

PATTON BOGGS, L.L.P.
2550 M STREET, N.W.
WASHINGTON, D.C. 20037-1350
(202) 457-6000

FACSIMILE: (202) 457-6315

WRITER'S DIRECT DIAL

(202) 457-5270

November 21, 1994

MEMORANDUM FOR THE VINYL CHLORIDE PANEL

Re: EPA Solicitation of Voluntary Testing
Proposals for ATSDR Test Rule

During the conference call on November 7, it was agreed that the Panel would look more closely at the option of offering to conduct reproductive and developmental toxicity studies of vinyl chloride to meet ATSDR's data needs. Jim Barter agreed to give some thought to arguments for a one- as opposed to a two-species developmental study. At the same time, it was decided to investigate whether it might be possible to address certain neurotoxicity endpoints in a way that might also satisfy EPA. In this regard, it was agreed that Jim Knaak and Frank Hawk would look at how a reproductive toxicity study protocol might be modified to provide information relevant to neurotoxicity, and I was asked to learn more about the basis for the neurotoxicity study requirement proposed by the EPA Air Office.

After the conference call, I spoke with Brian Riedel and Gary Timm about vinyl chloride. Riedel, as you know, is the EPA project manager for the test rule. Timm, who used to be in charge of the Test Rules Branch, has been seconded to ORD to help the Air Office come up with its data needs for the hazardous air pollutants.

Timm indicated that, because ATSDR's referral was received first by OPPT, the Air Office needs for those chemicals were added to the ATSDR test rule proposal. Apparently, the Air Office needs were not very well researched, and it was decided that the Air Office needed assistance from ORD. Timm said that there is no question about the acute toxicity of vinyl chloride, but there were certain questions as to its neurotoxicity. He was not able to tell me more than this. He said that he would need to consult with Bob McPhail and Kevin Crofton (who are I believe with ORD at Research Triangle Park), and that they would need to get "up to speed" before talking to us. Timm indicated that he thought it made sense to sit down and talk about these issues before any kind of testing program was submitted, as it might be possible to design a

CMA 115608

PATTON BOGGS, L.L.P.

subchronic study that could cover some neurotoxicity endpoints without the need for a full neurotoxicity guidelines study.

Both Timm and Riedel said that, since EPA's solicitation of testing proposals for the ATSDR data needs was published on September 30, there has been some rethinking at EPA as to the respective roles of EPA and ATSDR with regard to voluntary testing programs. In particular, Timm indicated that EPA is sensitive to the problem that would be posed for ATSDR if the public were to perceive that there is no point in participating in the ATSDR voluntary testing program.

I also spoke with Bill Cibulas, the ATSDR Research Implementation Branch Chief. I told Cibulas that I did not think the Panel would be able at this time to offer anything more specific than an intent to meet with scientists from ATSDR and EPA in the first half of December to learn more about the needs of each agency and to discuss a voluntary testing program that might be acceptable to all sides. Last week, Cibulas told me that, as a result of discussions with EPA and the affected industry, ATSDR and EPA had decided to issue a policy statement clarifying the respective roles of ATSDR and EPA in connection with voluntary testing of four of the chemicals that were referred to EPA by ATSDR including vinyl chloride. The effect of this policy statement, a copy of which is attached, is to extend the deadline for developing testing programs with ATSDR.

As a result of the policy statement, the Panel will have the opportunity to try to develop a voluntary testing program that satisfies both ATSDR and EPA. Should this prove impossible, EPA reserves the right (as it did in the September 30 notice) to move forward with a test rule to require the testing identified in the notice. If it wishes to do so, the Panel will need to indicate by November 29 its intent to enter into negotiations that would lead to a memorandum of understanding (MOU) to fill at least the data needs identified by ATSDR being executed by May 31, 1995.

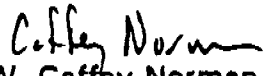
A draft response to the EPA solicitation notice is attached for your review. Submitting such a response will commit the Panel, in principle, to meeting the data needs identified by ATSDR for vinyl chloride by conducting inhalation studies of reproductive and developmental toxicity, and to working with EPA to see if its need for neurotoxicity data can also be met as part of the voluntary testing program. The response also seeks to hold open the possibility of conducting whatever kind of neurotoxicity study might ultimately be agreed under an enforceable consent agreement with EPA.

It is a question of judgment whether the Panel should, in this response, put forward its proposal to conduct a one-species as opposed to a two-species developmental study. I would prefer to avoid surprises but others may have a different view.

CMA 115609

PATTON BOGGS, L.L.P.

Dan Kracov and I look forward to discussing this matter and the proposed response with you on a conference call later this week. In any event, we will need your comments by Monday, November 28, so that the letter can be submitted by November 29.


W. Caffey Norman, III

Attachments



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 18 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

W. Caffey Norman, Esq.
Patton, Boggs & Blow, L.L.P.
2550 M Street, N.W.
Washington, D.C. 20037

Dear Mr. Norman:

In the interest of coordinating the processes and clarifying several issues associated with the voluntary research program of the Agency for Toxic Substances and Disease Registry (ATSDR) and the Enforceable Consent Agreement (ECA)/test rule program of the Environmental Protection Agency (EPA), we have developed and plan to follow the approach outlined in the enclosed policy statement.

As the policy indicates, the testing proposals under the ATSDR voluntary testing research program or under EPA's ECA program must address all testing needs identified in the solicitation notice of September 30, 1994 or EPA intends to proceed with a test rule to meet these needs. The chemical endpoints identified for testing in the solicitation notice are the product of a considerable amount of coordination among EPA programs and Federal Agencies.

ATSDR and EPA strongly encourage submission of testing proposals under either program and look forward to working with you.

Sincerely,

Dr. Christopher DeRosa
Director, Division of Toxicology
Agency for Toxic Substances and
Disease Registry

Charles M. Auer
Director, Chemical Control Division
Environmental Protection Agency

Enclosure



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

CMA 115611

Development and Finalization of Agreements under
the Voluntary Research Program of the Agency for
Toxic Substances and Disease Registry (ATSDR) versus
Development and Submittal to the Environmental Protection Agency
(EPA) of Proposals for Enforceable Consent Agreements (ECAs)
in Response to EPA's 9/30/94 Notice of Solicitation

Section 104(i) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) provides that ATSDR will develop a substance-specific research program to fill data needs identified for chemicals that are most commonly found at Superfund sites and that are posing the most significant potential threat to human health. Under CERCLA, section 104(i)(5)(D), Congress contemplates that authorities under the Toxic Substances Control Act (TSCA) would be utilized to collect needed health effects data.

