III. What is the Agency Authority for Taking This Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for use deletion must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked May 2, 2000.

V. Provisions for Disposition of Existing Stocks

The Agency has authorized the registrants to sell or distribute product under the previously approved labeling for a period of 18–months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

List of Subjects

Environmental protection,

Dated: October 4, 1999.

Richard D. Schmitt,

Acting Director, Information Resources & Services Division.

[FR Doc. 99–28890 Filed 11–3–99; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6458–9]

Sanders Aviation Superfund Site, Proposed Notice of Administrative Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past response costs concerning the Sanders Aviation Superfund Site in Tempe, Arizona with the Alfred P. Sanders Trust (''Trust'') and the trustees of the Trust. Pursuant to the Agreement, the Trust will arrange for the sale of the Trust property. Seventy-five percent of the proceeds of the sale will be paid to the Hazardous Substance Superfund and twenty-five percent will be paid to the Trust. This allocation is a close approximation of the costs each party has contributed to cleaning up the site. The settlement includes a covenant not to sue the settling parties pursuant to Sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606, 9607(a). For thirty (30) days following the date of publication of this notice, EPA will receive written comments relating to the settlement. EPA will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

The United States' response to any comments received will be available for public inspection at the U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105.

DATES: Comments must be submitted on or before December 6, 1999.

ADDRESSES: Comments should reference the Sanders Aviation Removal Site, Tempe, Arizona and EPA Docket No. 99–06 and should be addressed to Kara Christenson, Office of Regional Counsel, U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105.

AVAILABILITY: The proposed settlement is available for public inspection at the U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105. A copy of the proposed settlement may be obtained from Kara Christenson, Office of Regional Counsel U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105; and at the Tempe Public Library, 3500 South Rural Road, Tempe, Arizona.

FOR FURTHER INFORMATION CONTACT: Kara Christenson, Office of Regional Counsel U.S. Environmental Protection Agency, 75 Hawthorne Street, San Francisco, CA 94105, telephone: (415) 744–1330.

Dated: October 25, 1999.

Michael Feeley,

Deputy Director, Superfund Division, Region IX.

[FR Doc. 99–28885 Filed 11–3–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–53171A; FRL–6097–7]

Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Policy statement.

SUMMARY: EPA groups new chemical substances with similar structural and toxicological properties into categories to facilitate premanufacture assessment and regulation. These groupings enable both Toxic Substances Control Act (TSCA) section 5(a)(1) Premanufacture Notice (PMN) submitters and EPA reviewers to benefit from accumulated data and decisional precedents and have streamlined the process for Agency review of and regulatory follow-up on new chemical substances. Consistent with TSCA section 26(c), which allows EPA action under TSCA with respect to categories of chemical substances or mixtures, EPA is issuing this policy statement regarding a category of persistent, bioaccumulative, and toxic (PBT) new chemical substances.

DATES: This document will become effective January 3, 2000.

FOR FURTHER INFORMATION CONTACT: For general information contact: Christine Augustyniak, Associate Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone numbers: 202–554–1404 and TDD: 202–554–0551; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Kenneth Moss, Chemical Control Division (7405), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: 202–260–3395; fax number: 202–260–0118; e-mail address: moss.kenneth@epa.gov.

SUPPLEMENTARY INFORMATION: On October 5, 1998 (63 FR 53417) (FRL–5571–6), EPA published a **Federal Register** notice soliciting comments on proposed criteria for identifying PBT chemical substances and their supporting scientific rationale. This policy statement responds to comments on the proposed criteria for identifying PBT new chemical substances and their supporting scientific rationale. Please consult the October 5, 1998 (63 FR 53417) **Federal Register** notice for further information on the TSCA new chemicals program. The docket control

number for this document is OPPTS–53171A.

I. General Information

A. Does This Document Apply to Me?

You may be potentially affected by this document if you are or may in the future be a submitter of a PMN under TSCA. Potentially affected entities may include, but are not limited to the following:

Category	NAICS Code	SIC Codes	Examples of Potentially Affected Entities
Chemical manufacturers or importers	325, 32411	28, 2911	Anyone who plans to manufacture or import a new chemical substance (as defined in TSCA Section 3) for a non-exempt commercial purpose is required to provide the EPA with a PMN at least 90 days prior to the activity. Any TSCA chemical substance that is not on the TSCA Inventory is classified as a new chemical. New chemical substances submitted by chemical manufacturers or importers as PMNs and which are determined by EPA to meet the PBT criteria described here may be subject to regulatory controls under TSCA section 5(e).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this document. Other types of entities not listed above could also be affected. The four-digit Standard Industrial Classification (SIC) codes or the six-digit North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this document might apply to certain entities. To determine whether you or your business is affected by this document, you should carefully examine the applicability provisions in 40 CFR 720.22. If you have any questions regarding the applicability of this document to a particular entity, consult the technical person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How Can I Get Additional Information, Including Copies of This Document and Other Related Documents?

1. *Electronically*. You may obtain copies of this document from the EPA Internet Home Page at http://www.epa.gov/. On the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register** - Environmental Documents.'' You can also go directly to the ''**Federal Register**'' listings at http://www.epa.gov/fedrgstr/. To access information about the TSCA New Chemicals Program, go directly to the Home Page for the New Chemicals Program, within the Office of Pollution Prevention and Toxics, at http://www.epa.gov/opptintr/newchms/.

2. *In person*. The Agency has established an official record for this document under docket control number OPPTS–53171A. The official record consists of the documents specifically referenced in this document, any public comments received during an applicable comment period, and other information related to this document, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the TSCA Nonconfidential Information Center, Rm. NE B–607, Waterside Mall, 401 M St., SW., Washington, DC. The Center is open from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number of the Center is 202–260–7099.

3. *By phone*. If you need additional information about this document, you may also contact the person identified in the ''FOR FURTHER INFORMATION CONTACT'' section.

II. Background

A. Overview of the PMN Process

Under section 5(a) of TSCA, persons must notify EPA at least 90 days before manufacturing or importing a new chemical substance for non-exempt purposes. A new chemical substance, as defined in section 3(9) of TSCA, is any chemical substance (as defined by section 3(2)) that is not included on the Inventory compiled under section 8(b) of TSCA.

Section 5 of TSCA gives EPA 90 days to review a PMN (also referred to as a ''section 5 notice''). However, the review period can be extended under TSCA section 5(c) for good cause; it may also be suspended voluntarily by the mutual consent of EPA and the PMN submitter. During the review period, EPA may take action under TSCA section 5(e) or (f) to prohibit or limit the production, processing, distribution in commerce, use, and disposal of new chemical substances that raise health or environmental concerns. If EPA has not taken action under TSCA section 5(e) or (f), the PMN submitter may manufacture or import the new chemical substance when the review period expires.

No later than 30 days after the PMN submitter initiates manufacturing or importing, it must provide EPA with a notice of commencement of manufacture or import. Section 8(b) of TSCA provides that, upon receipt of such a notice, EPA must add the substance to the TSCA Inventory. Thereafter, other manufacturers and importers may engage in activities involving the new substance without submitting a PMN, unless the Agency has used its Significant New Use Rule (SNUR) authority under TSCA section 5(a)(2) to designate a use of a chemical substance as a ''significant new use.'' Section 5(a)(1)(B) of TSCA would then require persons to submit a Significant New Use Notice (SNUN) to EPA at least 90 days before they manufacture, import, or process the substance for the use designated as significant. The required SNUN provides EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit that activity before it occurs.

