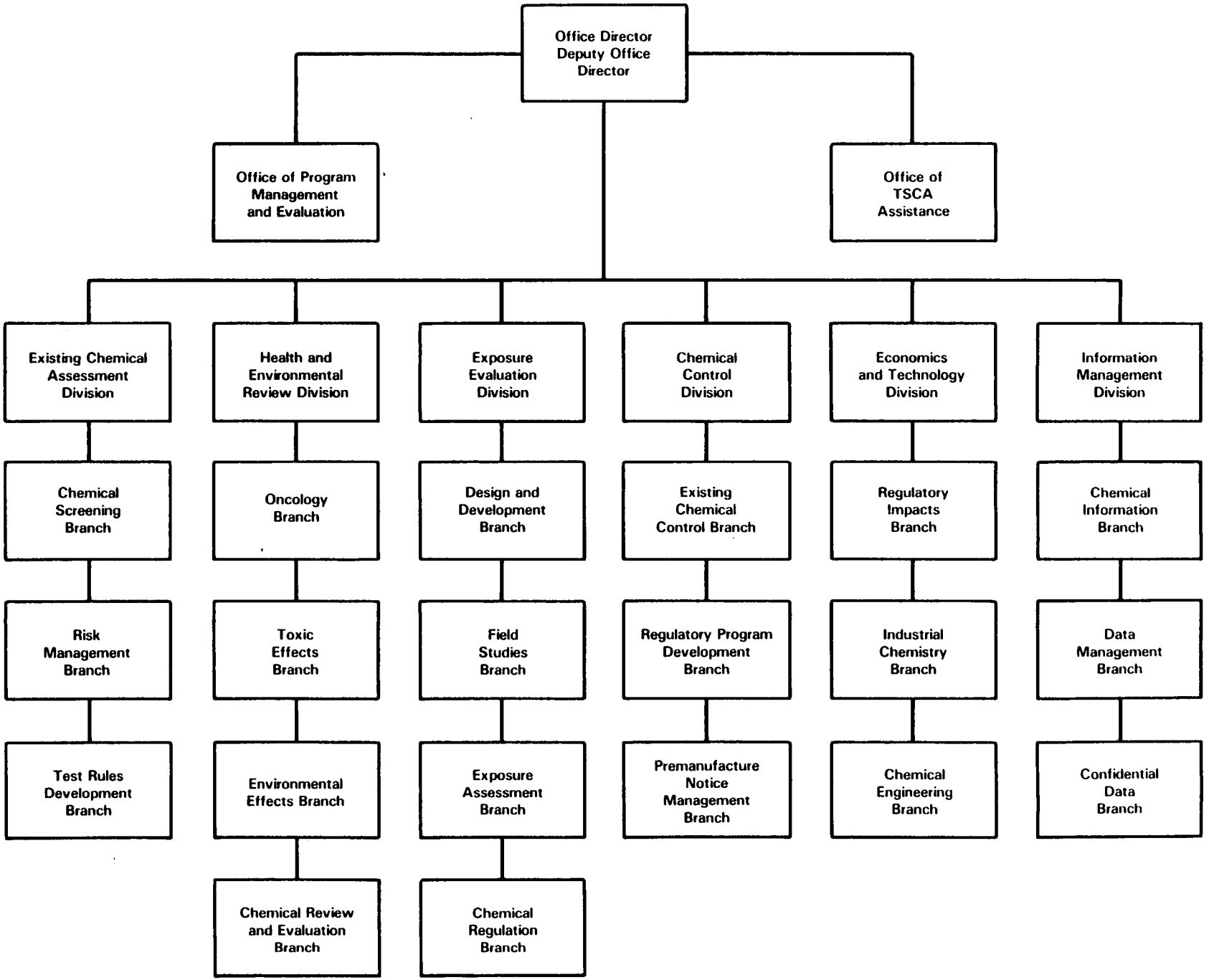
  Ensures adequate security and control of documents (or other forms of communication) that transmit CBI. Specifies proper handling of CBI. Manages the TSCA Inventory. Searches the TSCA Inventory for information in support of identification, evaluation, and naming of submissions requiring new chemical review under §5 of TSCA. Evaluates confidentiality claims associated with NOCs and other TSCA submissions.

- Data Management Branch of the Information Management Division (DMB/IMD).

  Provides development and user support for CBI and non-CBI systems in OTS.