In October, 1992, ATSDR referred 38 chemicals to EPA for testing under TSCA authorities. See Notice, Status of the Superfund Substance-Specific Applied Research Program, Federal Register, March 10, 1994 (59 FR 11434-11435). As required under CERCLA, section 104(i), ATSDR's substance-specific research program was coordinated with testing programs under TSCA/Federal Insecticide, Fungicide, Rodenticide Act and with the National Toxicology Program. Such coordination was required "to avoid duplication of effort" and to assure that the chemicals are tested "thoroughly at the earliest practicable date." ATSDR also considered the recommendations of the Interagency Testing Committee established under TSCA, section 4(e) on the types of research to be done, as required under CERCLA. In addition, EPA considered and coordinated the data needs of its program offices and other Federal Agencies on these chemicals. Thus, the resulting list of chemicals and endpoints identified by EPA for testing under TSCA is the product of considerable coordination and represents the current federal testing priorities for these chemicals.

On September 30, 1994, EPA published a notice in the Federal Register (59 FR 49934) soliciting testing proposals from manufacturers and processors that wish to participate in negotiations for an ECA on chemicals which ATSDR referred to EPA for testing under TSCA. These chemicals are vinyl chloride, benzene, trichloroethylene, tetrachloroethylene, hydrogen cyanide, sodium cyanide, toluene, methylene chloride, and chloroethane.

EPA understands that ATSDR is anticipating concluding voluntary agreements for testing of certain chemicals listed in the solicitation. ATSDR and EPA agree that the scope of each agency's testing program should be clearly defined. Accordingly, ATSDR and EPA have developed the following approach to meeting the identified testing priorities for the chemicals on the solicitation list:

Application. This policy applies to development of testing proposals on methylene chloride, trichloroethylene, tetrachloroethylene, and vinyl chloride. Testing proposals for the other chemicals on the solicitation list will fall under the auspices of EPA's testing program and will be governed by the procedures set forth in the solicitation notice.

Methylene Chloride. The Halogenated Solvents Industry Alliance, Inc. (HSIA) has submitted a voluntary research proposal to ATSDR on methylene chloride and, as of this date, is revising the proposal to meet ATSDR's concerns. If HSIA concludes a Memorandum of Understanding (MOU) with ATSDR for voluntary testing of methylene chloride by December 30, 1994, ATSDR will within 30 days notify EPA of the specific testing included in the voluntary agreement. In considering whether to remove methylene chloride from the solicitation list EPA will consider whether the ATSDR voluntary research agreement addresses all testing needs identified in the solicitation notice. Pursuant to the process described in the solicitation notice, HSIA may submit a proposal to conduct testing of methylene chloride under an ECA for testing needs identified in the solicitation notice but not included under the voluntary research plan. HSIA may request a reasonable extension for such submission. If HSIA and ATSDR do not conclude a MOU on methylene chloride by December 30, 1994, EPA will proceed with development of an ECA or, if an acceptable response to the solicitation notice has not been received, with a test rule.

Trichloroethylene, Tetrachloroethylene, and Vinyl Chloride. In order to participate in ATSDR's voluntary research program for trichloroethylene, tetrachloroethylene, or vinyl chloride, a party must submit, by November 29, 1994, a "statement of intent" to enter into a MOU with ATSDR for voluntary testing of trichloroethylene, tetrachloroethylene, or vinyl chloride. If a party and ATSDR conclude a MOU for voluntary testing of trichloroethylene, tetrachloroethylene, or vinyl chloride by May 31, 1995, ATSDR will within 30 days notify EPA of the specific testing included in the voluntary agreement. In considering whether to remove trichloroethylene, tetrachloroethylene, or vinyl chloride from the solicitation list EPA will consider whether the ATSDR research proposal addresses all testing needs identified in the solicitation notice. Pursuant to the process described in the solicitation notice, a party may submit a testing proposal to conduct testing of trichloroethylene, tetrachloroethylene, or vinyl chloride under an ECA for testing needs identified in the solicitation notice but not included

under the voluntary research plan. A party may request a reasonable extension for such submission. If a party does not submit a "statement of intent" by November 29, 1994, or does not enter into a MOU with ATSDR by May 31, 1995, EPA will proceed with development of an ECA or, if an acceptable response to the solicitation notice has not been received, with a test rule.

CMA 115614

PATTON BOGGS, L.L.P.
2550 M STREET, N.W.
WASHINGTON, D.C. 20037-1350
(202) 457-6000

FACSIMILE (202) 457-6315

WRITER'S DIRECT DIAL

(202) 457-5270

November 10, 1994

MEMORANDUM FOR THE VINYL CHLORIDE PANEL

Re: ATSDR Test Rule

During the conference call on November 7, it was agreed that the Panel would look more closely at the option of offering to conduct reproductive and developmental toxicity studies of vinyl chloride to meet ATSDR's data needs, and to determine whether it might be possible to address certain neurotoxicity endpoints in a way that might also satisfy EPA. It was agreed that Jim Knaak and Frank Hawk would look at how a reproductive toxicity study protocol might be modified in this regard. I was asked to learn more about the basis for the neurotoxicity study requirement proposed by the EPA Air Office. I have now spoken with Brian Riedel and Gary Timm about vinyl chloride. Riedel, as you know, is the project manager for the test rule. Timm, who used to be in charge of the Test Rules Branch, has been seconded to ORD to help the Air Office come up with its data needs for the hazardous air pollutants.

Timm indicated that, because ATSDR's referral was received first by OPPT, the Air Office needs for those chemicals were added to the ATSDR test rule proposal. Apparently, the Air Office needs were not very well researched, and it was decided that the Air Office needed assistance from ORD. Timm said that for vinyl chloride, there was no question about its acute toxicity, but there were certain questions about its neurotoxicity. He was not able to tell me more than this. He said that he would need to consult with Bob McPhail and Kevin Crofton, and that they would need to get "up to speed" before talking to us. Timm volunteered that he thought it made sense to sit down and talk about these issues before any kind of testing program was submitted, as it might be possible to design a

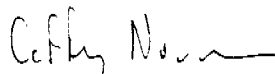
CMA 115615

PATTON BOGGS, L.L.P.

subchronic study that could cover some neurotoxicity endpoints without the need for a full neurotoxicity guidelines study.

Both Timm and Riedel indicated that, since the solicitation of testing proposals was published on September 30, there has been some rethinking at EPA as to the respective roles of EPA and ATSDR with regard to voluntary testing programs. In particular, Timm indicated that EPA is sensitive to the problem that would be posed for ATSDR if people were to perceive that they need not deal with ATSDR on voluntary proposals because they could submit proposals directly to EPA. Riedel suggested that a notice or memorandum of some kind may be issued shortly to clarify the role of EPA and ATSDR with regard to voluntary testing efforts. Timm indicated that it would not be possible to resolve all the scientific issues before November 29. I am hopeful that EPA will be able to clarify its position by next week.

