180 days of receipt. To receive EPA approval, a State or Tribe must demonstrate that its program is at least as protective of human health and the environment as the Federal program, and provides for adequate enforcement (section 404(b) of TSCA). Notice of Ohio's application, a solicitation for public comment regarding the application, and background information supporting the application was published in the **Federal Register** of May 21, 1998 (63 FR 27960) (FRL–4790–2). As determined by EPA's review and assessment, Ohio's application successfully demonstrated that the State's lead-based paint activities program achieves the protectiveness and enforcement criteria, as required for Federal authorization. Furthermore, no public comments were received regarding any aspect of Ohio's application.

II. Federal Overfiling

TSCA section 404(b), makes it unlawful for any person to violate, or fail or refuse to comply with, any requirement of an approved State or Tribal program. Therefore, EPA reserves the right to exercise its enforcement authority under TSCA against a violation of, or a failure or refusal to comply with, any requirement of an authorized State or Tribal program.

III. Withdrawal of Authorization

Pursuant to TSCA section 404(c), the Administrator may withdraw a State or Tribal lead-based paint activities program authorization, after notice and opportunity for corrective action, if the program is not being administered or enforced in compliance with standards, regulations, and other requirements established under the authorization. The procedures EPA will follow for the withdrawal of an authorization are found at 40 CFR 745.324(i).

IV. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

EPA's actions on State or Tribal lead-based paint activities program applications are informal adjudications, not rules. Therefore, the requirements of the Regulatory Flexibility Act (RFA, 5 U.S.C. 601 *et seq.*), the Congressional Review Act (5 U.S.C. 801 *et seq.*), Executive Order 12866 (''Regulatory Planning and Review,'' 58 FR 51735, October 4, 1993), and Executive Order 13045 (''Protection of Children from Environmental Health Risks and Safety Risks,'' 62 FR 1985, April 23, 1997), do not apply to this action. This action does not contain any Federal mandates, and therefore is not subject to the requirements of the Unfunded Mandates Reform Act (2 U.S.C. 1531–1538). In addition, this action does not contain any information collection requirements and therefore does not require review or approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

B. Executive Order 12875

Under Executive Order 12875, entitled ''Enhancing Intergovernmental Partnerships'' (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or Tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and Tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and Tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's action does not create an unfunded Federal mandate on State, local, or Tribal governments. This action does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this action.

C. Executive Order 13084

Under Executive Order 13084, entitled ''Consultation and Coordination with Indian Tribal Governments'' (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the Tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected Tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's action does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this action.

List of Subjects

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

Dated: September 24, 1998.

Gail C. Ginsberg,

Acting Regional Administrator, Region V.

[FR Doc. 98–26629 Filed 10–2–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–53171; FRL–5771–6]

Proposed Category for Persistent, Bioaccumulative, and Toxic Chemical Substances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has grouped new chemical substances with similar structural and toxicological properties into working categories. These groupings enable the Toxic Substances Control Act (TSCA) section 5(a)(1), Premanufacture Notice (PMN) submitters, and EPA reviewers to benefit from accumulated data and decisional precedents. The establishment of over 45 of these chemical categories has 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 developing a category of persistent, bioaccumulative, and toxic (PBT) chemical substances. This notice solicits comments on proposed criteria for identifying PBT chemical substances and their supporting scientific rationale.

DATES: Written comments should be received on or before December 4, 1998.

ADDRESSES: Comments may be submitted by regular mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of this document.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. E–531, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, telephone: (202) 554–1404, TDD: (202) 554–0551; e-mail: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this notice apply to me?

You may be potentially affected by this notice if you are or may in the future be a submitter of a Premanufacture Notice (PMN) under TSCA. Potentially affected categories and entities may include, but are not limited to:

Category	Examples of Potentially Affected Entities
Chemical manufacturers or importers	Anyone who plans to manufacture or import a new chemical substance for a non-exempt commercial purpose is required to provide the EPA with a PMN at least 90 days prior to the activity. Any substance that is not on the TSCA Inventory is classified as a new chemical.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this table could also be affected. To determine whether you or your business is affected by this action, you should carefully examine the applicability provisions in 40 CFR 720.22. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed in the ''FOR FURTHER INFORMATION CONTACT'' section.