Appendix B

OTS Organizational Structure

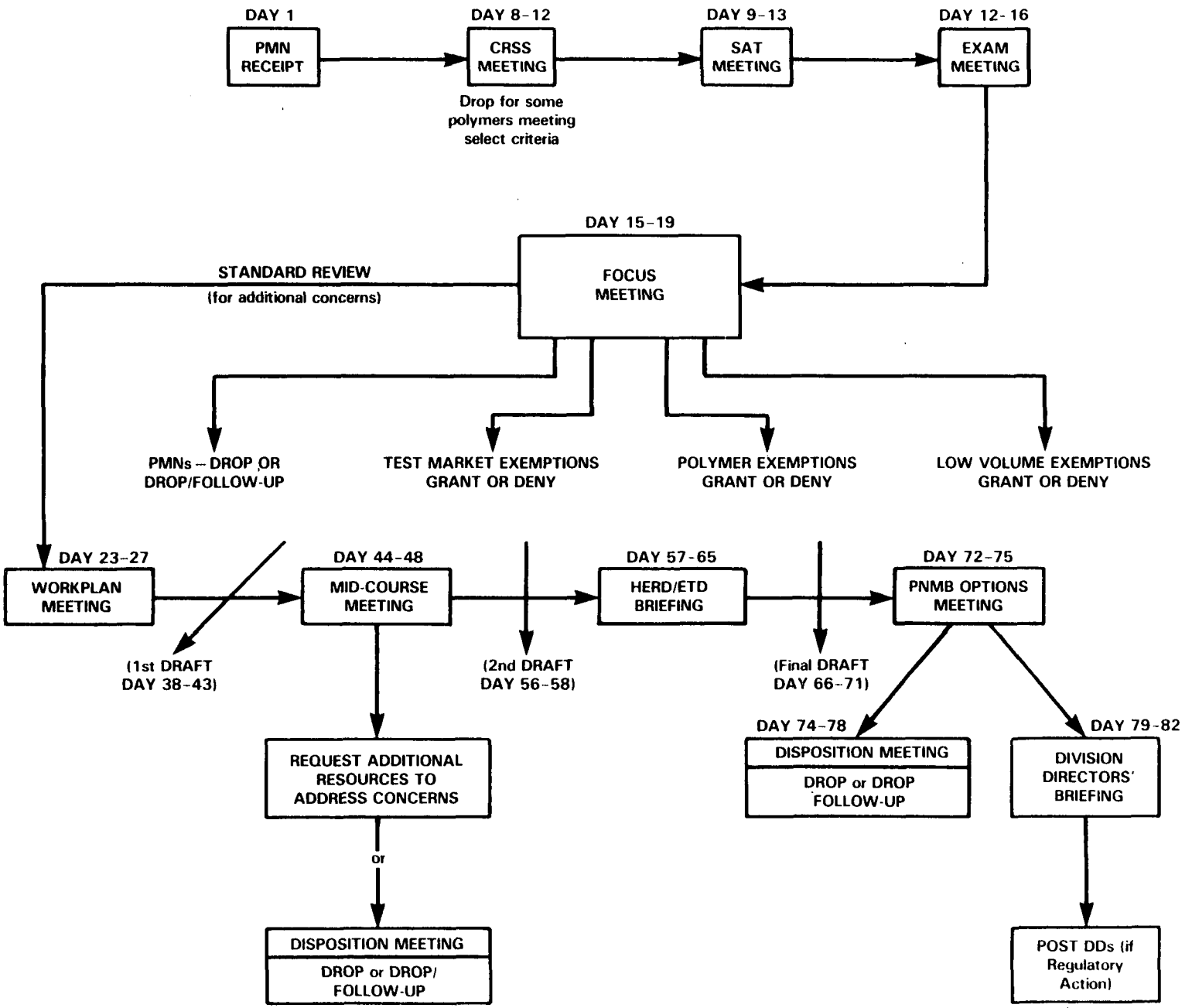

Office Director
Deputy Office Director
Office of Program Management and Evaluation
Office of TSCA Assistance
Existing Chemical Assessment Division
Health and Environmental Review Division
Exposure Evaluation Division
Chemical Control Division
Economics and Technology Division
Information Management Division
Chemical Screening Branch
Oncology Branch
Design and Development Branch
Existing Chemical Control Branch
Regulatory Impacts Branch
Chemical Information Branch
Risk Management Branch
Toxic Effects Branch
Field Studies Branch
Regulatory Program Development Branch
Industrial Chemistry Branch
Data Management Branch
Test Rules Development Branch
Environmental Effects Branch
Exposure Assessment Branch
Premanufacture Notice Management Branch
Chemical Engineering Branch
Confidential Data Branch
Chemical Review and Evaluation Branch
Chemical Regulation Branch

Appendix C

New Chemical Review Process Diagram

New Chemical Review Process

Standard Review



Appendix D

New Chemical Review Process
Meeting Schedule

New Chemical Review Process Meeting Schedule

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
8:00 HERD DISPO (8:30–10:00) CRSS MTG (8:45–10:00)	SAT MTG (8:45–10:30)		CRSS MTG (8:45–10:00)	SAT MTG (8:45–10:30)
9:00				
10:00 MID-COURSE MTG (10:00–12:00/45″ intervals)	WORKPLAN MTG (10:30–12:00/30″ intervals)	MID-COURSE MTG (10:00–12:00/45″ intervals)	WORKPLAN MTG (10:30–12:00/30″ intervals)	
11:00				ETD DISPO (11:00–12:30)
12:00 Noon — Lunch				
1:00 FOCUS MTG (1:00–2:30)	PNMB OPTIONS MTG (1:00–2:00)	EXAM MTG (1:00–2:00) HERD DISPO (1:30–3:00)	FOCUS MTG (1:00–2:30)	PNMB OPTIONS MTG (1:00–2:00) EXAM MTG (1:00–2:30)
2:00 CCD DISPO MTG (2:30–3:00)			CCD DISPO MTG (2:30–3:00)	DD BRIEFING (2:00–3:00)
3:00	DD BRIEFING (3:00–4:00)			

Appendix E

Confidential Business Information

Confidential Business Information (CBI)

Confidential Business Information (CBI) is defined as proprietary or trade secret information submitted under the Toxic Substances Control Act (TSCA) and claimed confidential by the submitter under §14 of the Act (5 U.S.C. 552(b)(4)). PMNs and exemption applications and notices usually contain TSCA CBI.

The Confidential Data Branch, Information Management Division, provides security and control of documents, whether in hardcopy or any other form. CDB/IMD maintains proper control and handling of TSCA CBI documents during storage, use, transmittal, document reproduction, and destruction.

The TSCA Security Staff, Information Management Division, establishes policy and standards for control and accountability of TSCA CBI documents for Federal employees and contractor employees performing work that requires the use of CBI information. This includes performing inspections of Federal and contractor facilities as well as initiating background investigations of persons requiring access to TSCA CBI. The TSCA Security Staff also investigates any inadvertent unauthorized disclosure of TSCA CBI and violations of TSCA CBI handling procedures as outlined in the TSCA Confidential Business Information Security Manual.

Appendix F

Major Databases Searched

Major Databases Searched for PMN Literature Review

The primary databases searched for PMN Literature Review follow. Additional databases are searched as needed.

