

**ENVIRONMENTAL PROTECTION
AGENCY**

[TSH-FRL-1974-4; OPTS-42006]

**Polychlorinated Terphenyls; Response
to the Interagency Testing Committee**
AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: This notice is EPA's response to the Interagency Testing Committee's designation of polychlorinated terphenyls (PCT's) for health and environmental effects testing under section 4(a) of the Toxic Substances Control Act (TSCA). EPA is not initiating rulemaking under section 4(a) rule to require further effects testing of PCT's because information indicates that PCT's are no longer produced or used in the U.S. The Agency is requesting comments on alternatives to issuing a test rule.

DATE: Please submit comments by December 2, 1981.

ADDRESS: Document Control Officer,
Office of Toxic Substances (TS-793),
U.S. Environmental Protection Agency,
Rm. E-401, 401 M Street SW.,
Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT:
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1404.

SUPPLEMENTARY INFORMATION:
I. Background

Section 4(e) of TSCA (Sec. 4(a); 90 Stat. 2003; (15 U.S.C. 2601 et seq.)) establishes an Interagency Testing Committee (ITC) to recommend a list of chemicals for EPA to consider for promulgation of testing rules under section 4(a) of the Act. The ITC may designate up to 50 substances or categories of substances at any one time for priority consideration by EPA. TSCA requires EPA to respond within twelve months of the date they are recommended, by initiating rulemaking under section 4(a) or by publishing reasons in the Federal Register for not initiating rulemaking.

The ITC designated polychlorinated terphenyls (PCT's) for testing in April 1978 (43 FR 16684), recommending that they be tested for carcinogenic, mutagenic, teratogenic and environmental effects. The recommendations were based on (1) a chemical structure similar to PCB's, (2) increasing quantities imported after

domestic production stopped in 1972, (3) wide environmental dispersion from PCT's use in waxes for investment casting, (4) PCT's residues found in human blood, fat and milk, and in samples of water and sludge, and (5) no data on suspected carcinogenic, mutagenic, teratogenic or ecological effects, with incomplete characterization of chronic and environmental effects.

PCT's are very similar in chemical structure to polychlorinated biphenyls (PCB's). PCB's cause well-documented adverse health effects. PCB's also have a very stable chemical structure, so they persist in the environment. PCT's, likewise, are known to persist in the environment, and potentially have the same adverse health effects as PCB's. PCB's and PCT's were widely used and dispersed into the environment before their adverse health effects were recognized. Consequently, both chemicals are now ubiquitous in the environment, resulting in wide-range human exposure. In 1976, PCB's were restricted to totally enclosed uses by section 6(e) of TSCA. Because PCT's contain PCB's as an impurity (typically 1-5%), PCT's are at the present time effectively controlled by the regulations covering PCB's.

This notice is intended to serve as EPA's response to the ITC designation of PCT's for testing. EPA previously responded to the ITC's designation of PCT's by publishing an explanation in the Federal Register that it was not yet prepared to initiate rulemaking. However, a district court ruled that EPA's response did not meet the legal requirements of section 4(e) of TSCA. *Natural Resources Defense Council vs. Costle*, 79 Civ. 2411 (S.D.N.Y., Feb. 4, 1980). The court required EPA to submit a plan for complying with section 4(e) including a schedule for dealing with the backlog of chemicals from the ITC list. On January 9, 1981, the court ordered EPA to follow the compliance schedule the Agency submitted. Action on PCT's is required by 1982.

II. Decision Not to Require Testing

EPA has decided that section 4 testing for PCT's is not warranted. The only domestic manufacturer of PCT's stopped producing them in 1972 because of environmental concerns. Although PCT imports increased each successive year until 1976, the last import was recorded in November of 1979. The only United States importer decided to stop marketing PCT's because the level of PCB contamination in the imported chemical was greater than that allowed by PCB regulations and PCT's are no longer in use in the United States.

III. Alternatives to Testing

EPA is considering several alternatives to requiring testing. These are briefly discussed below.

1. A significant new use rule (SNUR) under section 5(a) would define certain new uses of PCT's as "significant new uses." A person responsible for manufacturing or processing for a use defined by the rule would be required to submit a notice of intent under section 5(a)(1) at least 90 days before the new use occurs. The information required to be submitted includes identity of the compound and by-products, projected uses, amounts of substance to be produced and processed for each use, environmental and health data, numbers of persons expected to be exposed and duration of the exposure, and the manner in which the material is to be disposed. The Agency would be responsible for reviewing data on any significant new use to assess its effect on human health and the environment. A SNUR would let EPA take appropriate followup action if a significant increase in exposure is projected. EPA has a period of 90 days in which to review the health and environmental implications of the new use, but may extend the period up to an additional 90 days for good cause.