In the meantime, in light of the current uncertainty, I propose that the conference call be postponed until next week. Perhaps we will then have a better indication as to whether a response is necessary by November 29 and what the form of any such response should be. Both Timm and Bill Cibulas of ATSDR expressed interest in a meeting or conference call between representatives of the Panel, ATSDR, and EPA to discuss a voluntary testing program that would be acceptable to all sides.



W. Caffey Norman, III

TABLE 2. — REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Com- pany No.	Company Name and Address
000264	Rhone-Poulenc Ag Co., Box 12014, Research Triangle Park, NC 27709.
000499	Whitmire Research Laboratories, Inc., 3568 Tree Ct., Industrial Blvd, St Louis, MO 63122.
001864	Central Petroleum Co., 1449 W. 117th St, Cleveland, OH 44107.
002935	Wilbur Ellis Co., 191 W. Shaw Ave., Fresno, CA 93704.
003125	Miles Inc., Agriculture Division, 8400 Hawthorn Rd., Box 4913, Kansas City, MO 64120.
004822	S.C. Johnson & Son Inc., 1525 Howe Street, Racine, WI 53403.
005905	Helena Chemical Co, 6075 Poplar Ave., Suite 500, Memphis, TN 38119.
008590	Agway Inc., c/o Universal Cooperatives Inc., Box 460, Minneapolis, MN 55440.
009444	Waterbury Companies Inc., Box 640, Independence, LA 70443.
035900	Ionics, Inc., 3039 Washington Pike, Bridgeville, PA 15017.
037425	Smithkline Beecham Animal Health, 1600 Paoli Pike, West Chester, PA 19380.
044716	Fearing Mfg. Co Inc., 490 Villaume Ave. So., St. Paul, MN 55075.
050534	ISK Biosciences Corp., 5966 Heisley Rd., Box 8000, Mentor, OH 44061.
059639	Valent U.S.A. Corp., 1333 N. California Blvd, Ste 600, Walnut Creek, CA 94596.

For Distribution by CMA
CHEMSTAR DIVISIONFrom JOHN BUSCH

Ref No.

Date OCT 3, 1994**III. Procedures for Withdrawal of Request**

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before December 29, 1994. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

IV. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1-year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in Federal Register No. 123, Vol. 56, dated June 26, 1991. Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and

which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: September 22, 1994.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

(FR Doc. 94-24247 Filed 9-29-94; 8:45 am)

BILLING CODE 6560-60-P02

[OPPTS-42052P; FRL-4756-5]

Notice of Opportunity to Initiate Negotiations for TSCA Section 4 Enforceable Consent Agreements; Solicitation of Testing Proposals for ATSDR Chemicals

AGENCY: Environmental Protection Agency (EPA)

ACTION: Notice.

SUMMARY: This notice invites manufacturers and processors of certain chemical substances who wish to participate in testing negotiations for various chemicals to develop and submit testing program proposals to EPA. The chemicals are hazardous substances identified for data needs by the Agency for Toxic Substances and Disease Registry (ATSDR), National Toxicological Program (NTP) and EPA pursuant to section 104(i)(5) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA or Superfund)(42 U.S.C. 9601-9675). These 12 chemical substances are vinyl chloride, benzene, trichloroethylene, tetrachloroethylene, hydrogen cyanide, sodium cyanide, toluene, methylene chloride, chloroethane, mercury, chromium, and beryllium. These substances and associated data needs appear in Table 1 below. The specific forms of the metals mercury, chromium, and beryllium to be tested are yet to be determined; EPA will solicit testing proposals for the specific forms of these metals at a later date. Testing proposals should cover all identified data needs of a substance (or multiple substances) in order to be considered for Enforceable Consent Agreement (ECA) negotiation. If, after receiving testing proposals, EPA elects to pursue negotiations for one or more ECAs applicable to specific chemicals, EPA will solicit requests to be designated an interested party at that point. EPA has authority to require testing for these 12 chemical substances under section 4 of the Toxic Substances

CMA 115622

Control Act (TSCA)(15 U.S.C. 2601-2692) and if an ECA-based approach does not prove viable, EPA would proceed with rulemaking to require the needed testing.

DATES: Written testing proposals must be received by November 29, 1994. EPA may extend the deadline for receipt of testing proposals upon a showing of good faith efforts to develop testing proposals by the initial deadline.

ADDRESSEES: Submit three copies of written testing proposals to TSCA Docket Receipts (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. NE B607, 401 M St., SW., Washington, DC 20460. Submissions should bear the document control number (OPPTS-42052P; FRL-4756-5). The public record supporting this action, including comments, is available for public inspection at the above address from 12 noon to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551. For specific information regarding this action or related activities, contact Brian P. Riedel, Project Manager, Chemical Testing and Information Branch (7405), Rm. NE-1606, 401 M St., SW., Washington, DC 20460, (202) 260-0321.

SUPPLEMENTARY INFORMATION:

I. Background

A. Solicitation for Testing Proposals

EPA's procedures for requiring the testing of chemical substances under section 4 of TSCA include the adoption of ECAs and the promulgation of test rules. On numerous occasions, chemical companies have approached EPA to negotiate ECAs for testing chemicals which are likely to become the subject of proposed test rules. EPA will follow the procedures outlined in unit II of this notice to develop ECAs.

B. Chemical Data Needs

The data needs which are the subject of this notice were determined in accordance with the requirements of the Superfund Amendments and Reauthorization Act (SARA) of 1986 which amended and extended CERCLA.

Section 104(i) of CERCLA requires ATSDR and EPA to prepare and revise a list of hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL) and which ATSDR and EPA, in their sole discretion, determine are posing the most significant potential

threat to human health. The lists of these 275 hazardous substances were published in the Federal Register on April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43615); October 17, 1990 (55 FR 42067); October 17, 1991 (55 FR 52166); October 28, 1992 (57 FR 48801); and October 18, 1993 (58 FR 53739).

Section 104(i) of CERCLA also directs ATSDR to prepare toxicological profiles of each listed hazardous substance. Section 104(i)(3) outlines the content of these profiles. Each profile is required to include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations in order to ascertain the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or in the process of development. ATSDR has prepared 110 toxicological profiles covering 195 substances. (One toxicological profile may cover several related substances).

Under CERCLA, section 104(i)(5), when adequate information is not available on the health effects of each substance, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of a research program designed to determine such health effects (and techniques for developing methods to determine such health effects).

As the first step in developing its health effects research program, ATSDR identified data needs for each substance in the toxicological profiles. These data needs were reviewed by scientists from ATSDR, NTP, EPA and the Centers for Disease Control, peer reviewed by an external review panel, and made available for public comment. Prior to final publication of the toxicological profiles, ATSDR considered all public comments it received regarding identification of data needs for the substances.