B. How can I get additional information or copies of support documents?

1. *Electronically*. Electronic copies of this document are available from the EPA Home page at the **Federal Register**-Environmental Documents entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

2. *In person*. The official record for this notice, as well as the public version, has been established under docket control number OPPTS–53171 (including comments and data submitted electronically as described in Unit I.C.3. of this preamble). A public version of this record, including printed, paper versions of any electronic comments, which does not include any information claimed as Confidential Business Information (CBI), is available for inspection from 12 noon to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located in the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC.

C. How and to whom do I submit comments?

All comments must be identified by the docket control number OPPTS–53171. You may submit comments through the mail, in person, or electronically:

1. *By mail*. Submit written comments to: Document Control Office (7407), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 401 M St., SW., Rm. G–099, East Tower, Washington, DC 20460. The Document Control Office telephone number is (202) 260–7093.

2. *In person*. Deliver written comments to: Document Control Office in Rm. G–099, East Tower, Waterside Mall, 401 M St., SW., Washington, DC.

3. *Electronically*. Submit your comments and/or data electronically to: oppt.ncic@epa.gov. Please note that you should not submit any information electronically that you consider to be CBI. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. Electronic comments on this notice may also be filed online at many Federal Depository Libraries.

D. How should I handle information that I believe is confidential?

You may claim information that you submit in response to this document as confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential will be included in the public docket by EPA without prior notice.

II. New Chemicals Program

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 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. 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.

B. Actions under TSCA Sections 5(e) and (f)

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 that:

1. 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, under TSCA section 5(e)(1)(A)(ii)(I)).

2. 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, under TSCA section 5(e)(1)(A)(ii)(II)).

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.

Section 5(f) of TSCA authorizes EPA to take action where it finds that there is a reasonable basis to conclude that the activities involving a new chemical substance will present an unreasonable risk of injury to health or the environment. If EPA makes such a determination, it may prohibit or limit manufacture (including import), distribution in commerce, processing, use, and disposal of the new substance to protect against the unreasonable risk.

C. EPA's Strategy under TSCA Section 5(e)

On occasion, EPA may have concerns about a new chemical substance based on test data included in the PMN or obtained from other sources. However, because test data on PMN chemical substances are not required, EPA typically receives few PMNs that contain sufficient data on health or environmental effects, or on the potential to persist or bioaccumulate in the environment. As a result, the Agency often relies on computer models and structural or functional analogues as indicators of the potential toxicity and environmental fate of a PMN chemical substance.

Due to the generally limited test data that are submitted or are otherwise available on a new chemical substance, EPA often identifies the substance for TSCA section 5(e) action because it is similar in molecular structure or function to other chemical substances known or suspected to have adverse health or environmental effects. These predictive methods, which estimate the properties of a chemical, e.g., melting point, vapor pressure, toxicity and ecotoxicity, on the basis of its structure, are referred to as Structure-Activity Relationships (SAR). A joint US/European Union (EU) study evaluated the predictive power of the SAR by applying SAR methods to chemical substances for which ''base set'' test data were already available and then comparing the properties predicted by SAR with the properties observed in laboratory testing. The available test data were part of a minimum pre-market data set (MPD) submitted on chemical substances in the context of the notification scheme established in the EU. Analysis of the results of this study showed that while this SAR approach was largely successful in identifying chemical substances of concern, the process could be improved by selectively incorporating specific testing schemes into the process (USEPA, 1994, see Unit IV.1. of this preamble).

As indicated in Unit II.B., during PMN review, EPA may determine that the available information is insufficient to permit a reasoned evaluation of the new chemical substance that is the subject of the PMN. At the same time, EPA may determine, under TSCA section 5(e)(1)(A)(ii)(I), based on SAR analysis that activities involving the new substance ''may present an unreasonable risk of injury to health or the environment.'' When EPA makes both of these two findings, it acts under TSCA section 5(e) to regulate the activities involving the new substance which contribute to the potential risk. The new chemicals program determines the effectiveness of environmental release controls, consistency with existing chemical regulatory activity in the Agency, and the affordability of certain testing, etc. in formulating the appropriate regulatory response for each new chemical. In cases where a potential hazard is identified, EPA believes that it is appropriate to negotiate an order (known as a ''consent order'') under TSCA section 5(e) with the PMN submitter to control human exposure and/or environmental releases until test data or other information sufficient to assess adequately the potential risk become available. Section 5(e) of TSCA ''risk-based'' consent orders have specified a variety of control measures, including protective equipment, use limitations, process restrictions, labeling requirements, and limits on environmental release. Some recent consent orders have included testing requirements that are triggered when specified levels of production volume or other indices of increased exposure are reached; under these orders, the submitter may not exceed the production volume limitation or any other restriction imposed by EPA until test data specified by EPA have been submitted to and reviewed by EPA.