2. Placing PCT's on the 5(b)(4) list in combination with issuing a SNUR for these chemicals would provide EPA the information and opportunity for followup action in alternative 1 and also provide additional data that may help EPA assess the potential risks of these chemicals. Section 5(b)(2)(A) requires persons submitting a notice on chemicals subject to a SNUR which are also on the 5(b)(4) list to submit data which they believe show that the manufacturing, processing, distribution in commerce, use and disposal of the chemical substance will not present an unreasonable risk of injury to health or the environment.

3. A section 8(a) reporting rule would require the same information to be reported as a SNUR in alternative 1. However, there are differences in who is required to report and the frequency of reporting. For example, a section 8(a) rule could require regular periodic reporting or could require persons to report when certain events occurred. Furthermore, it would extend to all manufacturers and processors (except small ones), unlike a SNUR which reaches only persons manufacturing and processing a chemical for a new use. Unlike a SNUR, a section 8(a) rule, on its own, could not require reporting by small manufacturers and processors.

Placing PCT's on the 5(b)(4) list in continuation with a section 8(a) reporting requirement would have the same effect as alternative 3 but would also subject small manufacturers and processors to the section 8(a) reporting requirement.

5. Taking no further action on PCT's on the basis that they are adequately controlled by the PCB regulations.

EPA requests comments on these alternatives.

(Sec. 4, 90 Stat. 2003; (15 U.S.C. 2601))

Dated: October 23, 1981.

Anne M. Gorsuch,

Administrator.

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COMMENTS OF THE CHEMICAL
MANUFACTURERS ASSOCIATION ON
THE RESPONSES OF EPA TO THE ITC
RECOMMENDATIONS FOR POLYCHLORINATED
TERPHENYLS AND CHLORINATED NAPHTHALENES

On November 2, 1981, the Environmental Protection Agency (EPA) responded to the testing recommendations of the Interagency Testing Committee (ITC) for polychlorinated terphenyls (PCTs) and chlorinated naphthalenes. 46 Fed. Reg. 54482; 46 Fed. Reg. 54491. In these responses, EPA announced that it was not initiating test rule proceedings under Section 4(a) of the Toxic Substances Control Act (TSCA) because manufacture and importation of PCTs and chlorinated naphthalenes have either ceased entirely or declined to insubstantial levels. Nevertheless, EPA indicated that, as an alternative to promulgating test rules, it was considering various mechanisms for monitoring and perhaps restricting future manufacture and importation of these chemicals. The Agency requested comments on the specific regulatory mechanisms under consideration.

The Chemical Manufacturers Association (CMA) submits these comments on the issues presented by EPA's notices concerning PCTs and chlorinated naphthalenes. CMA is a nonprofit trade association whose approximately 190 United States member companies account for more than 90 percent of the total production capacity for basic industrial chemicals in this country. Many CMA members manufacture or use chemicals that have been or may be recommended for testing by the ITC.

Accordingly, CMA has a substantial interest in the actions that EPA takes in evaluating and responding to the ITC's recommendations.

CMA agrees with EPA that chemicals which are no longer produced or imported in significant quantities should not be considered for testing requirements under Section 4 of TSCA. Such chemicals do not have significant human exposure or substantial environmental release. As a result, testing would be unnecessary to protect the human population and the environment against unreasonable risks of injury. Moreover, because these chemicals lack commercial importance, industry would have little incentive to marshal the resources required to finance and conduct testing.

As EPA recognizes, it is possible that chemicals which are now produced and imported in insignificant quantities may become commercially important in the future. Reconsideration of the need for testing may be appropriate if human or environmental exposure to these chemicals becomes substantial. Accordingly, EPA may wish to monitor future commercial activities involving chemicals now produced in insignificant quantities so that it is informed of changes in exposure potential that may justify a reevaluation of testing needs.

EPA should not, however, automatically monitor a chemical simply because it was recommended for testing by the ITC, but should reserve such monitoring for those situations where it is clearly appropriate. Accordingly, EPA should

independently review the available information on the ITC chemical and determine if the chemical would be a strong candidate for testing in the event that exposure becomes significant. Where the Agency cannot make this determination, the preferable course would be to take no follow-up action of any kind.

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Where follow-up monitoring is justified, moreover, EPA should avoid regulatory requirements that impose undue reporting burdens on industry and needlessly restrict the commercial development of the chemicals involved. For this reason, CMA has substantial reservations about the routine use of two of the approaches that EPA is considering for PCTs and chlorinated naphthalenes: (1) issuing significant new use rules (SNURs) under Section 5(a)(2), and (2) placing these chemicals on the Section 5(b)(4) "risk list" in conjunction with issuing SNURs.