The next step in the development of the health effects research program (or the substance-specific research program) involved the creation of the "Decision Guide for Identifying Substance-Specific Data Needs Related to Toxicological Profiles" (Decision Guide), published in the Federal Register on September 11, 1989 (54 FR 37618). Applying the principles discussed in the Decision Guide, ATSDR published the "Identification of Priority Data Needs for 38 Priority Hazardous Substances" in the Federal Register on October 17, 1991 (56 FR 52178). As required by CERCLA, section 104(i)(5), ATSDR considered recommendations from the

Interagency Testing Committee (ITC), and, with EPA, coordinated development of these priority data needs with NTP and with programs of toxicological testing established under TSCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)(7 U.S.C. 136). The purpose of such coordination is to avoid duplication of effort and to assure that the listed hazardous substances are tested thoroughly at the earliest practicable date. ATSDR also considered public comments on identification of the priority data needs. On November 16, 1992, ATSDR published the "Announcement of Final Priority Data Needs for 38 Priority Hazardous Substances" in the Federal Register (57 FR 54150). Copies of the FR actions cited above are available in the docket established for this action (OPPTS-42052P; FRL-4756-5).

CERCLA, section 104(i)(5)(C) provides that TSCA authorities may be used to carry out the health effects research program. CERCLA, section 104(i)(5)(D) declares that:

[It is the sense of the Congress that the costs of [conducting health effects research programs] be borne by the manufacturers and processors of the hazardous substances in question, as required in programs of toxicological testing under the Toxic Substances Control Act.

In October 1992, ATSDR requested that EPA test 38 substances using authorities under TSCA and FIFRA. EPA coordinated extensively with other Federal agencies (including the Occupational Safety and Health Administration, National Institute for Occupational Safety and Health, Mine Safety and Health Administration, and the Consumer Product Safety Commission) and among its own programs (including Office of Air and Radiation, Office of Water, Office of Solid Waste and Emergency Response, and Office of Research and Development) to evaluate ATSDR's request for testing. In addition, EPA, ATSDR, and the National Institute of Environmental Health Sciences (NIEHS) met as members of the Tri-Agency Superfund Applied Research Committee (TASARC) to discuss ATSDR's data needs and EPA's response. Copies of the minutes of the TASARC meetings are available in the docket established for this action.

In response to ATSDR's initial request to test 38 substances, EPA deleted substances from the initial list and deleted and added associated data needs based on various factors including, but not limited to, the appropriateness of using TSCA authority to require testing

TABLE 1.—DATA NEEDS AND TESTING GUIDELINES—Continued

Chemical and CAS No.	Proposed Testing	Guideline (40 CFR)
	Developmental inhalation	D
	Neurotoxicity subchronic inhalation	N
	Functional observational battery	
	Motor activity	
	Neuropathology	
Sodium cyanide (143-33-8)	Developmental oral	D
Toluene (108-88-3)	Comparative pharmacokinetic	PK
	Immunotoxicity oral	I
Methylene chloride (75-09-2)	Subchronic oral	798.2650
	Developmental oral	D
	Neurotoxicity subchronic oral	N
	Functional observational battery	
	Motor activity	
	Neuropathology	
	Immunotoxicity oral	I
Chloroethane* (Ethyl chloride) (75-00-3).	Comparative pharmacokinetic	PK
Mercury** (TBD)		
Chromium** (TBD)		
Beryllium** (TBD)		

Notes:

*Note that a soon-to-be-published proposed test rule on hazardous air pollutants (HAPs) will cover chloroethane.

**A workgroup set up by TASARC is in the process of identifying the specific forms of these metals.

TBD -- The Chemical Abstract Service Registry Number(s) for the chemical(s) to be tested is yet to be determined.

R -- Proposed revised EPA guidelines for reproductive toxicity testing are under development and are anticipated to be finalized in the near future. Copies of the latest draft to date are available in the docket established for this action.

D -- Proposed revised EPA guidelines for developmental toxicity testing are under development and are anticipated to be finalized in the near future. Copies of the latest draft to date are available in the docket established for this action.

N -- EPA intends for parties subject to neurotoxicity testing requirements under this rule to follow the 1991 Neurotoxicology Testing Guidelines which are available in the docket established for this action.

I -- A workgroup established by the Tri-Agency Superfund Applied Research Committee (TASARC) is developing immunotoxicity testing guidelines.

A -- Revised EPA guidelines for acute inhalation testing are under development and will soon be published with a proposed test rule on HAPs. Copies of the latest draft to date are available in the docket established for this action.

PK -- EPA has developed testing guidelines which may be used for conducting comparative pharmacokinetic testing. These final guidelines are awaiting publication and

are available in the docket established for this action.

II. Procedures for Development of ECAs

EPA will follow the procedures outlined below to develop ECAs for the chemical substances listed in Table 1 above.

1. *Submission of testing proposals for ECA negotiations.* Following publication of this Notice, manufacturers and processors have 60 days to develop testing proposals for the chemical substances listed in Table 1 above that they wish EPA to consider as candidates for ECA negotiations. EPA may extend the deadline for receipt of testing proposals upon a showing of good faith efforts to develop testing proposals by the initial deadline. The testing proposals should describe the testing to be performed in detail (test guideline or protocol, including route of administration, species, etc.) and explain in detail where there are deviations from tests proposed by EPA in Table 1 above. The Agency suggests as a model the testing proposal submitted on *N*-methylpyrrolidone (NMP) by the NMP Producers Group on September 11, 1992 found in the docket established for this action. In order for a testing proposal to be eligible for consideration, the proposal should cover all identified data needs of a substance (or multiple substances).

2. *Agency selection of most likely candidates for the ECA program.* EPA will review the submissions and select the most promising submissions as candidates for negotiation. Submissions which fully address EPA's concerns will have a higher chance of success than those which do not fully address all data needs issues.

3. *Formal solicitation of "interested parties" in the Federal Register.* If EPA selects a proposal as a candidate for negotiations, such negotiations will be conducted pursuant to procedures described in 40 CFR 790.28. Accordingly, EPA will publish a notice in the Federal Register soliciting persons interested in participating in or monitoring negotiations for the development of an ECA, to so notify the Agency in writing. Those individuals and groups who respond to EPA's notice by the deadline established in the notice will have the status of "interested parties" and will be afforded opportunities to participate in the negotiation process. Designation as an "interested party" will not incur any obligations. Submitters of testing proposals will be considered interested parties with regard to the subject(s) of their proposals and need not respond to the solicitation notice.

4. *Negotiation of testing program and development of an ECA.* Negotiations will be conducted in meetings open to

of certain substances and the needs of other Federal Agencies and EPA programs for certain test data. Relevant correspondence between EPA and ATSDR regarding these selections is available in the docket established for this action. In a letter dated November 9, 1993, EPA informed ATSDR that EPA would pursue testing of ATSDR substances under section 4 of TSCA. The ATSDR list of 38 substances was modified to contain the 12 substances shown in Table 1 below with a summary description of data needs. These substances will be added to the next edition of the Office of Pollution Prevention and Toxics' Master Testing List scheduled for release in FY '95. Further description of the data needs are available in the docket established for this action.