In other instances, during PMN review EPA may determine under TSCA section 5(e)(1)(A) (ii)(II) 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. Since 1988, EPA has used internally developed guidelines to assist in identifying new chemical substances received as PMNs which would meet the TSCA section 5(e)(1)(A)(ii)(II) exposure-based finding (USEPA, 1988 and 1989, see Unit IV.2. and 3. of this preamble). Data received as a result of EPA's implementation of this exposure-based policy via TSCA section 5(e) consent orders have been used by EPA to better characterize the fate and effects of the new chemical, confirm or refute a prediction of low risk, and supplement and validate the use of SAR in the review of PMNs. These exposure-based guidelines capture all PMN chemical substances with estimated production volumes greater than or equal to 100,000 kilograms (kg) per year and exceeding specific exposure/release criteria. In some cases, however, where these thresholds are not met, it may be more appropriate to use a case-by-case approach for making findings by applying other considerations (i.e., toxicity or physical/chemical properties). For reasons that have been articulated in the proposed statement of policy for TSCA section 4(a)(1)(B) (July 15, 1991, 56 FR 32294), where persistence and bioaccumulation were used as examples, EPA may consider additional factors for making findings for substances which do not meet the numerical thresholds for evaluating new chemical substances under TSCA section 5(e)(1)(A)(ii)(II). Conversely, EPA may not take action under this TSCA section 5(e)(1)(A)(ii)(II) policy when the chemical substance meets the proposed criteria if EPA finds that existing data are sufficient to evaluate health or environmental effects of the new chemical substance, or that regulation and the development of information is not otherwise necessary.

Exposure-based consent orders issued to address concerns under TSCA section 5(e)(1)(A)(ii)(II) include testing requirements, record keeping provisions, and production volume limits. The proposed PBT category criteria would impact EPA's development of both risk-based and exposure-based TSCA section 5(e) consent orders for new PBT chemical substances.

D. EPA's Use of Chemical Substance Categories in PMN Review and in Regulatory Decision Making under TSCA Section 5(e)

In 1987, EPA grouped chemical substances with similar physicochemical, structural, and toxicological properties into working categories. Candidate categories for the new chemicals review process, such as the category being proposed today for PBT chemical substances, are proposed by new chemicals program staff based

on available data and experience reviewing PMNs on related substances. These groupings enable both PMN submitters and EPA reviewers to benefit from the accumulated data and decisional precedents. The first category defined by SAR was ''acrylates and methacrylates.'' Currently, there are over 45 categories, the detailed summaries of which can be found on the Internet at http://www.epa.gov/opptintr/newchms/chemcat.htm.

The establishment of these categories has streamlined the process for Agency review of new chemical substances. As it gained experience with reviews of chemical substances in categories, EPA moved certain decisions for the category chemical substances to points much earlier in the 90-day PMN review period. One such point is the Focus Meeting, where exposure and hazard information about a PMN substance is first brought together for a risk management decision. If, for example, a new substance is identified as being a member of the proposed PBT chemical substances category, the chemical would be evaluated in the context of the potential health or environmental concerns associated with that category.

The Agency recommends that regulatory action be taken under TSCA section 5(e) to control potential risks to health or the environment on about 10 percent of the approximately 2,000 PMNs submitted yearly. Only 2–3 percent of the total number of PMNs submitted (20–30 percent of the above 10 percent) now undergo a detailed review that takes most of the standard 90-day PMN period, while the remaining 7–8 percent are identified for expedited review by virtue of them being members of the new chemicals program chemical categories. In response to pending regulatory action by the Agency, half of this 10 percent total are voluntarily withdrawn by PMN submitters.