Database	Searched On
Chemical Substance Identification	
CAS ONLINE REGISTRY FILE	STN International
CHEMLINE	MEDLARS National Library of Medicine
CHEMNAME	DIALOG Information Services, Inc.
CHEMSIS	DIALOG Information Services, Inc.
CHEMZERO	DIALOG Information Services, Inc.
SANSS (Substructure and Nomenclature Search System)	Chemical Information System, Inc. or Information Consultants, Inc.
Chemical Structures	
CAS ONLINE REGISTRY FILE	STN International
SANSS (Substructure and Nomenclature Search System)	Chemical Information System, Inc. or Information Consultants, Inc.
Environmental Effects	
APTIC (Air Pollution Technology Information Center)	DIALOG Information Services, Inc.
BIOSIS PREVIEWS	DIALOG Information Services, Inc.
CA SEARCH	DIALOG Information Services, Inc.
CAS ONLINE CA FILE	STN International
ENVIROLINE	DIALOG Information Services, Inc.
ENVIRONMENTAL BIBLIOGRAPHY	DIALOG Information Services, Inc.
HAZARDOUS SUBSTANCES DATABANK	MEDLARS National Library of Medicine
POLLUTION ABSTRACTS	DIALOG Information Services, Inc.
SPHERE (Scientific Parameters in Health and the Environment: Retrieval and Estimation • ACQUIRE • ENVIROFATE	Chemical Information System, Inc. or Information Consultants, Inc.
TOXLINE	MEDLARS National Library of Medicine
Exposure	
APTIC (Air Pollution Technology Information Center)	DIALOG Information Services, Inc.
AQUALINE	DIALOG Information Services, Inc.
BIOSIS PREVIEWS	DIALOG Information Services, Inc.
CANCERLIT	MEDLARS National Library of Medicine
CA SEARCH	DIALOG Information Services, Inc.
CAS ONLINE CA FILE	STN International
CHEMICAL EXPOSURE	DIALOG Information Services, Inc.
EMBASE (Excerpta Medica)	DIALOG Information Services, Inc.
HAZARDOUS SUBSTANCES DATABANK	MEDLARS National Library of Medicine

Major Databases Searched for PMN Literature Review (continued)

Database	Searched On
MEDLINE MED80, MED77, MED66 (Backfiles)	MEDLARS National Library of Medicine
NIOSH	DIALOG Information Services, Inc.
POLLUTION ABSTRACTS	DIALOG Information Services, Inc.
SPHERE (Scientific Paramters in Health and the Environment: Retrieval and Estimation • ENVIROFATE	Chemical Information System, Inc. or Information Consultants, Inc.
TOXLINE	MEDLARS National Library of Medicine
Health Effects	
CANCERLIT	MEDLARS National Library of Medicine
EMBASE (Excerpta Medica)	DIALOG Information Services, Inc.
GLOBAL INDEXING SYSTEM	USEPA Office of Toxic Substances Database
HAZARDOUS SUBSTANCES DATABANK	MEDLARS National Library of Medicine
MEDLINE MED80, MED77, MED66 (Backfiles)	MEDLARS National Library of Medicine
NIOSH	DIALOG Information Services, Inc.
RTECS (Registry of Toxic Effects of Chemical Substances)	MEDLARS National Library of Medicine
SPHERE (Scientific Paramters in Health and the Environment: Retrieval and Estimation • DERMAL • GENETOX	Chemical Information System, Inc. or Information Consultants, Inc.
TOXLINE	MEDLARS National Library of Medicine
Physical/Chemical Properties	
HAZARDOUS SUBSTANCES DATABANK	MEDLARS National Library of Medicine
RTECS (Registry of Toxic Effects of Chemical Substances)	MEDLARS National Library of Medicine
SPHERE (Scientific Parameters in Health and the Environment: Retrieval and Estimation • ACQUIRE • ENVIROFATE • ISHOW	Chemical Information System, Inc. or Information Consultants, Inc.
Production/Processing	
BIOSIS PREVIEWS	DIALOG Information Services, Inc.
CA SEARCH	DIALOG Information Services, Inc.
CAS ONLINE CA FILE	STN International
HAZARDOUS SUBSTANCES DATABANK	MEDLARS National Library of Medicine

Major Databases Searched for PMN Literature Review (continued)

Database	Searched On
Regulation/Control	
CASR (Chemical Activities Status Report)	USEPA Office of Toxic Substances Database
Use/Disposal	
BIOSIS PREVIEWS	DIALOG Information Services, Inc.
CA SEARCH	DIALOG Information Services, Inc.
CAS ONLINE CA FILE	STN International
GLOBAL INDEXING SYSTEM	USEPA Office of Toxic Substances Database
HAZARDOUS SUBSTANCES DATABANK	MEDLARS National Library of Medicine
NIOSH	DIALOG Information Services, Inc.
POLLUTION ABSTRACTS	DIALOG Information Services, Inc.

Appendix G

Premanufacture Notice for New Chemical Substances, EPA Form 7710-25

Form Approved. O.M.B. No. 2070-0012. Approval Expires 1-31-94.

U. S. ENVIRONMENTAL PROTECTION AGENCY

PREMANUFACTURE NOTICE

FOR NEW CHEMICAL SUBSTANCES

AGENCY USE ONLY

Date of receipt

When completed send this form to

DOCUMENT CONTROL OFFICER
OFFICE OF TOXIC SUBSTANCES, TS-790
U.S. E.P.A.
401 M STREET, SW
WASHINGTON, D.C. 20460

Enter the total number of pages in the Premanufacture Notice

Document control number

EPA case number

GENERAL INSTRUCTIONS

TS- ☐☐☐☐☐☐

- You must provide all information requested in this form to the extent that it is known to or reasonably ascertainable by you. Make reasonable estimates if you do not have actual data.
- Before you complete this form, you should read the "Instructions Manual for Premanufacture Notification" (Instructions Manual).
- If a user fee has been remitted for this notice (40 CFR 700.45), indicate in the TS boxes above the TS-user fee identification number you have generated. *Remember, your user fee ID number must also appear on your corresponding fee remittance.*

Part I – GENERAL INFORMATION

You must provide the chemical identity of the new chemical substance, even if you claim the identity as confidential. You may authorize another person to submit the identity for you, but your submission will not be complete and review will not begin until EPA receives this information. A letter of support from another person should reference your TS user fee identification number.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

You may need additional copies of part II, sections A and B if there are several manufacture, processing, or use operations that you will describe in the notice. You should reproduce these sections as needed.

Part III – LIST OF ATTACHMENTS

You should attach additional sheets if you do not have enough space on the form to answer a question fully. Label each continuation sheet with the corresponding section heading. In part III, list these attachments, any test data or other data and any optional information that you include in the notice.

OPTIONAL INFORMATION

You may include in the notice any information that you want EPA to consider in evaluating the new substance. The Instructions Manual identifies categories of optional information that you may want EPA to review. On page 11 of this form, space has been provided for you to describe pollution prevention and recycling information you may have regarding the new substance.