B. History

Since 1979, EPA has reviewed over 30,000 TSCA section 5 submissions for new chemical substances. During the intervening years, EPA has implemented various initiatives which have enabled the Agency to review a greater number of new chemicals more

efficiently. In 1988, for example, EPA's Office of Toxic Substances (now the Office of Pollution Prevention and Toxics) first used its accumulated experience to group chemical substances with similar physicochemical, structural, and toxicological properties into working categories (USEPA, 1988, see Unit VI.8.). These categories, including the subject one for PBT chemical substances, are developed by EPA based on available data and experience reviewing PMNs on similar substances. Such groupings enable both PMN submitters and EPA reviewers to benefit from the accumulated data and decisional precedents and facilitates the assessment of new chemical substances.

PBT chemical substances possess characteristics of persistence (P) in the environment, accumulation in biological organisms (bioaccumulation (B)), and toxicity (T) that make them priority pollutants and potential risks to humans and ecosystems. Prominent examples of PBT chemical substances include the insecticide DDT and polychlorinated biphenyls (PCBs).

Establishment of a PBT category alerts potential PMN submitters to possible assessment or regulatory issues associated with PBT new chemicals review. It also provides a vehicle by which the Agency may gauge the flow of PBT chemical substances through the TSCA New Chemicals Program and measure the results of its risk screening and risk management activities for PBT new chemical substances; as such, it is a major element in the Agency's overall strategy to further reduce risks from PBT pollutants.

As described in the **Federal Register** notice of October 5, 1998 (63 FR 53417), development of the TSCA new PBT chemicals policy has occurred in coordination with U.S. national, U.S./Canada binational, and international efforts to identify and control the environmental release of persistent organic pollutants (POPs). The proposed TSCA PBT category has been provided to the Criteria Expert Group (CEG) established at the first session of the Intergovernmental Negotiating Committee (INC) for an International Legally Binding Instrument for Implementing International Action on Certain Persistent Organic Pollutants, in accordance with the mandate given by the Governing Council of the United Nations Environment Programme (UNEP) in paragraph 9 of its decision 19/13 C (http://irptc.unep.ch/pops/gcpops_e.html). The CEG is an open-ended technical working group with a mandate to present to the INC proposals for science-based criteria and a procedure for identifying additional POPs as candidates for future international action. The CEG is to incorporate criteria pertaining to persistence, bioaccumulation, toxicity and exposure in different global regions and should take into account the potential for regional and global transport, including dispersion mechanisms for the atmosphere and the hydrosphere, migratory species, and the need to reflect possible influences of marine transport and tropical climates. At its first meeting, October 26–30, 1998 in Bangkok, the CEG recommended that the INC consider developing a provision encouraging countries and regions to include in their new chemicals schemes elements relating to development and introduction of new chemical POPs. The U.S. described its proposed TSCA new chemicals program policy for the category of PBT new chemicals, and the full text of the October 5, 1998 **Federal Register** notice was distributed to all delegations as a Conference Room Paper. The CEG's recommendation was accepted at the second meeting of the INC (January 25–29, 1999 in Nairobi) and the INC will consider it further in its deliberations.

This policy statement is important in our new chemical assessment and TSCA regulatory programs, and represents the first formal statement of national policy regarding new chemical ''persistent organic pollutants.'' Under our domestic program, the policy statement provides guidance criteria for persistence, bioaccumulation, and toxicity for new chemicals and advises the industry about our regulatory approach for chemicals meeting the criteria. Internationally, the **Federal Register** notice of October 5, 1998 (63 FR 53417) alerted the parties involved in negotiation of the POPs Convention to the need for inclusion of a new chemicals provision in the Convention. The issuance of the final policy statement will reaffirm US leadership on this issue and serve as a model for other countries in taking steps to discourage the introduction of POPs as new chemicals and pesticides.

III. Discussion of Final Policy Statement and Response to Comments

Today's policy statement adopts the criteria and testing strategy of the **Federal Register** notice of October 5, 1998 (63 FR 53417), with minor revisions. The Agency reviewed and considered all comments received on the October 5, 1998 (63 FR 53417) notice. A complete copy of all comments received is available in the public docket for this document. A discussion of the policy statement, including a summary of significant comments and the Agency's response follows:

A. Pigments

Comment 1-Pigments. Commenters suggested that EPA not identify pigments as bioaccumulators and were concerned that testing could end up being expensive for pigments, which are persistent by design.

Response. EPA assesses PMN chemical substances for PBT attributes on a chemical-by-chemical basis, regardless of whether or not they fall into a chemical use category such as pigments. Not all pigments are the same and a precise definition of the term ''pigment'' is not available. As a result, EPA does not have general ''pigments'' or ''dyes'' assessment categories; there are, however, more specifically described categories of dyes or pigments that have been described by EPA (e.g., acid or amphoteric dyes, dichlorobenzidine-based pigments, and others; see categories document at http://www.epa.gov/opptintr/newchms/chemcat.htm). Moreover, the fact that a substance is ''persistent by design'' by itself is not a sufficient basis for identifying a PBT new chemical substance. Persistence is only one of three criteria used to identify a chemical as PBT. When combined with a potential to bioaccumulate, toxicity concern, and sufficient release to the environment to result in potential risk or significant exposure, pigments may be of concern, whether or not they are persistent by design. If a PMN chemical is persistent by design, and becomes subject to testing requirements by EPA, it would be counterproductive to test initially for persistence, but rather to address the ''B'' and ''T'' criteria instead.

B. Ready Biodegradability Testing

Comment 2-Ready biodegradability testing. Commenters suggested that EPA avoid the use of strict pass/fail criteria for ready biodegradability of poorly water-soluble substances.

Response. Poor water solubility does not necessarily lead to inability to pass a ready biodegradability test, as amply demonstrated by the fact that many fats, oil, petroleum hydrocarbons, etc. easily pass ready biodegradability tests. While strict OECD (Organization for Economic Co-operation and Development) pass/fail criteria are given in the OPPTS Ready Biodegradability test guidelines (see http://www.oecd.org//ehs/test/degrad.htm and Testing Strategy for PBT Chemical Substances, Unit IV.B. of this document), the Agency recognizes the limitations in applying such criteria

rigidly given that many substances of concern as potential PBTs are unlikely to pass ready biodegradability tests. A variety of critical aspects beyond the pass/fail result will be considered when evaluating potential new chemical PBTs or when testing decisions are made about specific PMN substances. These more critical aspects include those related to chemical structure (e.g., degree of branching) and bioavailability (e.g., uptake of a substance by fish or microorganisms), and their influence on both biodegradation and bioaccumulation.

C. Bioconcentration Factor and Kow

Comment 3-Bioconcentration factor. Commenters requested clarification on how bioconcentration factor (BCF) will be estimated using calculations based on octanol-water partition coefficient.