E. New Chemical Significant New Use Rules (SNURs)

TSCA section 5(e) consent orders (as described in Unit II.C.) apply only to PMN submitters. When a PMN submitter commences commercial manufacture of the substance and submits a Notice of Commencement of Manufacture to EPA, EPA adds the substance to the TSCA Chemical Substance Inventory maintained pursuant to section 8(b) of TSCA. When a substance is listed on the Inventory, it is no longer a ''new chemical substance'' for which a PMN would be required. Thus, other persons would be able to manufacture, import, or process the substance without EPA review and without the restrictions imposed on the PMN submitter by the TSCA section 5(e) consent order.

In addition to consent orders issued under section 5(e) of TSCA regulating the PMN submitter, EPA uses its Significant New Use Rule (SNUR) authority under TSCA section 5(a)(2) to extend limitations in TSCA section 5(e) consent orders to other manufacturers, importers, and processors of the PMN substance. Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a ''significant new use.'' EPA must make this determination in a SNUR after considering relevant information about the toxicity of the substance and the 4 factors listed in section 5(a)(2) of TSCA (projected production volume, the extent to which a use changes the type or form of exposure to the chemical substance, the extent to which a use changes the magnitude and duration of exposure to the chemical substance, and the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substance). EPA designates the significant new uses of each chemical substance based on these considerations. Once EPA determines that a use of a chemical substance is a significant new use, section 5(a)(1)(B) of TSCA requires persons to submit a notice to EPA at least 90 days before they manufacture, import, or process the substance for that use. The required notice provides EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit that activity before it occurs.

EPA's use of its SNUR authority ensures that the original PMN submitters and subsequent manufacturers, importers, and processors are treated in an equivalent manner. These SNURs are framed so that non-compliance with the control measures or other restrictions in the TSCA section 5(e) consent orders is defined as a ''significant new use.'' Thus, other manufacturers, importers, and processors of the substances must either observe the SNUR restrictions or submit a significant new use notice to EPA at least 90 days before initiating activities that deviate from these restrictions. After receiving and reviewing such a notice, EPA has the option of either permitting the new use or acting to regulate the new submitter's activities.

EPA also reviews some new chemical substances that do not warrant direct regulation of the PMN submitter under TSCA section 5(e) but merit other follow-up monitoring and evaluation. On the basis of test data or SAR analysis, EPA may identify potential health or environmental effects that could create a basis for concern if the substances exposure or release potential later changes or increases beyond that described in the PMN. In most of these cases, EPA believes it is appropriate to use SNUR authority to monitor the commercial development of these substances so that EPA can be apprised of significant increases in exposure potential, which may warrant control measures or testing.

In addition to ensuring that all manufacturers, importers, and processors are subject to similar reporting requirements and restrictions, SNURs have the following additional objectives:

1. EPA will receive notice of any company's intent to manufacture, import, or process a chemical substance listed on the TSCA Inventory for a significant new use before that activity begins.

2. EPA will have an opportunity to review and evaluate data submitted in a SNUR notice before the notice submitter begins manufacturing, importing, or processing a listed chemical substance for a significant new use.

3. When necessary, EPA will be able to take regulatory action under TSCA section 5(e), 5(f), 6, or 7 to control the activities for which it received a SNUR notice before a significant new use of that substance occurs.

III. EPA's PBT Chemical Substances Initiative

A. Background

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 DDT and polychlorinated biphenyls (PCBs). Consistent with TSCA section 26(c), which allows EPA action under TSCA with respect to categories of chemical substances or mixtures, EPA is developing a category of persistent, bioaccumulative, and toxic (PBT) chemical substances. The category being proposed is for the purposes of facilitating the assessment of new chemical substances under TSCA section 5(e) prior to their entry into the marketplace.

The proposed category description draws upon ongoing international efforts (e.g., the U.S.-Canada Binational Strategy for virtual elimination of PBTs; the North American Free Trade

Agreement (NAFTA) Commission for Environmental Cooperation negotiations on Persistent Organic Pollutants (POPs); the United Nations Economic Commission for Europe (UNECE) convention on Long-Range Transboundary Air Pollution (LRTAP); and the POPs Initiative under the United Nations Environment Programme (UNEP)) as well as Agency efforts (e.g., the Waste Minimization Prioritization Tool (WMPT)) to craft a coordinated and scientifically supportable approach to identifying PBT chemical substances. In particular, the proposed category is viewed by the Agency as furthering the objectives of UNECE's convention on LRTAP, Article 7, paragraphs 2 (b) and (c), which state that ''Each Party shall....encourage the implementation of other management programmes to reduce emissions of persistent organic pollutants'' and ''consider the adoption of additional policies and measures as appropriate in its particular circumstances'' (UNECE-LTRAP, 1998, see Unit IV.4. of this preamble).