Binding Options: In order to effectively implement risk management options, EPA may wish to exercise its authority under section 5(e) to make certain statements in your notice such as use, production volume, protective equipment and/or process description legally binding and enforceable. If you wish to initiate such discussions with the EPA, precisely describe those aspects in this notice deliberately designed to protect against unreasonable risk to human health or the environment and indicate your willingness to be bound to the appropriate statements by marking (X) in the boxes provided. Should the Agency wish to pursue this option, you will be contacted by an EPA staff person.

CONFIDENTIALITY CLAIMS

You may claim any information in this notice as confidential. To assert a claim on the form, mark (X) the confidential box next to the information that you claim as confidential. To assert a claim in an attachment, circle or bracket the information you claim as confidential. If you claim information in the notice as confidential, you must provide a sanitized version of the notice, including attachments, to EPA with your submission. For additional instructions on claiming information as confidential, read the Instructions Manual.

☐ Mark (X) if any information in this notice is claimed as confidential.

TEST DATA AND OTHER DATA

You are required to submit all test data in your possession or control and to provide a description of all other data known to or reasonably ascertainable by you if these data are related to the health and environmental effects of the manufacture, processing, distribution in commerce, use, or disposal of the new chemical substance. Standard literature citations may be submitted for data in the open scientific literature. Complete test data (written in English), not summaries of data, must be submitted if they do not appear in the open literature. Following are examples of test data and other data. You should submit these data according to the requirements of §720.50 of the Premanufacture Notification Rule (40 CFR Part 720).

Test Data (See Appendix A of the Instructions Manual and the Physical and Chemical Properties Worksheet on the last page of this form for examples of data to be submitted).

- Environmental fate data ☐ Yes ☐ No
- Health effects data ☐ Yes ☐ No
- Environmental effects data ☐ Yes ☐ No
- Physical/Chemical Properties ☐ Yes ☐ No

Other data ☐ Yes ☐ No
- Risk assessments
- Structure/activity relationships
- Test data not in the possession or control of the submitter

TYPE OF NOTICE (Check Only One)

☐ PMN

☐ CONSOLIDATED PMN - # OF CHEMICALS _____
(Prenotice Communication # required, enter # on page 3)

☐ SNUN (Significant New Use Notice)

☐ INTERMEDIATE PMN - AS DEFINED AT 40 CFR 700.43

☐ TMEA (Test Marketing Exemption)

☐ LVE (Low Volume Exemption)

☐ POLYMER EXEMPTION - ☐ e(1) or ☐ e(2)

☐ OTHER EXEMPTION - SPECIFY

_____

CERTIFICATION

I certify that to the best of my knowledge and belief:

1. The company named in Part I, section A, subsection 1a of this notice form intends to manufacture or import for a commercial purpose, other than in small quantities solely for research and development, the substance identified in Part I, Section B.

2. All information provided in this notice is complete and truthful as of the date of submission.

3. I am submitting with this notice all test data in my possession or control and a description of all other data known to or reasonably ascertainable by me as required by §720.50 of the Premanufacture Notification Rule.

Additional Certification Statements:

If you are submitting a PMN, (including a polymer exemption notice in accordance with 40 CFR 723.250), Intermediate PMN, Consolidated PMN, or SNUN, check the following **user fee** certification statement that applies:

☐ The Company named in Part I, Section A has remitted the fee specified in 40 CFR 700.45 (b), or

☐ The Company named in Part I, Section A is a small business concern under 40 CFR 700.43 and has remitted a fee of $100 in accordance with 40 CFR 700.45 (b).

If you are submitting a **polymer exemption** notice in accordance with 40 CFR 723.250, check the following:

☐ The new chemical substance meets the definition of polymer, is not specifically excluded from the exemption, and meets the conditions of the exemption.

If you are submitting a **low volume exemption** application in accordance with 40 CFR 723.50, check the following certification statements:

☐ The manufacturer submitting this notice intends to manufacture or import the new chemical substance for commercial purposes, other than in small quantities solely for research and development, under the terms of 40 CFR 723.50.

☐ The manufacturer is familiar with the terms of this section and will comply with those terms; and

☐ The new chemical substance for which the notice is submitted meets all applicable exemption conditions.

The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical subtance described herein. Any knowing and willful misinterpretation is subject to criminal penalty pursuant to 18 USC 1001.

		Confidential
Signature and title of Authorized Official (Original Signature Required)	**Date**	
Signature of agent - (if applicable)	**Date**	

Part I -- GENERAL INFORMATION

Section A -- SUBMITTER IDENTIFICATION

Confidential

Mark (X) the "Confidential" box next to any subsection you claim as confidential.

1a. Person Submitting Notice (in U.S.)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code

b. Agent (if applicable)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

c. If you are submitting this notice as part of a joint submission, mark (X) this box. → ☐

Joint Submitter (if applicable)

Name of authorized official | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

2. Technical Contact (in U.S.)

Name | Title

Company

Mailing address (number and street)

City, State, ZIP Code | Telephone: Area Code | Number

3. If you have had a prenotice communication (PC) concerning this notice and EPA assigned a PC Number to the notice, enter the number. →

Mark (X) if none → ☐

4. If you have submitted an exemption notice/application for the chemical substance covered by this notice, enter the exemption number assigned by EPA. If you have withdrawn a previously submitted PMN enter the PMN number. →

Mark (X) if none → ☐

5. If you have submitted a bona fide request for the chemical substance covered by this notice, enter the bona fide request number assigned by EPA. →

Mark (X) if none → ☐

6. Type of Notice -- Mark (X)

1. ☐ Manufacture Only
   ☐ Binding Option Mark (x)

2. ☐ Import Only
   ☐ BindingOption Mark (x)

3. ☐ Both

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

Complete either item 1 (Class 1 or 2 substances) or 2 (Polymers) as appropriate. Complete all other items.

If another person will submit chemical identity information for you (for either item 1 or 2), mark (X) the box at the right. ☐ → Identify the name, company, and address of that person in a continuation sheet.