Response. The octanol-water partition coefficient (Kow) is correlated with the potential for a chemical to bioaccumulate in organisms; the BCF can be predicted from log Kow, via computer programs based on structure activity relationship (SAR). The Agency process for predicting bioaccumulation factors (BAFs) and BCFs, along with literature references, is described in some detail in the proposed rule for lowering of reporting thresholds for certain PBT toxic chemicals subject to reporting under section 313 (Toxic Release Inventory, or TRI) of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 (January 5, 1999 (64 FR 688) (FRL–6032–3), see page 704).

Comment 4-Log Kow and low solubility chemicals. Commenters suggested that the October 5, 1998 (63 FR 53417) **Federal Register** notice identified methods for calculating log Kow that are not appropriate for organic pigments, which are insoluble in octanol. They wanted to know how EPA handles low octanol or water soluble chemicals.

Response. EPA believes that the methods cited in the October 5, 1998 (63 FR 53417) **Federal Register** notice for experimental measurement of the octanol/water partition coefficient (Kow), or SAR to predict Kow, are appropriate, and the results of either can then be used to predict the Fish BCF. Chemicals are unlikely to be accorded special treatment in the new chemicals review process solely because of low solubility in octanol or water alone. The test guidelines (OPPTS 830.7570 or 830.7560) cited in the October 5, 1998 (63 FR 53417) **Federal Register** notice are viewed as the most appropriate for measuring Kow, and alternatively, the shake-flask method (OPPTS 830.7550 test guideline) or the new ''slow-stir'' method currently under development by the OECD, can be used. However, if the chemical manufacturer still views these methods as inappropriate for a given chemical, it would be advisable to proceed to more definitive testing to address bioaccumulation potential (i.e., the Fish BCF study). This approach can be applied to other testing endpoints as well; for example, based on physicochemical properties of a particular PMN chemical substance, a company might forgo a lower tier acute Daphnia toxicity study in favor of the chronic study because it would yield the best information for the screening level risk assessment.

Comment 5-Use of octanol solubility data alone. Commenters wanted to know if octanol or fat solubility data can be used before determining which chemical substances have the potential for bioaccumulation.

Response. By itself, solubility in octanol (as a surrogate for fat) is not a good predictor of potential bioaccumulation in fish. Kow is correlated with the potential for a chemical to bioaccumulate in organisms; the bioconcentration factor (BCF) can be predicted from log Kow, via SAR. Kow is a coefficient which serves as a surrogate for the partitioning of chemicals between water and fat, and cannot be accurately estimated via separate determinations of solubility in pure octanol and water (i.e., by calculating the ratio of the pure-solvent solubilities) (Sijm et al., 1999, see Unit VI.1.). The Agency uses and recommends the use of computer models to predict Kow where there are no measured data.

D. Environmental Half-Life

Comment 6-Calculation of half-life. Commenters wanted to know how half-life is calculated in the review of PBT new chemicals.

Response. Multimedia fate models like the Environmental Quality Criteria (EQC) model (Mackay et al., 1996, see Unit VI.2.) require compartmental half-lives for air, water, soil and sediment, which cannot necessarily be interpreted as half-lives for any specific process such as biodegradation. Data on air half-lives for input to models would be either measured or derived from the Atmospheric Oxidation Program (AOP or AOPWIN) or similar methodology. Studies by Boethling et al. (1995, see Unit VI.3.) and Federle et al. (1997, see Unit VI.4.) suggest that half-lives in bulk soil may be assumed for screening purposes to be about the same as for surface water, and that sediment half-lives may be assumed to be 3–4 times longer. EPA's current suggested approach to finding water half-life is to use the Ultimate Survey Model (USM) in the EPI BIOWIN program (Boethling et al., 1994, see Unit VI.5.). Estimation of bulk compartment half-lives from USM model data requires several assumptions, including that (1) biodegradation is the only significant fate process in water, soil, sediment; (2) water and soil half-lives are the same; and (3) sediment is dominated by anaerobic conditions and therefore sediment half-life is four times longer than water half-life.

E. Computer Models and the Use of Models vs. Actual Data

Comment 7-Use of models vs. actual data. Commenters support the use of the Mackay/EQC model, but stressed the importance of having a process for using actual data in place of the model.

Response. This is a reasonable suggestion. The EQC model is based on the fugacity approach and subsequently applied to numerous environmental processes. It uses an ''evaluative environment'' in which environmental parameters such as bulk compartment dimensions and volumes (e.g., total area, volume of soil and sediment, etc.) are standardized, so that overall persistence for chemicals with different properties and rates of transformation may be compared on an equal basis. In general, measured values of toxicity, chemical properties, compartmental transformation half-lives, etc., provided the data are of acceptable quality, are preferred over those that are predicted or estimated via a model or computer program.

Comment 8-Modeling of air releases. Commenters noted that the October 5, 1998 (63 FR 53417) **Federal Register** notice considered only biodegradation and aqueous hydrolysis and asked about fate of a chemical upon release to air. They suggested that EPA estimate atmospheric oxidation using AOPWIN.

Response. Although the testing strategy for this policy statement focuses on biodegradability, all relevant transport and transformation processes will be considered in evaluating the potential for a PMN substance to behave as a PBT. Transformation processes not mentioned in the **Federal Register** notice but which may be important for specific PMN substances include atmospheric oxidation and photolysis, photolysis in water, and redox transformations (of which there are various types) in water, soil, and sediment. Although EPA believes that for most organic chemicals, biodegradation in water, soil, and sediment will be the most important

transformation process, each suspected PBT chemical substance will be evaluated on its use and disposal patterns.

Clearly the atmosphere is an important environmental medium, and is especially relevant where a substance is emitted directly to the atmosphere or transported there via volatilization or aerosolization. We know by deduction that it is only, or at least chiefly, through the atmosphere that POPs like dioxins and Polychlorinated biphenyls (PCBs) reach remote locations, and it will be an important factor in determining the ultimate fate of many PMN substances as well. It is through multimedia fate models such as EQC that atmospheric fate will be considered in developing an overall prediction of environmental persistence for suspected PBT substances. Where measured data are not available, appropriate estimation methods such as that in the AOPWIN program will be used to generate screening-level estimates of atmospheric half-lives.

F. Use of ''Weight of Evidence'' and Professional Judgment

Comment 9-Laboratory vs. field behavior of chemicals. Commenters indicated that EPA needs to incorporate any differences between lab and field behavior of chemicals into its analysis of new chemical substances, acknowledge the limitations of screening-level biodegradation tests, and acknowledge the value of using professional judgment when interpreting data from extended (> 60 day) degradation studies.

Response. EPA recognizes that laboratory tests at best provide a snapshot of expected environmental behavior, which ideally is studied in the field. But since field testing is nearly always impractical for PMN chemical substances, it is necessary to conduct laboratory tests and to apply scientific judgment in extrapolating from lab to field. EPA similarly acknowledges the limitations of ready biodegradability and other screening tests as indicators of ultimate environmental behavior. Finally, it is well known that even this policy statement's higher tier (Testing Tiers 2 and 3) environmental fate guidelines, despite being designed to provide test conditions closer to those expected in the field, become less reliable when tests are run for longer than the maximum duration specified in the guidelines. EPA will give appropriate weight to these and other complexities in its assessments.