The proposed PBT category reflects the exchange of information across offices within EPA and results, in part, from the opportunity for programs to collaborate and complement each other's work. The category statement includes the boundary conditions, such as fish bioconcentration/bioaccumulation factors and environmental persistence values, that would determine inclusion in (or exclusion from) the category, and standard hazard and fate tests to address P, B, and T concerns for the chemical substances fitting the category description.

It should be noted that the Agency is separately considering lower manufacture, processing, and ''otherwise use'' reporting thresholds for PBT chemical substances subject to reporting under the Emergency Planning and Community Right-To-Know Act (42 U.S.C. 11023), section 313 or Toxic Chemical Release Inventory (TRI) program. Rather than rely exclusively on statutorily separate, single-medium approaches to address these pollutants, an Agency-wide PBT Strategy is presently being developed and implemented. The PBT Strategy coordinates the efforts being made by various EPA offices on PBT chemical substances and directs them in a targeted fashion to chemical substances that may present the greatest health and environmental risks. Establishment of this category would thus provide 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 new chemical members of this category of chemical substances as one component in the Agency's overall PBT initiative.

B. Proposed Evaluation Criteria and Process for PBT Chemical Substances

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 (Veith et al., 1979, see Unit IV.5. of this preamble). EPA is proposing 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 Action	
	5(e) Order/Significant New Use Rule (SNUR)[1]	Ban Pending Testing[2]
Persistence (transformation half-life).	> 2 months	> 6 months
Bioaccumulation (Fish BCF or BAF)[3].	≥ 1000	≥ 5000
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 P, B, other physical/chemical factors, and predicted toxicity.

The half-life/persistence criterion for aquatic environments of > 2 months is the same as that proposed under the UNECE-LRTAP negotiations (UNECE-LRTAP, 1997, see Unit IV.6. of this preamble). It represents a chronic exposure to aquatic organisms, as well as approximating the duration of some standard bioconcentration (28–56 days) and chronic toxicity (14–90 days) tests, and is therefore thought to be adequate for detecting many long-term toxic effects as well as any tendency for a substance to accumulate in fatty tissue of aquatic organisms. The bioconcentration or bioaccumulation factor (BCF/BAF) measures the potential for a chemical to accumulate in living organisms relative to its concentration in the surrounding environment. BCF/BAF is estimated using calculations based on octanol-water partition coefficients (Kow), although data can also be provided from field or laboratory measurements (Spacie et al., 1995, see Unit IV.7. of this preamble). Chemical substances having a BCF or BAF > 1000 are characterized by a tendency to accumulate in organisms (Smrchek et al., 1998, Zeeman, 1995, Smrchek et al., 1993, see Unit IV.8., 9., and 10. of this preamble). The relationship between BCF/BAF and log Kow, which is a complex one above log Kow = 7, is discussed by several authors (Fisk et al., 1998, Bintein et al., 1993, Gobas et al., 1989, Mackay et al., 1996, see Unit IV.11., 12., 13., and 14. of this preamble).

Chemical substances meeting the persistence criterion of > 6 months and the bioaccumulation criterion of ≥ 5000 have properties consistent with substances widely acknowledged to be persistent, bioaccumulative, and toxic (e.g., DDT, PCBs, and other chemical substances identified as persistent organic pollutants during negotiations on LRTAP) and, as such, are accorded an appropriate level of concern. Other support for this higher tier can be found in the Chemical Manufacturers Association's (CMA's) product risk management guidance for PBT chemical substances (Chemical Manufacturers Association, 1996, see Unit IV.15. of this preamble). This guidance, which underscores CMA's commitment to the principles of the industry's Responsible Care® initiative, cites these P and B criteria as benchmarks in the screening process for PBT chemical substances.

Releases to all environmental media, such as air emissions from stacks, wastes disposed of in landfills or on land, and waste discharged into water, will be factored into the Agency's determination of potential risk posed by a given PMN chemical substance's total environmental load. In making this determination of potential risk the Agency may employ multimedia fate models, such as the Environmental Quality Criteria (EQC) model (Mackay, 1982, see Unit IV.16. of this preamble), in order to account for all potential sources and loadings, environmental transformation processes, and intermedia partitioning, in an integrated fashion. EPA solicits comments on this approach.