Confi-dential

1. **Class 1 or 2 chemical substances** (for definitions of class 1 and class 2 substances, see the **Instructions Manual**)

   a. Class of substance -- Mark (X) 1 ☐ Class 1 **or** 2 ☐ Class 2

   b. Chemical name (preferably CAS or IUPAC nomenclature)

   c. Molecular formula and CAS Registry Number (if known)

   CAS #

   d. For a **class 1** substance, provide a structural diagram. For a **class 2** substance -- (1) List the immediate precursor substances with their respective CAS Registry Numbers. (2) Describe the nature of the reaction or process. (3) Indicate the range of composition and the typical composition (where appropriate). (4) Provide a representative structural diagram (if possible).

☐ Mark (X) this box if you attach a continuation sheet.

Part I. -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

2. **Polymers** (For a definition of polymer, see the **Instructions Manual.**)

Confi-dential

a. Indicate the number-average weight of the lowest molecular weight composition of the polymer you intend to manufacture. Indicate maximum weight percent of low molecular weight species (not including residual monomers, reactants, or solvents) below 500 and below 1,000 absolute molecular weight of that composition. **Describe the methods of measurement or the bases for your estimates.** GPC ☐ Other ☐ (Specify) _____

- **lowest** number average molecular weight:
- maximum weight % below 500 molecular weight:
- maximum weight % below 1000 molecular weight:

☐ Mark (X) this box if you attach a continuation sheet.

b. You must make separate confidentiality claims for monomer or other reactant identity, composition information, and residual information. Mark (X) the "Confidential" box next to any item you claim as confidential.

(1) -- Provide the chemical name and CAS Registry Number of each monomer or other reactant used in the manufacture of the polymer.
(2) -- Mark (X) this column if entry in column (1) is confidential.
(3) -- Indicate the typical weight percent of each monomer or other reactant in the polymer.
(4) -- **Mark (X) the identity column if you want a monomer or other reactant used at two weight percent or less to be listed as part of the polymer description on the TSCA Chemical Substance Inventory.**
(5) -- Mark (X) this column if entries in columns (3) and (4) are confidential.
(6) -- **Indicate the maximum weight percent of each monomer or other reactant that may be present as a residual in the polymer as manufactured for commercial purposes.**
(7) -- Mark (X) this column if entry in column (6) is confidential.

Monomer or other reactant and CAS Registry Number (1)	Confi-dential (2)	Typical composition (3)	Identity Mark (X) (4)	Confi-dential (5)	Maximum residual (6)	Confi-dential (7)
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	
		%			%	

☐ Mark (X) this box if you attach a continuation sheet.

c. Provide a representative structural diagram of the polymer, if possible.

☐ Mark (X) this box if you attach a continuation sheet.

Part I -- GENERAL INFORMATION -- Continued

Section B -- CHEMICAL IDENTITY INFORMATION -- Continued

3. **Impurities**
   (a) -- **Identify each impurity that may be reasonably anticipated to be present in the chemical substance as manufactured for commercial purposes. Provide the CAS Registry Number if available. If there are unidentified impurities, enter "unidentified."**
   (b) --**Estimate the maximum weight % of each impurity. If there are unidentified impurities, estimate their total weight %.**

Impurity and CAS Registry Number (a)	Maximum percent (b)	Confi-dential
	%	
	%	
	%	
	%	
	%	
	%	
	%	

☐ Mark (X) this box if you attach a continuation sheet.

4. **Synonyms** -- Enter any synonyms for the new chemical substance identified in subsection 1 or 2. | Confi-dential

☐ Mark (X) this box if you attach a continuation sheet.

5. **Trade identification** -- List trade names for the new chemical substance identified in subsection 1 or 2.

☐ Mark (X) this box if you attach a continuation sheet.

6. **Generic chemical name** -- If you claim chemical identity is confidential, you must provide a generic chemical name for your substance that reveals the specific chemical identity of the new chemical substance to the maximum extent possible. Refer to the TSCA Chemical Substance Inventory, 1985 Addition, Appendix B for guidance on developing generic names.

☐ Mark (X) this box if you attach a continuation sheet.

7. **Byproducts** -- Describe any byproducts resulting from the manufacture, processing, use, or disposal of the new chemical substance at sites you control. Provide the CAS Registry Number if available.

Byproduct (1)	CAS Registry Number (2)	Confi-dential

☐ Mark (X) this box if you attach a continuation sheet.

Part I -- GENERAL INFORMATION -- Continued

Section C -- PRODUCTION, IMPORT, AND USE INFORMATION

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. **Production volume** -- Estimate the maximum production volume during the first 12 months of production. Also estimate the maximum production volume for any consecutive 12-month period during the first three years of production.		Confi-dential	**Binding Option Mark (x)**
Maximum first 12-month production (kg/yr)	Maximum 12-month production (kg/yr)		

2. **Use Information** -- You must make separate confidentiality claims for the description of the category of use, the percent of production volume devoted to each category, the formulation of the new substance, and other use information. Mark (X) the "Confidential" Box next to any item you claim as confidential.
   a. (1) -- Describe each intended category of use of the new chemical substance by function and application.
   (2) -- Mark (X) this column if entry in column (1) is confidential business information (CBI).
   (3) -- Indicate your willingness to have the information provided in column (1) binding.
   (4) -- Estimate the percent of total production for the first three years devoted to each category of use.
   (5) -- Mark (X) this column if entry in column (4) is confidential business information (CBI).
   (6) -- Estimate the percent of the new substance as formulated in mixtures, suspensions, emulsions, solutions, or gels as manufactured for commercial purposes at sites under your control associated with each category of use.
   (7) -- Mark (X) this column if entry in column (6) is confidential business information (CBI).
   (8) -- Mark (X) whether the use is site-limited, industrial, commercial and/or consumer. Mark more than one box if appropriate. Mark (X) to indicate your willingness to have the information provided in (8) binding.
   (9) -- Mark (X) this column if entry(ies) in column (8) is (are) confidential business information (CBI).