Comment 10-''Check the box'' vs. ''weight of evidence.'' Commenters noted that the TSCA PMN requirements for PBT chemicals look more like ''check-the-box'' than ''weight of evidence'' and wanted to know how EPA will make professional judgment and use SAR and assessment methods to identify PBT new chemicals.

Response. These tools (professional judgment, SAR, computer models, assessment methods, etc.) would be applied to potential PBT chemical substances in the same way they are applied to any other chemical substance in the PMN review process. Using predictive tools (in the absence of test data) and professional judgment, EPA leans towards a ''reasonable worst case'' when there is lack of chemical-specific data. Industry always has the option of assisting and enhancing the Agency's determinations by submitting scientifically valid test data. There are a number of existing documents describing the PMN process and the critical role played by SAR and professional judgment in that process, including the Chemistry Assistance Manual for Premanufacture Notification Submitters (USEPA, 1997, see Unit VI.6.) and parts of the report on the joint U.S./European Union study that evaluated the predictive power of the SAR (USEPA, 1994, see Unit VI.7.). EPA believes that, where no or insufficient actual toxicity data exist upon which to base a decision, toxicity estimates generated by SARs and other predictive techniques may constitute sufficient evidence to be used in human health and environmental hazard and environmental fate assessment as components in certain risk determinations under TSCA (see also the **Federal Register** of December 1, 1993 (58 FR 63507) for a similar statement related to meeting section 313 listing criteria under EPCRA of 1986).

Comment 11-Implement PBT policy within risk assessment framework. Commenters suggested that EPA risk management decisions should not be made solely on hazard information; these PBT criteria should be implemented within a risk assessment framework. They indicated that toxicity has been largely overlooked in the PBT scheme and no criteria have been provided for toxicity. Commenters suggested that EPA needs to take into account P and B and T before requiring further testing or identifying a chemical as a ''true'' PBT, and asked whether persistence and log Kow would be sufficient to determine that a PBT PMN chemical substance may pose a significant risk. Commenters also suggest that EPA should except non-toxic and low exposure/release substances from consideration under this category and were concerned that the current proposed criteria do not consider any health and safety benefits of a PBT chemical substance.

Response. New chemicals identified as potential PBT chemicals are assessed on a case-by-case basis. Section 5(e) of TSCA authorizes EPA to control commercial activities involving a new chemical substance for which available information is insufficient to permit a reasoned evaluation of potential health and environmental effects if EPA determines either (1) that the manufacture (including import), processing, distribution in commerce, use, or disposal of the substance may present an unreasonable risk of injury to health or the environment (''risk-based'' finding), or (2) that the substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance (''exposure-based'' finding). The restrictions under TSCA section 5(e) are imposed pending the development of the test data or other information needed to evaluate the new substance's health or environmental effects. EPA draws on information and data submitted with the PMN form, other information available to the Agency, and modeling (e.g., exposure, release, SAR, etc.).

The Agency will consider P and B and T, individually and together, and exposure in making risk-based judgments. Risk, specific to the PMN substance as well as its risk relative to substitutes currently on the market, is predicted as a function of the potential hazard of the substance and the expected exposure. In other instances, as discussed in the October 5, 1998 (63 FR 53417) **Federal Register** notice, during PMN review EPA may determine that a new substance 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 to the substance,'' and that the available information is insufficient to determine the effects of the substance. For such exposure-based determinations on suspected PBT new chemicals, EPA will use a case-by-case approach for making findings by applying considerations beyond P and B (i.e., toxicity or physical/chemical properties), and consider P and B aspects as factors which might argue for regulatory action under TSCA section 5(e) at lower levels of production or exposure/release than are described in the general guidelines for the new chemicals program's

exposure-based policy (USEPA, 1988, USEPA, 1989, see Unit VI.8. and 9.). Overall, companies are not being prevented from developing and using new substances that are judged to be potential PBT chemicals, but EPA may require certain controls (e.g., limiting the release of the PMN chemical to the environment) or testing as a result of its assessments.

In order to be so identified as a PBT new chemical based on a risk-based finding, all three criteria must be satisfied. The Agency has adopted a 1 to 3 rating system for each of P, B, and T. If chemical has a low Kow (i.e., ''B1,'' with BCF estimated as less than 1,000), the B1 rating does not support the new chemical's identification as a potential ''PBT chemical.'' For example, some surfactants could be P3B1T3; they are highly persistent in the environment and chronically toxic to organisms, but with low bioaccumulation potential. However, Agency action may still be taken under TSCA on chemicals not meeting all of the PBT criteria, if they otherwise meet the risk or exposure-based elements of TSCA section 5(e). Similarly, calcium would also not be considered a PBT chemical, as it would be ranked P3B3T1; it is persistent in the environment, it bioaccumulates, but it is not considered toxic. Although the Agency does not promote the environmental discharge of more persistent materials, the environmental ''desirability'' of a given chemical often depends on a balance of various factors, including toxicity and ability of the chemical to bioaccumulate. Like the previous surfactant example, the Agency may nonetheless take action on a P3B3T1 chemical (not calcium per se), most likely under its exposure-based authority.

The toxicity rating for a PBT chemical applies to repeated exposures which result in human or environmental toxicity, including, for example, systemic toxicity, mutagenic damage, reproductive toxicity, or developmental toxicity. An example of this is chronic toxicity towards aquatic organisms of organotins from contaminated marine environments, which ultimately resulted in the regulation of use of tributyl tin in marine anti-fouling paints. Repeated exposures result from a PBT chemical after it has been released into the environment, usually via contaminated water, sediments, or food. The classic PBT problems (i.e., PCBs and Dichloro diphenyl trichloroethane (DDT)) have been associated with food chain contamination.

G. Scientific Justification for PBT Technical Criteria

Comment 12-Support for lower threshold criteria for ''P'' and ''B.'' Commenters believed that there is little precedent, scientific justification, evidence or data to support the lower regulatory threshold of bioaccumulation factor of 1,000 and environmental persistence of 2 months. They suggested that EPA needs a rationale for these criteria beyond ''...are characterized by a tendency to accumulate in organisms.''

Response. There is no ''bright line'' that clearly identifies a bioaccumulation factor of 1,000 or a half-life of 2 months as the best bioaccumulation or persistence criterion from a scientific perspective. However, it is not accurate to state that there is no precedent or basis for using these values. As outlined in EPA's recent proposal to lower the reporting thresholds for PBT chemicals that are subject to reporting under section 313 of EPCRA (64 FR 688; January 5, 1999), similar values have been proposed by several authorities, including the Ontario, Canada Ministry of Environment and Energy (MOEE) for its Candidate Substances List for Bans or Phaseouts (MOEE, 1992, see Unit VI.10.); the Canadian initiative for Accelerated Reduction/Elimination of Toxics (ARET) (ARET, 1995 and ARET, 1994, see Unit VI.11. and 12.); the International Joint Commission (IJC)'s Great Lakes Water Quality Agreement (GLWQA) (IJC, 1993, see Unit VI.13.); and the United Nations Economic Commission for Europe Convention on Long-Range Transboundary Air Pollution (UNECE-LRTAP), which did adopt 2 months as the persistence criterion of record for water (UNECE-LRTAP, 1998, see Unit VI.14.).