Note that TASARC has set up a workgroup to identify the specific forms of the metals mercury, chromium and beryllium to be tested. This workgroup will consider the needs of other Federal Agencies and EPA programs. In addition, EPA will solicit testing proposals for the specific forms of these metals at a later date. Note also that EPA has not yet developed testing guidelines for certain endpoints indicated in Table 1 below. EPA particularly encourages

submission of testing guidelines for these endpoints which may be used as part of a testing proposal.

EPA realizes that under certain circumstances, as outlined below, route-to-route extrapolation based on valid pharmacokinetic (PK) data can offer a useful and less expensive alternative to retesting by another route of exposure to chemical substances that have already been tested by one route. Therefore, EPA will consider entering into ECAs for PK testing under protocols proposed by prospective test sponsors.

EPA will consider route-to-route extrapolation of toxicity data from routes other than those proposed in Table 1 below when it is scientifically reasonable to empirically derive the risk. Derivation of the risk is only reasonable when portal-of-entry effects and first-pass effects can be ruled out or adequately characterized. Regardless of the toxic endpoint considered, EPA's ability to perform quantitative route-to-route extrapolation is critically dependent on the amount and type of data available. The minimum information needed includes both the nature of the toxic effects and a description of the relationship between exposure and the toxic effect.

The preferred method for performing route-to-route extrapolation involves the development of a physiologically-based pharmacokinetic (PBPK) model that describes the disposition (deposition, absorption, distribution, metabolism, and elimination) of the chemical for the routes of interest. PBPK models must be used in conjunction with toxicity and mechanistic studies in order to relate the effective dose associated with an effect for the test species and conditions to other scenarios.

The primary purpose of this ATSDR/EPA health effects testing program is to meet the substance-specific information needs of the public and the scientific community, and, consistent with the guidelines discussed in the Decision Guide, this testing program will supply toxicity and exposure information which will assist in the development of Superfund health assessments by ATSDR. In addition, because of the involvement by other Federal Agencies and EPA offices in reviewing the testing needs identified for these chemicals, this testing program will supply test data which will also meet the needs of other Federal Agencies and EPA programs.

TABLE 1.—DATA NEEDS AND TESTING GUIDELINES

Chemical and CAS No.	Proposed Testing	Guideline (40 CFR)
Vinyl chloride (75-01-4)	Reproductive inhalation	R
	Developmental inhalation	D
	Neurotoxicity inhalation	N
Benzene (71-43-2)	Subchronic oral	798.2650
	Subchronic inhalation	798.2450
	Neurotoxicity inhalation	N
	Functional observational battery	
	Motor activity	
	Neuropathology	
Trichloroethylene (79-01-6)	Reproductive inhalation	R
	Acute oral	798.1175
	Subchronic oral	798.2650
	Immunotoxicity oral	I
Tetrachloroethylene (127-18-4)	Acute inhalation	A
	Reproductive inhalation	R
	Neurotoxicity subchronic inhalation	N
	Functional observational battery	
	Motor activity	
	Neuropathology	
	Developmental inhalation	D
	Immunotoxicity inhalation	I
	Acute inhalation	A
Hydrogen cyanide (74-90-8)	Subchronic inhalation	798.2450

the public. Notification of meetings will be given only to persons identified as interested parties. The first negotiation meeting will establish the period for negotiation. If agreement is not reached within this prescribed time limit and EPA chooses not to extend the negotiation period, negotiations will be terminated and testing will be required under a rule.

5. *Approval of the ECA by interested parties and EPA and publication of a notice in the Federal Register.* After EPA and interested parties have agreed in principle on the terms of the ECA, the ECA text will be sent for approval to interested parties who are actual participants in the negotiation. Subsequent to approval of the ECA, EPA will publish a notice in the Federal Register summarizing the testing program and announcing that in lieu of a test rule, the Agency has issued a testing Consent Order that incorporates the ECA.

III. Public Record

EPA has established a record for this action (docket control number OPPTS-42052P; FRL-4756-5). The record includes basic information considered by EPA in developing this action. EPA

will supplement the record with additional information as it is received.

A public version of this record is available in the TSCA Nonconfidential Information Center (NCIC) from 12 noon to 4 p.m., Monday through Friday, except legal holidays. The NCIC is located in Rm. NE-B607, Mail Code 7407, 401 M St., SW., Washington, DC, 20460. Written requests for copies of documents contained in this record may be sent to the above address or faxed to (202) 260-8555.

Authority: 15 U.S.C. 2603.

Dated: September 21, 1994.

Charles M. Auer,
Director, Chemical Control Division, Office
of Pollution Prevention and Toxics.

[FR Doc. 94-24250 Filed 9-29-94; 8:45 am]

BILLING CODE 5550-50-P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection
Requirement Submitted to Office of
Management and Budget for Review

September 27, 1994.

The Federal Communications
Commission has submitted the

following information collection request to OMB for review and clearance under the Paperwork Reduction Act of 1980, 44 U.S.C. Section 3507. Persons wishing to comment on this information collection should contact Timothy Fain, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, D.C. 20503, (202) 395-3561. For further information, contact Judy Boley, Federal Communications Commission, (202) 418-0214.

Please note: The Commission has requested expedited review of this collection by September 30, 1994, under the provisions of 5 CFR 1320.18.

Title: Implementation of Section 309(j) of the Communications Act—Competitive Bidding, Second Report and Order and Second Memorandum Opinion and Order, PP Docket No. 93-253.

OMB Control Number: 3060-0600.

Action: Revised Collections.

Respondents: Individuals, State or local governments, Non-profit institutions, Business or other for-profit, including small businesses.

Frequency of response: On occasion and recordkeeping requirements

Estimated Annual Burden:

Section/forms	No. of Respondents	Estimated average hrs per response	Estimated annual burden
Section 1.2105	13,400	.50	6,700
Section 1.2107	10,000	1	10,000
Section 1.2108	2,350	20	47,000
Section 1.2110	1,000	2	2,000
Section 1.2110*	1,000	1	1,000
Section 1.2111	100	.50	50
Microfiche	13,400	2	26,800
FCC Form 175	13,400	.50	6,700
FCC Form 175-S	6,400	.25	675

* Recordkeeping requirement.

Total Annual Burden: 100,925 Hours.

Needs and Uses: In the Second Memorandum Opinion and Order the Commission modified and supplemented several of its generic rules governing the auctioning of all licenses subject to competitive bidding. Applicants are required to file certain information so that the Commission can determine whether the applicants are legally, technically and financially qualified to be licensed and also whether applicants are entitled to receive certain benefits. Affected public are any member of the public who wants to become or remain a licensee.