Category of use (1)	CBI (2)	**Binding Option Mark (x)** (3)	Production % (4)	CBI (5)	% in Formulation (6)	CBI (7)	Mark (X) appropriate column(s) (8)					CBI (9)
							Site-limited	Con-* sumer	Industrial	Commercial	**Binding Option**	
			%		%							
			%		%							
			%		%							
			%		%							
			%		%							

*If you have identified a "consumer" use, please provide on a continuation sheet a detailed description of the use(s) of this chemical substance in consumer products. In addition include estimates of the concentration of the new chemical substance as expected in consumer products and describe the chemical reactions by which this substance loses its identity in the consumer product.

☐ Mark (X) this box if you attach a continuation sheet.

b. Generic use description -- If you claim any category of use description in subsection 2a as confidential, enter a generic description of that category. Read the **Instructions Manual** for examples of generic use descriptions.

☐ Mark (X) this box if you attach a continuation sheet.

3. **Hazard Information** -- Include in the notice a copy of reasonable facsimile of any hazard warning statement, label, material safety data sheet, or other information which will be provided to any person who is reasonably likely to be exposed to this substance regarding protective equipment or practices for the safe handling, transport, use, or disposal of the new substance. List in part III hazard information you include.	**Binding Option Mark (x)**
☐ Mark (X) this box if you attach hazard information.	

Part II -- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER

Complete section A for each type of manufacture, processing, or use operation involving the new chemical substance at industrial sites you control.

Mark (X) the "Confidential" box next to any item you claim as confidential.

1. Operation description

a. Identity -- Enter the identity of the site at which the operation will occur.

Confidential

Name

Site address (number and street)

City, County, State, ZIP Code

If the same operation will occur at more than one site, enter the number of sites. Identify the additional sites on a continuation sheet. →

☐ Mark (X) this box if you attach a continuation sheet.

b. Type -- Mark (X) ☐ Manufacturing ☐ Processing ☐ Use

c. Amount and Duration -- Complete 1 or 2 as appropriate

	Maximum kg/batch	Hours/batch	Batches/year
1. Batch			
	Maximum kg/day	**Hours/day**	**Days/year**
2. Continuous			

d. Process description ☐ **Mark (X) to indicate your willingness to have your process description binding.**

(1) Diagram the major unit operation steps and chemical conversions.
(2) Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts, etc.).
(3) Identify by number the points of release to the environment of the new chemical substance.

☐ Mark (X) this box if you attach a continuation sheet.

Part II -- HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section A -- INDUSTRIAL SITES CONTROLLED BY THE SUBMITTER -- Continued

2. **Occupational Exposure** -- You must make separate confidentiality claims for the description of worker activity, physical form of the new chemical substance, number of workers exposed, and duration of activity. Mark (X) the "Confidential" box next to any item you claim as confidential.
   (1) -- Describe the activities in which workers may be exposed to the new chemical substance.
   (2) -- Mark (X) this column if entry in column (1) is confidential business information (CBI).
   (3) -- Describe any protective equipment and engineering controls used to protect workers.
   (4) and (6) -- Indicate you willingness to have the information provided in column (3) or (5) binding.
   (5) -- Indicate the physical form(s) of the new chemical substance at the time of exposure.
   (7) -- Mark (X) this column if entry in column (5) is confidential business information (CBI).
   (8) -- Estimate the maximum number of workers involved in each activity.
   (9) -- Mark (X) this column if entry in column (8) is confidential business information (CBI).
   (10) and (11) -- Estimate the maximum duration of the activity for any worker in hours per day and days per year.
   (12) -- Mark (X) this column if entries in columns (10) and (11) are confidential business information (CBI).

Worker activity (1)	CBI (2)	Protective Equipment/ Engineering Controls (3)	Binding Option Mark (x) (4)	Physical form(s) (5)	Binding Option Mark (x) (6)	CBI (7)	# of Workers Exposed (8)	CBI (9)	Maximum duration		CBI (12)
									Hrs/day (10)	Days/yr (11)	

☐ Mark (X) this box if you attach a continuation sheet.

3. **Environmental Release and Disposal** -- You must make separate confidentiality claims for the release number and the amount of the new chemical substance released and other release and disposal information. Mark (X) the "Confidential" box next to each item you claim as confidential.
   (1) -- Enter the number of each release point identified in the process description, part II, section A, subsection 1d(3).
   (2) -- Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology (in kg/day or kg/batch).
   (3) -- Mark (X) this column if entries in columns (1) and (2) are confidential business information (CBI).
   (4) -- Identify the media (air, land, or water) to which the new substance will be released from that release point.
   (5) -- a. Describe control technology, if any, and control efficiency that will be used to limit the release of the new substance to the environment. For releases disposed of on land, characterize the disposal method and state whether it is approved for disposal of RCRA hazardous waste. On a continuation sheet, for each site describe any additional disposal methods that will be used and whether the waste is subject to secondary or tertiary on-site treatment. b. Estimate the amount released to the environment after control technology (in kg/day).
   (6) -- Mark (X) this column if entries in columns (4) and (5) are confidential business information (CBI).
   (7) -- Identify the destination(s) of releases to water. Please supply NPDES (National Pollutant Discharge Elimination System) numbers for direct dischargers or NPDES numbers of the POTW (Publicly Owned Treatment Works). Mark (X) if the POTW name or NPDES # is confidential business information (CBI).

Release Number (1)	Amount of new substance released (2a)	(2b)	CBI (3)	Media of release (4)	Control technology and efficiency (5a)	Binding Mark (x)	(5b)	CBI (6)

(7) Mark (X) the destination(s) of releases to water.	☐ POTW provide name(s) below: _____	CBI	☐ Navigable waterway	☐ Other - Specify	NPDES #	CBI

☐ Mark (X) this box if you attach a continuation sheet.

Part II – HUMAN EXPOSURE AND ENVIRONMENTAL RELEASE -- Continued

Section B -- INDUSTRIAL SITES CONTROLLED BY OTHERS

Complete section B for typical processing or use operations involving the new chemical substance at sites you do not control. Complete a separate section B for each type of processing, or use operation involving the new chemical substance. If the same operation is performed at more than one site describe the typical operation common to these sites and enter the number of sites _____. Identify additional sites on a continuation sheet.