In determining the thresholds for this policy statement, EPA concluded that it would be appropriate to reflect the levels of concern that the various PBT chemicals presented, based on the differing degrees to which the chemicals persist and bioaccumulate. The Agency ultimately chose to adopt a two-tier approach, and to establish two separate thresholds to reflect the chemicals' varying potentials to persist and bioaccumulate, as well as to reflect the Agency's belief that the different levels of regulatory action under TSCA are warranted for the two tiers. As discussed in detail in the preamble to the mentioned EPCRA proposed rule, EPA found that generally the criteria selected by various U.S. and international regulatory bodies for either persistence or bioaccumulation clustered around two values. For persistence in water, soil, and sediment, the criteria were grouped around half-lives of 1 to 2 months and 6 months, and for persistence in air, either 2 or 5 days. Bioaccumulation criteria were grouped around BAF/BCF values of 1,000 and 5,000. The preamble to the EPCRA proposed rule states ''Bearing in mind that one of Congress' articulated purposes for EPCRA section 313 was to provide local communities with relevant information on the release and other waste management activities of chemicals in their community that may present a hazard, EPA determined that the criteria that were most consistent with these purposes were, for persistence, half-lives of 2 months for water, sediment, and soil, and 2 days in air, and for bioaccumulation, bioaccumulation/bioconcentration factor values of 1,000 or greater'' (64 FR 692; January 5, 1999). EPA is making a similar determination for the PBT new chemicals policy under TSCA. The PMN process is one of EPA's cornerstone Pollution Prevention programs and plays a critical gatekeeper role in making sure that all new chemical substances do not present unreasonable risks when they are commercialized. Given this, and the uncertainty which often accompanies Agency review of a PMN chemical substance due to lack of data, the TSCA new chemicals program is and must be conservative by nature, which suggests that a half-life shorter than 6 months and a BCF criterion lower than 5,000—values that were selected solely or primarily to isolate substances already widely acknowledged to be POPs are appropriate for regulatory scrutiny of new chemicals under TSCA. Note that the CEG, at the October 26–30, 1998 Bangkok meeting described in Unit II.B. of this document, developed indicative numerical values as bracketed criteria text which included persistence of 2 vs. 6 months in water and log Kow of 4 vs. 5 (equivalent to a BCF of approximately 1,000 vs. 5,000, respectively).

A series of PMNs submitted to EPA in 1990 (Zeeman et al., 1999, see Unit VI.15.) illustrates (1) why EPA believes that the persistence criterion for bioaccumulating substances in soil, water, or sediment should be set substantially lower than 6 months; and (2) that concern for potential exposures to persistent and bioaccumulative toxics must extend beyond the UNEP's 12 widely acknowledged POPs. The substances in question were alkylated diphenyls, for which EPA expected discharge to receiving streams and rivers. The submitter supplied data on use and disposal, aquatic toxicity, and

biodegradability. The submitted environmental fate data and EPA estimates of biodegradability based on structural analogs suggested that half-lives in water would be well below 6 months, but not necessarily lower than 2 months. As a result of concerns expressed by EPA, use was limited to sites where resulting water concentrations could be limited to 1 microgram per liter or less; concomitantly, the submitter was also informed of EPA's belief that a potential for long-term risk existed, but that EPA could not quantify this risk since assessments typically evaluated releases over a period of only 1 year. In 1998, results of monitoring revealed that the PMN substances had been found in fish fillets and sediment samples from the receiving stream. If, for these 1990 PMNs, EPA were to have had in place the 2 month persistence criterion described in today's policy statement, further scrutiny under the new chemicals program would have been warranted, and beyond simply informing the PMN submitter of the potential for long-term risk, the Agency would likely have required further testing to obtain an experimental value for environmental persistence of the chemicals. This in turn would have given the Agency a better picture of the behavior of the chemicals in the environment and the environmental half-life relative to the 2 month value.

Comment 13-Deny commercialization to lower threshold PBT chemicals. Some commenters supported exercising the ''Precautionary Principle'' by not allowing commercialization under a TSCA 5(e) consent order or SNUR pending testing of the PMN chemicals which meet the P=2 month and BCF=1,000 criteria. They suggested that these chemicals should be banned instead, pending the necessary testing.

Response. Whereas a half-life of 2 months and BCF of 1,000 can be justified as lower-tier cutoffs in a deliberately conservative TSCA new chemicals program that is designed to prevent commercialization of potentially risky substances, it would not be appropriate to automatically trigger a ''ban pending testing'' at these cutoffs given the uncertainties about substance properties, release, and environmental behavior that normally characterize PMN review. The Agency believes that the available predictive tools and current knowledge of POPs lend support for this two-phased approach to screening of PBT chemicals and collection of information ''sufficient to permit a reasoned evaluation of potential health and environmental effects'' if EPA makes the requisite risk- or exposure-based findings under TSCA section 5(e).

Comment 14-Relationship of P, B, and T criteria. Commenters suggested that the October 5, 1998 (63 FR 53417) notice is inaccurate when it states that 2 months is adequate for detecting many long-term toxic effects as well as any tendency for a substance to bioaccumulate in aquatic organisms. Commenters pointed out that the persistence criterion is not related to detection of long-term toxicity.

Response. The statement in question was intended simply to note that the 2 months half-life in water persistence criterion closely tracks the duration of long-term environmental toxicity or bioaccumulation tests. If a new chemical substance is predicted to or measurably demonstrates chronic toxicity, potential to bioaccumulate, and environmental persistence over that same time period (2 months), it would meet the minimum TSCA PBT criteria. It is true that, in general, half-life cutoffs for identifying POPs warranting international action (e.g., in programs like UNECE-LRTAP and UNEP Global Negotiations on POPs) have not been selected based on the duration of toxicity or bioaccumulation tests. There are no cutoffs or ''fence lines'' for environmental persistence criteria that emerge as immutable quantities solely from scientific analysis; the choice of screening criteria is a policy decision guided by the anticipated scope of a negotiation or regulatory activity. In the case of the PMN program, 2 months represents a reasonable screening level value for ''persistence'' which is more than the 1-month period in a ready biodegradation study and less than the 6 month value widely agreed to internationally (U.S.-Canada binational agreement to control the discharge or release of POPs in the Great Lakes Basin, UNECE-LRTAP, North American Free Trade Agreement Commission for Environmental Cooperation (NAFTA-CEC), etc.) as reflecting the persistence of known POPs chemicals (e.g., DDT, hexachlorobenzene). As mentioned in the previous response, there is international support, through the CEG, for persistence values of 2 or 6 months in water.

Comment 15-Relationship of P and B. Commenters suggested that the October 5, 1998 (63 FR 53417) notice's statement, ''Generally, persistent bioaccumulators are chemical substances that partition to water, sediment or soil and are not removed at rates adequate to prevent their bioaccumulation in aquatic or terrestrial species,'' should be revised to reflect that persistence alone is not sufficient to cause a substance to bioaccumulate.