The foregoing estimates include the time for reviewing instructions,

searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimates or any other aspect of the collection of information, including suggestions for reducing the burden, to the Federal Communications Commission, Records Management Branch, Paperwork Reduction Project, Washington, D.C. 20554 and to the Office of Management and Budget Paperwork Reduction Project, Washington, D.C. 20503.

Federal Communications Commission.

Williams F. Caton,

Acting Secretary.

Subpart Q—Competitive Bidding Proceedings

Authority: 47 U.S.C. 309(j).

General Procedures

Section 1.2101 Purpose

The provisions of this subpart implement Section 309(j) of the Communications Act of 1934, as added by the Omnibus Budget Reconciliation Act of 1993 (P.L. 103-66), authorizing the Commission to employ competitive bidding procedures to choose from among two or more mutually exclusive applications for certain initial licenses.

TABLE 2. — REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company Name and Address
000264	Rhone-Poulenc Ag Co., Box 12014, Research Triangle Park, NC 27709.
000499	Whitmire Research Laboratories, Inc., 3558 Tree Ct., Industrial Blvd, St Louis, MO 63122.
001864	Central Petroleum Co., 1449 W. 117th St, Cleveland, OH 44107.
002935	Wilbur Ellis Co., 191 W. Shaw Ave., Fresno, CA 93704.
003125	Miles Inc., Agriculture Division, 8400 Hawthorn Rd., Box 4913, Kansas City, MO 64120.
004822	S.C. Johnson & Son Inc., 1525 Howe Street, Racine, WI 53403.
005905	Helena Chemical Co, 6075 Poplar Ave., Suite 500, Memphis, TN 38119.
008590	Agway Inc., c/o Universal Cooperatives Inc., Box 460, Minneapolis, MN 55440.
009444	Waterbury Companies Inc., Box 640, Independence, LA 70443.
035900	Ionics, Inc., 3039 Washington Pike, Bridgeville, PA 15017.
037425	Smithkline Beecham Animal Health, 1600 Paoli Pike, West Chester, PA 19380.
044716	Fearing Mfg. Co Inc., 490 Villaume Ave, So., St. Paul, MN 55075.
050534	ISK Biosciences Corp., 5966 Heisley Rd., Box 8000, Mentor, OH 44061.
059639	Valent U.S.A. Corp., 1333 N. California Blvd, Ste 600, Walnut Creek, CA 94596.

For Distribution by CMA
CHEMISTAR DIVISION

From JON BUSCH

Ref. No. OCT 3, 1994

III. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before December 29, 1994. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

IV. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1-year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in *Federal Register* No. 123, Vol. 56, dated June 26, 1991. Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and

which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: September 22, 1994.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

[FR Doc. 94-24247 Filed 9-29-94; 8:45 am]

BILLING CODE 6560-50-P02

[OPPTS-42052P; FRL-4756-5]

Notice of Opportunity to Initiate Negotiations for TSCA Section 4 Enforceable Consent Agreements; Solicitation of Testing Proposals for ATSDR Chemicals

AGENCY: Environmental Protection Agency (EPA)

ACTION: Notice.

SUMMARY: This notice invites manufacturers and processors of certain chemical substances who wish to participate in testing negotiations for various chemicals to develop and submit testing program proposals to EPA. The chemicals are hazardous substances identified for data needs by the Agency for Toxic Substances and Disease Registry (ATSDR), National Toxicological Program (NTP) and EPA pursuant to section 104(i)(5) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA or Superfund)(42 U.S.C. 9601-9675). These 12 chemical substances are vinyl chloride, benzene, trichloroethylene, tetrachloroethylene, hydrogen cyanide, sodium cyanide, toluene, methylene chloride, chloroethane, mercury, chromium, and beryllium. These substances and associated data needs appear in Table 1 below. The specific forms of the metals mercury, chromium, and beryllium to be tested are yet to be determined; EPA will solicit testing proposals for the specific forms of these metals at a later date. Testing proposals should cover all identified data needs of a substance (or multiple substances) in order to be considered for Enforceable Consent Agreement (ECA) negotiation. If, after receiving testing proposals, EPA elects to pursue negotiations for one or more ECAs applicable to specific chemicals, EPA will solicit requests to be designated an interested party at that point. EPA has authority to require testing for these 12 chemical substances under section 4 of the Toxic Substances

CMA 115627

Control Act (TSCA)(15 U.S.C. 2601-2692) and if an ECA-based approach does not prove viable, EPA would proceed with rulemaking to require the needed testing.

DATES: Written testing proposals must be received by November 29, 1994. EPA may extend the deadline for receipt of testing proposals upon a showing of good faith efforts to develop testing proposals by the initial deadline.

ADDRESSEES: Submit three copies of written testing proposals to TSCA Docket Receipts (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. NE B607, 401 M St., SW., Washington, DC 20460. Submissions should bear the document control number (OPPTS-42052P; FRL-4756-5). The public record supporting this action, including comments, is available for public inspection at the above address from 12 noon to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Rm. E-543B, 401 M St., SW., Washington, DC 20460, (202) 554-1404, TDD (202) 554-0551. For specific information regarding this action or related activities, contact Brian P. Riedel, Project Manager, Chemical Testing and Information Branch (7405), Rm. NE-1606, 401 M St., SW., Washington, DC 20460, (202) 260-0321.

SUPPLEMENTARY INFORMATION:

I. Background

A. Solicitation for Testing Proposals

EPA's procedures for requiring the testing of chemical substances under section 4 of TSCA include the adoption of ECAs and the promulgation of test rules. On numerous occasions, chemical companies have approached EPA to negotiate ECAs for testing chemicals which are likely to become the subject of proposed test rules. EPA will follow the procedures outlined in unit II of this notice to develop ECAs.

B. Chemical Data Needs

The data needs which are the subject of this notice were determined in accordance with the requirements of the Superfund Amendments and Reauthorization Act (SARA) of 1986 which amended and extended CERCLA.

Section 104(i) of CERCLA requires ATSDR and EPA to prepare and revise a list of hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL) and which ATSDR and EPA, in their sole discretion, determine are posing the most significant potential

threat to human health. The lists of these 275 hazardous substances were published in the Federal Register on April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43615); October 17, 1990 (55 FR 42067); October 17, 1991 (55 FR 52166); October 28, 1992 (57 FR 48801); and October 18, 1993 (58 FR 53739).

Section 104(i) of CERCLA also directs ATSDR to prepare toxicological profiles of each listed hazardous substance. Section 104(i)(3) outlines the content of these profiles. Each profile is required to include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations in order to ascertain the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or in the process of development. ATSDR has prepared 110 toxicological profiles covering 195 substances. (One toxicological profile may cover several related substances).