As an alternative to the use of SNURs or "risk list" designations, CMA favors the third option identified by EPA -- issuing a Section 8(a) reporting rule applicable to future manufacturers, importers and processors.^{1/}

^{1/} For PCTs, EPA is also considering taking no further action on the ground that these chemicals are already adequately controlled by the Agency's regulations governing polychlorinated biphenyls (PCBs). CMA takes no position on whether the PCB regulations are applicable to PCTs,

Section 8(a) reporting requirements could assure that EPA is aware of changes in exposure potential that may warrant a reevaluation of testing needs. At the same time, EPA would neither conduct risk assessments that may be unnecessary nor restrict future commercial development of the chemicals involved.

The reasons why CMA considers Section 8(a) reporting a preferable alternative -- and the shortcomings of the other two options identified by EPA -- are described more fully below.

1. Section 8(a) Reporting. If EPA concludes that the available information demonstrates an affirmative need to monitor future production and use of a chemical now manufactured or imported in inconsequential quantities, CMA believes that a Section 8(a) rule is the most reasonable means of bringing to EPA's attention information that may justify a reevaluation of the need for testing.

Under a Section 8(a) reporting rule, industry can inform EPA of increases in production or use that may be accompanied by significant human exposure or environmental release. At the same time, a Section 8(a) rule would not require a finding that the chemical in question may present an unreasonable risk to human health or the environment. Rather, EPA would only need to make a finding that monitoring the chemical's commercial development is

necessary to perform the Agency's functions under TSCA. Hence, EPA would not need to expend its resources on risk assessments that may later prove unnecessary. Similarly, future producers and users of the chemical would not be subjected to requirements that may unjustifiably curtail their commercial activities. Regulatory action concerning the chemical would thus be deferred until there is a concrete need for reviewing the chemical's potential adverse effects and industry has both the incentive and level of knowledge to participate meaningfully in the Agency's risk determinations.

While Section 8(a) is an appropriate vehicle for monitoring changes in the production or use of chemicals that are under consideration for testing, EPA should avoid using this provision of TSCA in an unfocused manner. The mere fact that the ITC has recommended a chemical for testing should not automatically trigger a Section 8(a) requirement if EPA decides not to proceed with a test rule. Rather, EPA should carefully and critically review all available information, including data on which the ITC relied in designating the chemical for testing. The Agency should utilize Section 8(a) to monitor the chemical's future production and use only if it independently determines that testing requirements would be seriously considered if exposure to the chemical became significant. If EPA cannot make such a determination, no follow-up action to monitor the chemical should be required.

CMA expresses no opinion on whether PCTs and chlorinated naphthalenes are proper subjects for Section 8(a) reporting under these criteria. It does stress, however, that the mere designation of these chemicals for testing by the ITC is not sufficient to justify reporting requirements and that EPA should carefully review the information underlying the ITC's recommendations.

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Any reporting rule that EPA promulgates for these chemicals should also be narrowly tailored to avoid the submission of unnecessary information. The objective of such a rule would be to enable EPA to monitor future changes in the nature or magnitude of commercial activity that may motivate the Agency to reconsider the need for testing. EPA's reporting requirements should therefore focus on increases in production or importation that are of sufficient scope to result in significant human exposure or environmental release. Reporting should not be triggered by commercial activities of little real consequence such as production or importation in miniscule quantities.^{1/} Moreover, EPA should avoid reporting requirements that call for information

^{1/} EPA correctly notes that a Section 8(a) rule cannot apply to "small" manufacturers and processors except in certain limited circumstances. 46 Fed. Reg. 54491. This limitation, however, should not prevent EPA from learning of commercial activities that are significant in scope. Moreover, it would be wholly unjustified for EPA to place a chemical on the Section 5(b)(4) "risk list" solely to circumvent the exemption from Section 8 for "small" manufacturers and processors.

(such as the identity of byproducts) that is not germane to the reevaluation of testing needs.

2. Promulgation of a SNUR. As CMA has discussed in prior comments,^{1/} SNURs are intended to cover those uses of a chemical that may significantly increase the risk that the chemical will cause unacceptable human or environmental harm. As a result, EPA cannot promulgate a SNUR without evaluating the available information on a chemical's risk potential and identifying the circumstances under which the chemical may be capable of harming human health or the environment.

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Such an analysis would normally be inappropriate for chemicals that are not manufactured, imported or used in quantities of any consequence. It is inefficient for EPA to expend its limited resources on detailed risk assessments for chemicals that are not now, and may never be, commercially important. Moreover, because such chemicals presently lack commercial importance, industry would have neither the incentive nor the expertise to assist EPA in making judgments about their potential risks. Thus, rulemaking proceedings to issue SNURs would not be based on a complete and informed evaluation of the potential adverse effects of the chemicals involved. For this reason, EPA could reach conclusions about a chemical that, with the benefit of fuller information and analysis, the Agency might later consider unjustified.