Response. EPA did not intend that the sentence be read to mean that persistence alone is sufficient to result in bioaccumulation. The point that was intended to be conveyed was that a certain level of persistence is a necessary condition for bioaccumulation to occur. There are other conditions that affect bioaccumulation, such as bioavailability and the metabolic transformation rate in the target species. These and other factors will be evaluated by EPA in the determination of the PBT concern level for PMN chemical substances.

H. Relationship of TSCA PBT Policy to Other Agency and International PBT Initiatives

Comment 16-Finalize overall Agency multimedia strategy first. Commenters suggested that the PBT classification criteria being proposed for TSCA section 5(e) may have broader application, e.g., international or other Agency PBT initiatives, and may be used to establish precedent in other programs. In addition to the TSCA October 5, 1998 (63 FR 53417) **Federal Register** notice, there have been three other notices published in **Federal Register** dealing with (1) the promotion of voluntary waste minimization efforts to reduce the generation of those PBT chemicals which are found in hazardous waste regulated under the Resource Conservation and Recovery Act (RCRA) (63 FR 60332; November 9, 1998 (FRL–6186–7)), (2) the Agency draft Multimedia PBT Strategy (63 FR 63926; November 17, 1998 (FRL–6045–2)), and (3) the lowering of reporting thresholds for certain PBT toxic chemicals subject to reporting under section 313 (Toxic Release Inventory, or TRI) of EPCRA of 1986 (64 FR 688; January 5, 1999). These commenters stated that the TSCA notice is premature, occurring before adoption of the overall Agency strategy, and is inconsistent with other initiatives, domestic and international, which have lists of chemicals and more selective criteria (i.e., specific to environmental media, fate and transformation processes). Commenters recommended that EPA finalize the Agency strategy first, before proceeding with the TSCA, RCRA, and TRI actions, and that there should be coordination among them all with uniform PBT criteria as part of the Agency strategy.

Response. The PBT Multimedia Strategy formalizes an Agency process for integration of program activities involving these types of substances. While the strategy intends to coordinate Agency PBT-related activities under its

framework, the strategy does not establish rigid criteria with respect to PBTs. Program offices must operate within the parameters of their legislative mandates and established regulatory and policy frameworks. For some programs such as the Toxics Release Inventory, the TSCA New Chemicals Program and the RCRA National Waste Minimization Plan, actions involving PBTs are a historical reality and their experience has, in fact, largely shaped the strategy. Therefore, EPA does not intend to halt all ongoing work involving PBTs until the strategy is ''finalized.'' With respect to the PMN process, it is important to understand and acknowledge its fundamental purpose, which is to allow EPA to evaluate the hazards, exposures, and risks of new chemicals, and the opportunity to protect against unreasonable risks, if any. The structure of that process and the tools used to implement it flow logically from its statutory purpose and suggest that the category approach outlined in this policy statement is the most appropriate means of addressing potential concerns for substances possessing PBT characteristics. It is EPA's intention that the strategy be a living document. Therefore, the strategy will be updated based upon public comment; it will not be ''finalized'' in the more traditional sense of a rulemaking. EPA does agree that consistency is a laudable goal where the criteria are meant to be used for similar purposes and is seriously considering comments within the context of the strategy regarding establishment of consistent criteria for priority PBTs.

Comment 17-Carefully communicate lower thresholds. Commenters suggested that EPA should use only the environmental persistence of 6 months/BCF of 5,000 screening levels for consistency among EPA and U.S./international programs and should carefully communicate proposed lower criteria internationally.

Response. As discussed in the response to Comment 12, EPA believes that a lower tier of 2 month/BCF of 1,000 is appropriate for risk screening activities under TSCA. Communication is occurring in the international forum. Unit II.B. of this document discusses the CEG for POPs, established under UNEP mandate. At its first meeting, on October 30, 1998 in Bangkok, the CEG recommended that the INC consider developing a provision encouraging countries and regions to include in their new chemicals schemes elements relating to development and introduction of new chemical POPs. The U.S. described its proposed TSCA new chemicals program policy for the category of PBT new chemicals, and the full text of the October 5, 1998 (63 FR 53417) **Federal Register** notice was distributed to all delegations as a Conference Room Paper. The CEG's recommendation was accepted at the second meeting of the INC (January 25–29, 1999 in Nairobi) and the INC will consider it further in its deliberations.

I. Testing Strategy

Comment 18-Toxicity testing. Commenters asked whether toxicity was considered at each testing tier or only in tier 3. It was not clear to them when toxicity testing would be requested, nor what results will be considered acceptable by the Agency.

Response. Each of P and B and T are weighed in the Agency's assessment. The testing strategy outlined in this policy statement is intended to build the case, starting with testing to establish persistence and bioaccumulation, and then determining toxicity and confirming a chemical's status as a PBT chemical in tier 3. Once a chemical becomes distributed in the environment at low concentrations, the combination of persistence and bioconcentration in organisms can result in residues high enough to approach a toxic dose. The first two tiers focus on P and B because of the critical role these aspects play in PBT determinations and because of their relatively lower cost to determine P and B. Thus, chronic toxicity testing, which is expected to be the most expensive testing, is reserved until tier 3 where it serves to establish PBT status. Although the early tier P and B testing may either obviate the need for toxicity testing or result in more directed and cost-effective toxicity testing, the need for toxicity testing is considered in each testing tier and will be obtained in lower tiers where needed on a case-specific basis. As with all new chemicals reviewed by the Agency under TSCA, the potential toxicity of the chemical is determined from test data, if any, or by analogy to structurally similar chemicals. If a company knows or suspects prior to testing that their chemical is likely to be persistent and bioaccumulative, consideration should be given to conducting chronic toxicity testing in the first tier. For any suspected PBT chemicals for which a risk finding has not been made, but which meet production, release, and exposure thresholds under the Agency's exposure-based policy (USEPA, 1988, USEPA, 1989, see Unit VI.8. and 9.), the standard screening level battery of testing (or an appropriate subset thereof) currently utilized for exposure-based cases in the new chemicals program could be required in addition to PBT testing.

Comment 19-Equivalent tests. Commenters suggested that all tests referenced in the testing strategy should also state ''or an equivalent test.''

Response. EPA realizes that often there are a number of different but acceptable means to providing testing information. However, EPA's acceptance of a guideline not specified in this policy statement and/or use of data generated under such guidelines depends on multiple factors including the specifics of the test substance, purpose of the testing, familiarity with specific procedures and equipment, validation of the method, etc. Typical TSCA 5(e) consent orders require that testing performed pursuant to the order must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR part 792 and using methodologies generally accepted at the time the study is initiated. Before starting to conduct any such study, the PMN submitter must obtain approval of test protocols from EPA by submitting written protocols. Published test guidelines specified in the Test Strategy section (see Unit IV. B. of this document) provide general guidance for development of test protocols, but are not themselves acceptable protocols.

J. Applicability of PBT Criteria to Metals

Comment 20-PBT criteria are not appropriate for metals. Commenters suggested that the application of Persistence and Bioaccumulation criteria appropriate for organic chemicals does not make sense for metals and metal compounds. They also suggested that EPA needs criteria to identify potential problems generated by organometals.

Response. The approach and the criteria are sufficiently flexible to apply to organic chemicals, inorganic metals and organometallics. It is important to distinguish between criteria for identifying potential PBTs, on the one hand, and on the other: (1) the means of generating information on the P, B, and T endpoints for comparison to the criteria, and (2) the applicability of existing test guidelines for generating such information experimentally.