Under CERCLA, section 104(i)(5), when adequate information is not available on the health effects of each substance, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of a research program designed to determine such health effects (and techniques for developing methods to determine such health effects).

As the first step in developing its health effects research program, ATSDR identified data needs for each substance in the toxicological profiles. These data needs were reviewed by scientists from ATSDR, NTP, EPA and the Centers for Disease Control, peer reviewed by an external review panel, and made available for public comment. Prior to final publication of the toxicological profiles, ATSDR considered all public comments it received regarding identification of data needs for the substances.

The next step in the development of the health effects research program (or the substance-specific research program) involved the creation of the "Decision Guide for Identifying Substance-Specific Data Needs Related to Toxicological Profiles" (Decision Guide), published in the Federal Register on September 11, 1989 (54 FR 37618). Applying the principles discussed in the Decision Guide, ATSDR published the "Identification of Priority Data Needs for 38 Priority Hazardous Substances" in the Federal Register on October 17, 1991 (56 FR 52178). As required by CERCLA, section 104(i)(5), ATSDR considered recommendations from the

Interagency Testing Committee (ITC), and, with EPA, coordinated development of these priority data needs with NTP and with programs of toxicological testing established under TSCA and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)(7 U.S.C. 136). The purpose of such coordination is to avoid duplication of effort and to assure that the listed hazardous substances are tested thoroughly at the earliest practicable date. ATSDR also considered public comments on identification of the priority data needs. On November 16, 1992, ATSDR published the "Announcement of Final Priority Data Needs for 38 Priority Hazardous Substances" in the Federal Register (57 FR 54150). Copies of the FR actions cited above are available in the docket established for this action (OPPTS-42052P; FRL-4756-5).

CERCLA, section 104(i)(5)(C) provides that TSCA authorities may be used to carry out the health effects research program. CERCLA, section 104(i)(5)(D) declares that:

[i]t is the sense of the Congress that the costs of [conducting health effects research programs] be borne by the manufacturers and processors of the hazardous substances in question, as required in programs of toxicological testing under the Toxic Substances Control Act.

In October 1992, ATSDR requested that EPA test 38 substances using authorities under TSCA and FIFRA. EPA coordinated extensively with other Federal agencies (including the Occupational Safety and Health Administration, National Institute for Occupational Safety and Health, Mine Safety and Health Administration, and the Consumer Product Safety Commission) and among its own programs (including Office of Air and Radiation, Office of Water, Office of Solid Waste and Emergency Response, and Office of Research and Development) to evaluate ATSDR's request for testing. In addition, EPA, ATSDR, and the National Institute of Environmental Health Sciences (NIEHS) met as members of the Tri-Agency Superfund Applied Research Committee (TASARC) to discuss ATSDR's data needs and EPA's response. Copies of the minutes of the TASARC meetings are available in the docket established for this action.

In response to ATSDR's initial request to test 38 substances, EPA deleted substances from the initial list and deleted and added associated data needs based on various factors including, but not limited to, the appropriateness of using TSCA authority to require testing

of certain substances and the needs of other Federal Agencies and EPA programs for certain test data. Relevant correspondence between EPA and ATSDR regarding these selections is available in the docket established for this action. In a letter dated November 9, 1993, EPA informed ATSDR that EPA would pursue testing of ATSDR substances under section 4 of TSCA. The ATSDR list of 38 substances was modified to contain the 12 substances shown in Table 1 below with a summary description of data needs. These substances will be added to the next edition of the Office of Pollution Prevention and Toxics' Master Testing List scheduled for release in FY '95. Further description of the data needs are available in the docket established for this action.

Note that TASARC has set up a workgroup to identify the specific forms of the metals mercury, chromium and beryllium to be tested. This workgroup will consider the needs of other Federal Agencies and EPA programs. In addition, EPA will solicit testing proposals for the specific forms of these metals at a later date. Note also that EPA has not yet developed testing guidelines for certain endpoints indicated in Table 1 below. EPA particularly encourages

submission of testing guidelines for these endpoints which may be used as part of a testing proposal.

EPA realizes that under certain circumstances, as outlined below, route-to-route extrapolation based on valid pharmacokinetic (PK) data can offer a useful and less expensive alternative to retesting by another route of exposure to chemical substances that have already been tested by one route. Therefore, EPA will consider entering into ECAs for PK testing under protocols proposed by prospective test sponsors.

EPA will consider route-to-route extrapolation of toxicity data from routes other than those proposed in Table 1 below when it is scientifically reasonable to empirically derive the risk. Derivation of the risk is only reasonable when portal-of-entry effects and first-pass effects can be ruled out or adequately characterized. Regardless of the toxic endpoint considered, EPA's ability to perform quantitative route-to-route extrapolation is critically dependent on the amount and type of data available. The minimum information needed includes both the nature of the toxic effects and a description of the relationship between exposure and the toxic effect.

The preferred method for performing route-to-route extrapolation involves the development of a physiologically-based pharmacokinetic (PBPK) model that describes the disposition (deposition, absorption, distribution, metabolism, and elimination) of the chemical for the routes of interest. PBPK models must be used in conjunction with toxicity and mechanistic studies in order to relate the effective dose associated with an effect for the test species and conditions to other scenarios.

The primary purpose of this ATSDR/EPA health effects testing program is to meet the substance-specific information needs of the public and the scientific community, and, consistent with the guidelines discussed in the Decision Guide, this testing program will supply toxicity and exposure information which will assist in the development of Superfund health assessments by ATSDR. In addition, because of the involvement by other Federal Agencies and EPA offices in reviewing the testing needs identified for these chemicals, this testing program will supply test data which will also meet the needs of other Federal Agencies and EPA programs.

TABLE 1.—DATA NEEDS AND TESTING GUIDELINES

Chemical and CAS No.	Proposed Testing	Guideline (40 CFR)
Vinyl chloride (75-01-4)	Reproductive inhalation	R
	Developmental inhalation	D
	Neurotoxicity inhalation	N
Benzene (71-43-2)	Subchronic oral	798.2650
	Subchronic inhalation	798.2450
	Neurotoxicity inhalation	N
	Functional observational battery	
	Motor activity	
	Neuropathology	
	Reproductive inhalation	R
Trichloroethylene (79-01-6)	Acute oral	798.1175
	Subchronic oral	798.2650
	Immunotoxicity oral	I
Tetrachloroethylene (127-18-4)	Acute inhalation	A
	Reproductive inhalation	R
	Neurotoxicity subchronic inhalation	N
	Functional observational battery	
	Motor activity	
	Neuropathology	
	Developmental inhalation	D
	Immunotoxicity inhalation	I
	Acute inhalation	A
Hydrogen cyanide (74-90-8)	Subchronic inhalation	798.2450

TABLE 1.—DATA NEEDS AND TESTING GUIDELINES—Continued

Chemical and CAS No.	Proposed Testing	Guideline (40 CFR)
	Developmental inhalation	D
	Neurotoxicity subchronic inhalation	N
	Functional observational battery	
	Motor activity	
	Neuropathology	
Sodium cyanide (143-33-9)	Developmental oral	D
Toluene (108-88-3)	Comparative pharmacokinetic	PK
	Immunotoxicity oral	I
Methylene chloride (75-09-2)	Subchronic oral	798.2650
	Developmental oral	D
	Neurotoxicity subchronic oral	N
	Functional observational battery	
	Motor activity	
	Neuropathology	
	Immunotoxicity oral	I
Chloroethane* (Ethyl chloride) (75-00-3).	Comparative pharmacokinetic	PK
Mercury** (TBD)		
Chromium** (TBD)		
Beryllium** (TBD)		

Notes:

*Note that a soon-to-be-published proposed test rule on hazardous air pollutants (HAPs) will cover chloroethane.