1. **Operation Description** - To claim information in this section as confidential, circle or bracket the specific information that you claim as confidential.
(1) – Diagram the major unit operation steps and chemical conversions. On the diagram, identify by letter and briefly describe each worker activity.
(2) – Provide the identity, the approximate weight (by kg/day or kg/batch), and entry point of all feedstocks (including reactants, solvents, and catalysts, etc). (3) -- Identify by number the points of release to the environment of the new chemical substance.

☐ Mark (X) this box if you attach a continuation sheet.

2. **Worker Exposure/Environmental Release**
(1) – From the diagram above, provide the letter for each worker activity. Complete 2-8 for each worker activity described.
(2) – Estimate the number of workers exposed.
(4) – Estimate the typical duration of exposure per worker in (a) hours per day and (b) days per year.
(6) – Describe any protective equipment and engineering controls, if any, used to protect workers.
(7) – Estimate the percent of the new substance as formulated when packaged or used as a final product.
(9) – From the process diagram above, enter the number of each release point. Complete 9-13 for each release point identified.
(10) – Estimate the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).
(12) – Describe control technology, if any, that will be used to limit the release of the new substance to the environment.
(14) – Identify byproducts which may result from the operation.
(3), (5), (8), (11), (13) and (15) - Mark (X) this column if any of the proceeding entries are confidential business information (CBI).

Letter of Activity (1)	# of Workers Exposed (2)	CBI (3)	Duration of Exposure (4a)	Duration of Exposure (4b)	CBI (5)	Protective Equip./ Engineering Controls (6)	% in Formulation (7)	CBI (8)	Release Number (9)	Amount of New Substance Released (10a)	Amount of New Substance Released (10b)	CBI (11)	Control Technology (12)	CBI (13)

(14) – Byproducts: (15)

☐ Mark (X) this box if you attach a continuation sheet.

OPTIONAL POLLUTION PREVENTION INFORMATION

To claim information in this section as confidential circle or bracket the specific information that you claim as confidential.

In this section you may provide information not reported elsewhere in this form regarding your efforts to reduce or minimize potential risks associated with activities surrounding manufacturing, processing, use and disposal of the PMN substance. Please include new information pertinent to pollution prevention, including source reduction, recycling activities and safer processes or products available due to the new chemical substance. Source reduction includes the reduction in the amount or toxicity of chemical wastes by technological modification, process and procedure modification, product reformulation, raw materials substitution, and/or inventory control. Recycling refers to the reclamation of useful chemical components from wastes that would otherwise be treated or released as air emissions or water discharges, or land disposal. Descriptions of pollution prevention, source reduction and recycling should emphasize potential risk reduction subsequent to compliance with existing regulatory requirements and can be either quantitative or qualitative. The EPA is interested in this information to assess overall net reductions in toxicity or environmental releases and exposures, not the shifting of risks to other environmental media or non-environmental areas (e.g., occupational or consumer exposure). In addition, information on the relative cost or performance characteristics of the PMN substance to potential alternatives may be provided. **All information provided in this section will be taken into consideration during the review of this substance.**

Describe the expected net benefits, such as (1) an overall reduction in risk to human health or the environment; (2) a reduction in the volume manufactured; (3) a reduction in the generation of waste materials through recycling, source reduction or other means; (4) a reduction in potential toxicity or human exposure and/or environmental release; (5) an increase in product performance, a decrease in the cost of production and/or improved operation efficiency of the new chemical substance in comparison to existing chemical substances used in similar applications; or (6) the extent to which the new chemical substance may be a substitute for an existing substance that poses a greater overall risk to human health or the environment.

☐ Mark (X) this box if you attach a continuation sheet.

Part III -- LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment.
Mark (X) the "Confidential" box next to any attachment name you claim as confidential. Read the **Instructions Manual** for guidance on how to claim any information in an attachment as confidential. You must include with the sanitized copy of the notice form a sanitized version of any attachment in which you claim information as confidential.

Attachment name	Attachment page number(s)	Confi-dential

☐ Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist EPA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notice. Identify the property measured, the page of the notice on which the property appears, the value of the property, the units in which the property is measured (as necessary), and whether or not the property is claimed as confidential. You are not required to submit this worksheet; however, EPA strongly recommends that you do so, as it will simplify review and ensure that confidential information is properly protected. You should submit this worksheet as a supplement to your submission of test data. This worksheet is not a substitute for submission of test data.

Property (a)	Mark (X) if provided	Page number (b)	Value (c)	Confi-dential Mark (X) (d)
Vapor pressure @ Temperature _____ °C			Torr	
Density/relative density			g/cm3	
Solubility @ Temperature _____ °C Solvent _____			g/L	
Solubility in water @ Temperature _____ °C			°C	
Melting temperature			°C	
Boiling/sublimation temperature @ _____ torr pressure				
Spectra				
Dissociation constant				
Particle size distribution				
Octanol/water partition coefficient				
Henry's Law constant				
Volitalization from water				
Volitalization from soil				
pH @ concentration _____				
Flammability				
Explodability				
Adsorption/coefficient				
Other - Specify				

Glossary

Bona fide	Document submitted by a chemical manufacturer or importer that states intent to introduce a chemical substance into U.S. commerce (see page I-1).
CBI	Confidential Business Information (see Appendix E).
CCD	Chemical Control Division.
CDB/IMD	Confidential Data Branch of the Information Management Division.
CDSCS/IMD	Confidential Document and Systems Control Section of the Information Management Division.
CEB/ETD	Chemical Engineering Branch of the Economics and Technology Division.
Chemical Substance	Any organic or inorganic substance of a particular molecular identity including (1) any combination of such substances occurring in whole or in part as a result of a chemical reaction occurring in nature and (2) any element or uncombined radical. The term does not include (1) mixtures; (2) pesticides defined under the Federal Insecticide, Fungicide, and Rodenticide Act that are regulated by the Office of Pesticide Programs, USEPA; (3) tobacco, alcohol, and firearms; (4) foods, food additives, drugs, cosmetics or devices defined under the Federal Food, Drug, and Cosmetic Act that are regulated by the Food and Drug Administration; and (5) source materials, special nuclear materials, or byproducts that are defined under the Atomic Energy Act of 1954.
CIB/IMD	Chemical Information Branch of the Information Management Division.
CIS/IMD	Chemical Inventory Section of the Information Management Division.
Consent Order	A binding agreement between EPA and the manufacturer or importer of a new chemical substance whereby the manufacturer or importer is allowed to produce the substance in compliance with EPA-imposed controls while developing sufficient data on health and/or environmental effects (see page IV-1).
CREB/HERD	Chemical Review and Evaluation Branch of the Health and Environmental Review Division.
DAPSS	Document and Personnel Security System. A confidential system that tracks the receipt, circulation, and archival of confidential and non-confidential documents at the Office of Toxic Substances (OTS), as well as tracking information on CBI-cleared government and contractor personnel. Typical submissions include Premanufacture Notices (PMNs), exemption applications, bona fides, Notices to Export, Follow-up documents, and other communcations related to the Toxic Substances Control Act. DAPSS serves several functions including: automatically assigning document control numbers to various types of documents; tracking the life cycle of documents, including number of copies made, distributed, returned and shredded; analyzing document workload patterns, CBI claims, 12(b) program accomplishments, and other document profiles; flagging overdue documents; flagging the CBI status of document borrowers; and flagging the CBI clearance end-dates for personnel. The system interfaces with a bar code numbering system that expedites document circulation and tracking.