EPA understands that metals are intrinsically not degradable in the sense of ultimate degradation of organics (although they may undergo biologically as well as chemically induced changes in, e.g., oxidation state), and therefore are persistent by definition, but nevertheless may not be bioaccumulative. It is widely accepted that elemental metals are persistent by definition, since they may take different

forms that can be interconverted, but the elemental metal itself cannot be destroyed. All elemental metals therefore meet the 6 month half-life criterion. Given this, it is not correct that EPA's proposed persistence criteria cannot be applied to metals. It may be more accurate to state that the persistence criteria are not themselves very helpful in screening or assessing metals and metal compounds with respect to the potential for risk, whether from direct exposure or through bioaccumulation. Relative to applicability of test guidelines, the same level of judgment will be brought to bear such that, for example, EPA would not require ready biodegradability testing for a metal or metal salt. (EPA may, however, request such testing for organometallics, which, depending on chemical structure, could still show significant degradation in such tests.)

EPA understands that bioavailability is important in determining the potential for risk, and notes that the same generalization applies to any substance whether metallic or not. Metals and organometallic compounds are no different from other organic chemicals with respect to the applicability of the proposed criteria for identifying persistent, bioaccumulative, and toxic substances, except that Kow determination may not be relevant for metals (although the fish BCF study is relevant). Similarly, it is not necessary to develop different criteria or assessment strategies for pigments (see first comments/responses in this policy statement) or any other specific classes of organics. What is necessary is to consider what is known about the behavior of substances like metals during the TSCA PMN review process, both in the assessment of whether a given chemical substance meets the established criteria and in subsequent testing decisions. For any untested PMN chemical substance, if there are no close analogs with data and no clear evidence that available estimation methods are unreliable for this or closely related substances, then the estimation methods can be assumed to apply and the resulting data compared to PBT criteria. Put another way, a metal or organometallic (or, similarly, a pigment) that is judged sufficiently persistent and meets the criteria for bioaccumulation potential and toxicity is of concern for ''PBTness'' regardless of theoretical arguments or generalizations.

The key is how persistence and bioaccumulation potential are determined in the PMN process, and by implication, how bioavailability is determined. This policy statement leaves unspecified how EPA intends to do this, but the Agency will consider all available and relevant data, and will use its professional judgment in considering issues like bioavailability of metals. Using lead as an example, many processes commonly observed in the environment can result in the presence of bioavailable (ionic) lead where it can be bioaccumulated by organisms. These processes may occur in soil and aquatic environments with low pH and low levels of organic matter. Under these conditions, the solubility of lead is enhanced and, in the absence of sorbing surfaces and colloids, lead ion can remain in solution for a sufficient period to be taken up by biota. Lead sorption to soil organic matter has been shown to be pH dependent. Decreasing pH can lead to increasing concentrations of lead in soil and water. Microbial transformations in soil, water, and sediment are also important in determining the overall fate of metals and metal compounds, and therefore the potential for formation of bioavailable forms. Metals are generally taken into cells by nutrient metal transport systems, and these are not sufficiently specific to completely exclude nonessential metals, some of which may be toxic and/or bioaccumulative. In this situation, nutrient metals can be displaced from their binding sites by undesirable, toxic metals, which then gain access to the cell interior with concomitant exclusion of the essential metal (Stumm and Morgan, 1996 see Unit VI.16.). Toxic metal ions are then free to react with critical enzymes or otherwise disrupt cellular functions if they reach certain levels. EPA concludes that under many environmental conditions, metals and metal compounds may be available to express toxicity and to bioaccumulate, and that these effects are not necessarily limited to metals that are not essential nutrients. It is appropriate, therefore, to be concerned about the potential for risk from these effects. It is the policy of the TSCA New Chemicals Program that if the metal in a metal compound cannot become available as a result of biotic or abiotic processes then the metal will not be available to express its toxicity, and by extension, to bioaccumulate. If the intact metal compound is not toxic and the metal is not available from the metal compound, then such a chemical would not be a strong candidate for regulation under TSCA section 5(e).

IV. Final TSCA New Chemicals Program Policy for PBT Chemical Substances

A. Evaluation Criteria and Process for New PBT Chemical Substances

EPA is adopting the following specific identification criteria and associated process for use in evaluating new chemical substances.

NEW CHEMICALS PROGRAM PBT CATEGORY CRITERIA AND PROCESS

	TSCA Section 5(e) Action	
	5(e) Order Pending Testing/Significant New Use Rule (SNUR)[1]	5(e) Ban Pending Testing[2]
Persistence (transformation half-life).	> 2 months	> 6 months
Bioaccumulation (Fish BCF or BAF)[3].	≥ 1,000	≥ 5,000
Toxicity	Develop toxicity data where necessary[4].	Develop toxicity data where necessary[4]

[1]Exposure/release controls included in order; testing required.

[2]Deny commercialization; testing results may justify removing chemical from ''high risk concern''.

[3]Chemicals must also meet criteria for MW (< 1000) and cross-sectional diameter (< 20A , or < 20×10^{-8} cm).

[4]Based upon various factors, including concerns for persistence, bioaccumulation, other physical/chemical factors, and toxicity based on existing data.

Chemical substances suspected as persistent bioaccumulators under the criteria listed in the table in Unit IV.A. of this document may need to undergo testing on ''P'' and ''B'' endpoints which, if confirmed, would be followed by appropriate toxicity testing to identify ''PBT chemical substances.'' Control action under TSCA section 5(e) may be needed in varying degrees, based upon the level of risk concern. Agency control actions taken under TSCA section 5(e) for chemical substances meeting these criteria would be based upon the level of certainty for the PBT properties of a PMN substance (e.g., measured vs. estimated values), the magnitude of Agency concerns, and conditions of expected use and release of the chemical. For example, new chemical substances meeting the PBT criteria listed under ''5(e) Order Pending Testing/Significant New Use Rule (SNUR)'' could be addressed via a negotiated consent agreement under

which necessary testing is ''triggered'' by specific production limits. While the PMN submitter would be allowed to commercialize the substance, certain controls could be stipulated, including annual TRI-type reporting on environmental releases of the PMN substance and specific limits on exposures, releases, or uses. The ''ban pending testing'' criteria are equivalent to those that have been used internationally to identify POPs. For the chemical substances meeting these criteria, the concern level is higher and the Agency would look carefully at any and all environmental releases. Because of the increased concern, more stringent control action would be a likely outcome, up to a ban on commercial production until data are submitted which allow the Agency to determine that the level of risk can be appropriately addressed by less restrictive measures. The control actions described in the table in Unit IV.A. of this document represent just one body of possible decisions and should not be considered as exclusive of other risk management options.