^{1/} See comments of the Chemical Manufacturers Association on EPA's Proposed Significant New Use Rule for N-Methanesulfonyl-P-Toluenesulfonamide, January 12, 1981.

A SNUR would also be an inefficient method of monitoring future commercial activities for prospective test chemicals. SNURs can only apply to uses of a chemical that are "new"; EPA cannot require SNUR notices for uses that existed at the time of or prior to the SNUR's issuance. Thus, EPA would be unable to promulgate a SNUR on a prospective test chemical without obtaining full information on the various functions and applications for which the chemical has been used in the past. Collecting this information would be a time-consuming task. Moreover, since EPA's SNUR would only apply to "new" uses of the chemical, the Agency would not receive SNUR notices from companies that have resumed manufacture or processing of the chemical for preexisting uses.^{1/} For this reason, the Agency might not be informed of commercial activities that would have a major bearing on whether a chemical should be reconsidered for testing under Section 4(a).

CMA recognizes that there may be a few chemicals under consideration for testing by the ITC for which imposition of a SNUR is justified, notwithstanding the absence of production or importation, because the evidence of significant adverse effects is especially clearcut and extensive. For

^{1/} As CMA has previously recognized, however, there may be circumstances in which a significant increase in production volume could make an existing use "new" for SNUR purposes because it is accompanied by a major change in the nature or magnitude of exposure to the SNUR chemical.

the reasons stated above, however, SNURs should not be used routinely to monitor the development of chemicals that are not presently produced in sufficient quantities to justify testing.

3. "Risk List" Designation. It would be especially undesirable for EPA to couple a SNUR with inclusion of the prospective test chemical on the "risk list" developed under Section 5(b)(4). A chemical can only be included on this list if EPA finds that the chemical's manufacture, processing, distribution, use or disposal "may present an unreasonable risk of injury to health or the environment." Such a determination will involve an even more detailed risk analysis than promulgation of a SNUR. Hence, inclusion of a chemical on the "risk list" would be particularly inappropriate where the chemical is not manufactured or used in significant quantities and industry lacks both the commercial incentive and the level of knowledge to participate meaningfully in a determination of the chemical's potential adverse effects.

Section 5(b)(2)(A) provides that, where a chemical on the Section 5(b)(4) "risk list" is subject to a SNUR, the SNUR notice must include data that the submitter believes will "show that the manufacturing, processing, distribution and commerce, use and disposal of the chemical substance will not present an unreasonable risk of injury to health or the environment." The effect of this provision is to shift to the SNUR submitter the burden of convincing EPA that the

significant new use of SNUR chemical is unlikely to have unreasonably harmful health or environmental effects. As a practical matter, it may often be impossible to bear this burden without conducting extensive testing of the SNUR chemical.

For this reason, the combination of a SNUR and "risk list" designation would operate as a de facto testing requirement. The imposition of such a requirement would be directly contrary to EPA's determination that a Section 4 test rule is unjustified for chemicals that presently lack significant production and use. Moreover, by utilizing Section 5(b)(4) to require testing, EPA would be bypassing the detailed criteria and procedural safeguards associated with the test rule development process under Section 4.

Thus, future manufacturers or importers of the chemical could be saddled with testing obligations that they never had a meaningful opportunity to contest.

When manufacture, importation and use of a chemical have declined to insignificant levels, EPA should defer consideration of potentially onerous regulatory measures until the chemical has again become commercially important. There will be ample opportunity at this stage for EPA to consider the need to invoke various TSCA provisions, including "risk list" designation under Section 5(b)(4), issuance of a SNUR under Section 5(a)(2), or imposition of a testing requirement under Section 4. To apply any of these measures to a chemical

which is not presently in production or use would unjustifiably restrict future commercial development of the chemical and needlessly consume EPA and industry resources.

CONCLUSION

CMA agrees that it is inappropriate for EPA to develop testing rules for ITC chemicals that are not presently manufactured or imported in significant quantities. Moreover, EPA should not automatically monitor the future development of such chemicals but should independently assess whether particular chemicals require continuing EPA scrutiny. If EPA's independent assessment supports a conclusion that such monitoring is justified, EPA should normally utilize Section 8(a), not the "risk list" provisions of Section 5(b)(4) or the SNUR provisions of Section 5(a)(2). Finally, EPA's Section 8(a) requirements should be narrowly tailored to obtain only that information which is necessary to enable the Agency to reexamine the need for testing.

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