Chemical substances characterized as suspected persistent bioaccumulators 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 level of risk concern. The ''ban'' criteria are equivalent to those that have been used internationally to identify PBT substances. 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 ''TSCA Section 5(e) Consent Order/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. For the chemical substances meeting the criteria listed under ''Ban Pending Testing,'' 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 described control actions represent just one body of possible decisions and should not be considered as exclusive of other risk management options.

C. 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. 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 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 a company from manufacturing, importing, processing, distributing in commerce, using, or disposing 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, if not otherwise available, EPA believes are needed to evaluate the potential persistence, bioaccumulation, and toxicity of a PBT chemical substance for which EPA has made the 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.

Tier 1. If, based upon 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. 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).

3. Hydrolysis in water (OPPTS 835.2110 test guideline) should be determined if, based upon SAR, susceptibility to hydrolysis is suspected.

If the measured log Kow is < 3.5 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 ≥ 3.5, the chemical does not pass the ready biodegradability test, and no further testing is deemed necessary in tier 1; the chemical would 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) or an equivalent test. 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 aquatic microcosms (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 > 1000, tier 3 testing will 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 (Organization for Economic Cooperation and Development (OECD) guideline no. 422) 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 and 40 CFR 797.1330, 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.

IV. References

The OPPTS harmonized test guidelines referenced in this document are available on EPA's World Wide Web site (http://www.epa.gov/epahome/research.htm) under the heading ''Test Methods and Guidelines/OPPTS Harmonized Test Guidelines.''

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List of Subjects

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

Dated: September 24, 1998.

Lynn R. Goldman,

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

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FARM CREDIT SYSTEM INSURANCE CORPORATION

Policy Statement on the Secure Base Amount and Allocated Insurance Reserve Accounts

AGENCY: Farm Credit System Insurance Corporation.

ACTION: Notice of policy statement; request for comments.

SUMMARY: The Farm Credit System Insurance Corporation (Corporation) is publishing for comment a Policy Statement on the Secure Base Amount and Allocated Insurance Reserve Accounts (AIRAs). This proposed Policy Statement establishes a framework for the periodic determination of the Farm Credit Insurance Fund's (Insurance Fund) secure base amount. It also implements the Corporation's authority to allocate excess Insurance Fund balances above the secure base amount into an account for each insured Farm Credit System Bank and one for the Farm Credit System Financial Assistance Corporation (FAC) stockholders.

DATES: Written comments must be submitted on or before January 4, 1999.

ADDRESSES: Comments should be mailed or delivered to Dorothy L. Nichols, General Counsel, Farm Credit System Insurance Corporation, 1501 Farm Credit Drive, McLean, Virginia 22102. Copies of all comments will be available for examination by interested parties in the offices of the Farm Credit System Insurance Corporation.

FOR FURTHER INFORMATION CONTACT: Dorothy L. Nichols, General Counsel, Farm Credit System Insurance Corporation, 1501 Farm Credit Drive, McLean, Virginia 22102. (703) 883–4380, TDD (703) 883–4444.

SUPPLEMENTARY INFORMATION: In 1987, Congress directed the Corporation to build and manage the Insurance Fund to achieve and maintain the secure base amount (SBA). For insurance premium purposes, the statute defines the SBA as 2 percent of the aggregate outstanding insured obligations of all insured banks (excluding a percentage of state and Federally guaranteed loans) or such other percentage of the aggregate amount as the Corporation in its sole discretion determines is ''actuarially sound.'' (12 U.S.C. 2277a–4(c)).

The statute specifies a limited form of risk-based premium assessments: 25 basis points for nonaccrual loans; 15 basis points for loans in accrual status (excluding certain state and Federally guaranteed loans); and a very modest premium for government-guaranteed loans. (12 U.S.C. 2277a–4(a)). This formula was designed as an incentive for the Farm Credit System to make quality loans and at the same time build the Insurance Fund to a level that Congress believed would prevent a default on System debt obligations. In the Farm Credit System Reform Act of 1996, Congress gave the Corporation the discretion to reduce premium assessments before reaching the SBA. (12 U.S.C. 2277a–4(a)(2)). The Board has