Glossary (continued)

DDB/EED	Design and Development Branch of the Exposure Evaluation Division.
DMB/IMD	Data Management Branch of the Information Management Division.
Document Control Number	Unique number assigned to any information that contains TSCA CBI.
EAB/EED	Exposure Assessment Branch of the Exposure Evaluation Division.
EED	Exposure Evaluation Division.
EEB/HERD	Environmental Effects Branch of the Health and Environmental Review Division.
ETD	Economics and Technology Division.
Follow-up Review	Process by which substances referred from the new chemical process and existing chemicals are monitored for potential unreasonable risks under circumstances where changes in manufacturing, processing, distribution in commerce, use, and disposal take place.
HERD	Health and Environmental Review Division.
ICB/ETD	Industrial Chemistry Branch of the Economics and Technology Division.
IMD	Information Management Division.
ISS/IMD	Information Services Section of the Information Management Division.
Low Volume Exemption	See page V-1
MITS	The Management Information Tracking System. A non-confidential tracking and scheduling system for PMNs and exemption applications and notices reviewed under the new chemicals review and follow-up review process. MITS serves several functions including: tracking and interim status of applications during the review process; recording and analyzing information on the final disposition and other characteristics of all applications received; and supporting Program Managers and other reviewers in their daily work with status update reports, workload reports, and upcoming calendars.
PENTA	A confidential §5 data base that contains scientific and regulatory information on all PMNs and exemption applications and notices reviewed under the new chemicals and Follow-up review process. The data base is designed so that cases can be quickly isolated and referenced by their pertinent properties. The objective of PENTA is to automate descriptive information for each case and to provide to reviewers information on how similar cases were handled in the past.
PMN	Premanufacture Notice. Required of manufacturers and importers of chemical substances under TSCA, this submission activates new chemical review by EPA. The submission reports data on health and environmental effects related to the manufacture, use, and disposal of the new chemical substances.
Polymer Exemption	See page V-1.
New Chemical Substance	Any chemical substance that is not included on the TSCA Chemical Substance Inventory.

Glossary (continued)

OB/HERD	Oncology Branch of the Health and Environmental Review Division.
PNMB/CCD	Premanufacture Notice Management Branch of the Chemical Control Division.
RIB/ETD	Regulatory Impacts Branch of the Economics and Technology Division.
RPDB/CCD	Regulatory Program Development Branch of the Chemical Control Division.
Standard Review	The process by which specific concerns raised at the Focus meeting are examined in detail by a case review team. Concerns for health and environmental effects are addressed in a series of meetings and resultant reports.
TEB/HERD	Toxic Effects Branch of the Health and Environmental Review Division.
Test Market Exemption	See page V-1.
TSCA Inventory	Computerized inventory of all chemical substances that are currently manufactured, imported, or processed in the United States (see page II-1).
Unilateral Order	Action by EPA that bans the manufacture or importation of a new chemical substance where the manufacturer does not enter into an agreement with EPA on the conditions of the Order.

Bibliography

The following citations provide background materials regarding legal authority and regulatory development of new chemical review. Reprints of regulatory background materials, Premanufacture Notices, Instructions, and other materials on new chemical review may be obtained by contacting the TSCA Assistance Office at 554-1404 or (800) 424-9065.

Legal Authority for New Chemical Review

Public Law 94-469. 1976 (October 11). Toxic Substances Control Act.

Final Rules Published in the Federal Register

USEPA. 1977. U.S. Environmental Protection Agency. Office of Toxic Substances. Inventory Reporting Regulations. (42 FR 64572).

USEPA. 1982. U.S. Environmental Protection Agency. Premanufacture Notification; Exemption for Chemicals Used In or for the Manufacture or Processing of Instant Photographic and Peel-Apart Film Articles. (47 FR 24308).

USEPA. 1983. U.S. Environmental Protection Agency. Office of Toxic Substances. Premanufacture Notification; Premanufacture Notice Requirements and Review Procedures. (48 FR 21722).

USEPA. 1983. U.S. Environmental Protection Agency. Office of Toxic Substances. Premanufacture Notification; Revision of Regulation and Partial Stay of Effective Date. (48 FR 41132).

USEPA. 1984. U.S. Environmental Protection Agency. Office of Toxic Substances. Premanufacture Notification Exemptions; Exemptions for Polymers. (49 FR 46066).

USEPA. 1984. U.S. Environmental Protection Agency. Significant New Uses of Chemical Substances; Certain Chemicals. (49 FR 35011).

USEPA. 1985. U.S. Environmental Protection Agency. Premanufacture Notification Exemption; Exemption for Chemical Substances Manufactured in Quantities of 1,000 kg or less per year. (50 FR 16477).

PMN Forms and Instructional Manual

USEPA. 1983. U.S. Environmental Protection Agency. Instructions Manual for Premanufacture Notification of New Chemical Substances. Washington, DC: Office of Toxic Substances, USEPA. EPA-7710-25(I) (5-23-83).

USEPA. 1984. U.S. Environmental Protection Agency. Premanufacture Notice for New Chemical Substances. EPA Form 7710-25 (12-18-84).