B. Testing Strategy for PBT Chemical Substances

Where EPA is unable to adequately determine the potential for bioaccumulation, persistence in the environment, and toxicity which may result from exposure of humans and environmental organisms to a possible PBT chemical substance, the Agency may conclude, pursuant to sections 5(e)(1)(A)(i) and 5(e)(1)(A)(ii)(I) and (II) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of that PMN substance, that the manufacturing, processing, distribution in commerce, use, or disposal of the substance may present an unreasonable risk of injury to human health or the environment, and/or that the PMN substance will be produced in substantial quantities and that there may be significant or substantial human exposure to the substance or the PMN substance may reasonably be anticipated to enter the environment in substantial quantities. Accordingly, the Agency may find it appropriate to prohibit or otherwise limit the manufacture, import, processing, distribution in commerce, use, or disposal of the PMN substance in the United States pending the development of information necessary for a reasoned evaluation of these effects. The following testing strategy describes test data which EPA believes are needed to evaluate the persistence, bioaccumulation, and toxicity of a PBT chemical substance for which EPA has made the above described risk and/or exposure-based findings under section 5(e)(1)(A)(i) and (ii) of TSCA. The tests are tiered; depending upon the circumstances, such as magnitude of environmental releases, results of testing, or SAR, testing could begin above Tier 1 or additional, higher levels of testing may be required. As discussed in the response to Comment 19 in Unit III.I. of this document, testing must be conducted according to TSCA Good Laboratory Practice Standards at 40 CFR part 792 and using methodologies generally accepted at the time the study is initiated. Before starting to conduct any such study under the terms of a Consent Order under TSCA section 5(e), the PMN submitter must obtain approval of test protocols from EPA by submitting written protocols. Published test guidelines specified in Unit IV.B. of this document provide general guidance for development of test protocols, but are not themselves acceptable protocols.

Tier 1. If, based upon available test data, SAR, and professional judgment, the Agency identifies a new chemical substance as a possible PBT chemical substance, Log Kow should be determined experimentally, using either the liquid chromatography (OPPTS 830.7570 test guideline) or generator column (OPPTS 830.7560 test guideline) method. Hydrolysis in water (OPPTS 835.2110 test guideline) should be determined if, based upon SAR, susceptibility to hydrolysis is suspected. Ready biodegradability should be determined according to either one of the following test guidelines:

1. Ready biodegradability (OPPTS 835.3110 test guideline) 6 methods (choose one): DOC Die-Away, CO_2 Evolution, Modified MITI (I), Closed Bottle, Modified OECD Screening, Manometric Respirometry.

2. Sealed-vessel CO_2 production test (OPPTS 835.3120 test guideline).

If the measured log Kow is < 4.2 (equivalent to an estimated BCF of 1,000) or if the test chemical passes (pass criteria are described in the test guidelines) the ready biodegradability test (i.e., not persistent in the environment), no further PBT-related testing is required. If the measured log Kow is greater than or equal to 4.2, and the chemical does not pass the ready biodegradability test, no further testing will normally be deemed necessary in tier 1; the Agency would likely require tier 2 testing. If hydrolysis testing is conducted and results in a half-life of < 60 days, further testing may not be needed, but the need for testing must be determined after consideration of factors specific to the case, such as physical/chemical properties, persistence and bioaccumulative qualities of hydrolysis products, and the nature of the expected releases.

Tier 2. Biodegradability should be determined according to the Shake-flask die-away test (OPPTS 835.3170 test guideline). This test is based on the principle of aerobic incubation of the test chemical in natural water with and without suspended sediment, requires a chemical-specific analytical method, and allows for the development of a first-order rate constant and half-life. It provides information on persistence that is relevant to the natural environment and is intermediate in cost between ready biodegradability tests (tier 1) and sediment/water microcosm biodegradation test (tier 3).

Bioaccumulation potential should be determined by experimental measurement of the bioconcentration factor (BCF), using the Fish bioconcentration test (OPPTS 850.1730 test guideline (public draft)). Measured BCF should be based on 100 percent active ingredient and measured concentration(s).

If the measured biodegradation half-life is > 60 days and measured BCF is > 1,000, tier 3 testing will normally be required. If only one condition is met, releases and exposure are further considered to determine if additional testing is required.

Tier 3. Toxicity/advanced environmental fate testing. Human health hazards should be determined in the combined repeated dose oral toxicity with the reproductive/developmental toxicity screening test (OECD No. 422 test guideline) in rats. Other health testing will be considered where appropriate.

Environmental fate testing should be conducted according to the Sediment/water microcosm biodegradation test (OPPTS 835.3180 test guideline). The principle of this method is the determination of the test chemical's fate, including transport and transformation, in core chambers containing intact benthic sediment and overlying site water. The method permits more accurate and reliable extrapolation to natural aquatic environments than is possible with lower tier test methods.

Chronic toxicity to fish (rainbow trout) and daphnids should be determined according to 40 CFR 797.1600 (same as OPPTS test guideline 850.1400 (public draft)) and 40 CFR 797.1330 (same as OPPTS test guideline 850.1300 (public draft)), respectively. Additional testing to evaluate other biota (e.g., avian, sediment dwelling organisms) or other effects (e.g.,

endocrine disrupting potential) will be considered where appropriate.

V. Intended Legal Affect of this Policy Statement

The policy discussed in this document provides general guidance on the Agency's use of a category grouping for PBT new chemical substances to facilitate the PMN assessment process for PMN submitters and EPA reviewers. EPA uses groupings of new chemical substances with similar structural and toxicological properties to allow PMN submitters and EPA reviewers to benefit from accumulated data and decisional precedents, as well as streamlined procedural requirements related to the review of and follow-up for new chemical substances.

As guidance, the policy presented in this document is not binding on either EPA or any outside parties, and this document is not intended, nor can it be relied upon, to create any rights enforceable by any party in litigation with the United States. Although this guidance provides a starting point for assessing PBT new chemical substances, EPA will depart from its policy where the facts or circumstances warrant. In such cases, EPA will explain why a different course was taken. Similarly, outside parties remain free to assert that this policy is not appropriate for a specific PMN or that the circumstances surrounding a specific PMN demonstrate that this policy should not be applied. Although the Agency has provided an opportunity for public comment on the guidance provided in this policy statement and is likely to request additional feedback if changes are necessary at some point in the future, the Agency may revise, clarify, or update the text of this guidance without public notice.

VI. References

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List of Subjects

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

Dated: October 22, 1999.

Susan H. Wayland,

Deputy Assistant Administrator for Prevention, Pesticides and Toxic Substances.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–6469–6]

Notice of Proposed Assessment of Clean Water Act Class II Administrative Penalty and Opportunity To Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is providing notice of a proposed administrative penalty for alleged violations of the Clean Water Act. EPA is also providing notice of opportunity to comment on the proposed penalty.

EPA is authorized under section 311(b)(6) of the Clean Water Act, 33 U.S.C. 1321(b)(6), to assess a civil penalty after providing the person subject to the penalty notice of the proposed penalty and the opportunity for a hearing, and after providing interested persons public notice of the proposed penalty and a reasonable opportunity to comment on its issuance. Under section 311(b)(6), any owner, operator, or person in charge of a vessel, onshore facility, or offshore facility in violation of the regulations issued under section 311(j) of the Clean Water Act, 33 U.S.C. 1321(j), (''Oil Pollution Prevention Regulations''—40 CFR part 112) may be assessed a civil penalty of up to $137,500 by EPA in a ''Class II'' administrative penalty proceeding. Class II proceedings under section 311(b)(6) of the Clean Water Act are