**A workgroup set up by TASARC is in the process of identifying the specific forms of these metals.

TBD -- The Chemical Abstract Service Registry Number(s) for the chemical(s) to be tested is yet to be determined.

R -- Proposed revised EPA guidelines for reproductive toxicity testing are under development and are anticipated to be finalized in the near future. Copies of the latest draft to date are available in the docket established for this action.

D -- Proposed revised EPA guidelines for developmental toxicity testing are under development and are anticipated to be finalized in the near future. Copies of the latest draft to date are available in the docket established for this action.

N -- EPA intends for parties subject to neurotoxicity testing requirements under this rule to follow the 1991 Neurotoxicology Testing Guidelines which are available in the docket established for this action.

I -- A workgroup established by the Tri-Agency Superfund Applied Research Committee (TASARC) is developing immunotoxicity testing guidelines.

A -- Revised EPA guidelines for acute inhalation testing are under development and will soon be published with a proposed test rule on HAPs. Copies of the latest draft to date are available in the docket established for this action.

PK -- EPA has developed testing guidelines which may be used for conducting comparative pharmacokinetic testing. These final guidelines are awaiting publication and

are available in the docket established for this action.

II. Procedures for Development of ECAs

EPA will follow the procedures outlined below to develop ECAs for the chemical substances listed in Table 1 above.

1. *Submission of testing proposals for ECA negotiations.* Following publication of this Notice, manufacturers and processors have 60 days to develop testing proposals for the chemical substances listed in Table 1 above that they wish EPA to consider as candidates for ECA negotiations. EPA may extend the deadline for receipt of testing proposals upon a showing of good faith efforts to develop testing proposals by the initial deadline. The testing proposals should describe the testing to be performed in detail (test guideline or protocol, including route of administration, species, etc.) and explain in detail where there are deviations from tests proposed by EPA in Table 1 above. The Agency suggests as a model the testing proposal submitted on *N*-methylpyrrolidone (NMP) by the NMP Producers Group on September 11, 1992 found in the docket established for this action. In order for a testing proposal to be eligible for consideration, the proposal should cover all identified data needs of a substance (or multiple substances).

2. *Agency selection of most likely candidates for the ECA program.* EPA will review the submissions and select the most promising submissions as candidates for negotiation. Submissions which fully address EPA's concerns will have a higher chance of success than those which do not fully address all data needs issues.

3. *Formal solicitation of "interested parties" in the Federal Register.* If EPA selects a proposal as a candidate for negotiations, such negotiations will be conducted pursuant to procedures described in 40 CFR 790.28. Accordingly, EPA will publish a notice in the Federal Register soliciting persons interested in participating in or monitoring negotiations for the development of an ECA, to so notify the Agency in writing. Those individuals and groups who respond to EPA's notice by the deadline established in the notice will have the status of "interested parties" and will be afforded opportunities to participate in the negotiation process. Designation as an "interested party" will not incur any obligations. Submitters of testing proposals will be considered interested parties with regard to the subject(s) of their proposals and need not respond to the solicitation notice.

4. *Negotiation of testing program and development of an ECA.* Negotiations will be conducted in meetings open to

the public. Notification of meetings will be given only to persons identified as interested parties. The first negotiation meeting will establish the period for negotiation. If agreement is not reached within this prescribed time limit and EPA chooses not to extend the negotiation period, negotiations will be terminated and testing will be required under a rule.

5. *Approval of the ECA by interested parties and EPA and publication of a notice in the Federal Register.* After EPA and interested parties have agreed in principle on the terms of the ECA, the ECA text will be sent for approval to interested parties who are actual participants in the negotiation. Subsequent to approval of the ECA, EPA will publish a notice in the Federal Register summarizing the testing program and announcing that in lieu of a test rule, the Agency has issued a testing Consent Order that incorporates the ECA.

III. Public Record

EPA has established a record for this action (docket control number OPPTS-42052P; FRL-4756-5). The record includes basic information considered by EPA in developing this action. EPA

will supplement the record with additional information as it is received.

A public version of this record is available in the TSCA Nonconfidential Information Center (NCIC) from 12 noon to 4 p.m., Monday through Friday, except legal holidays. The NCIC is located in Rm. NE-B607, Mail Code 7407, 401 M St., SW., Washington, DC, 20460. Written requests for copies of documents contained in this record may be sent to the above address or faxed to (202) 260-9555.

Authority: 15 U.S.C. 2603.

Dated: September 21, 1994.

Charles M. Auer,

Director, Chemical Control Division, Office of Pollution Prevention and Toxics.

(FR Doc. 94-24250 Filed 9-29-94; 8:45 am)

BILLING CODE 5560-50-P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

September 27, 1994.

The Federal Communications Commission has submitted the

following information collection request to OMB for review and clearance under the Paperwork Reduction Act of 1980, 44 U.S.C. Section 3507. Persons wishing to comment on this information collection should contact Timothy Fain, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, D.C. 20503, (202) 395-3561. For further information, contact Judy Boley, Federal Communications Commission, (202) 418-0214.

Please note: The Commission has requested expedited review of this collection by September 30, 1994, under the provisions of 5 CFR 1320.18.

Title: Implementation of Section 309(j) of the Communications Act—Competitive Bidding, Second Report and Order and Second Memorandum Opinion and Order, PP Docket No. 93-253.

OMB Control Number: 3060-0600.

Action: Revised Collections.

Respondents: Individuals, State or local governments, Non-profit institutions, Business or other for-profit, including small businesses.

Frequency of response: On occasion and recordkeeping requirements

Estimated Annual Burden:

Section/forms	No. of Respondents	Estimated average hrs per response	Estimated annual burden
Section 1.2105	13,400	.50	6,700
Section 1.2107	10,000	1	10,000
Section 1.2108	2,350	20	47,000
Section 1.2110	1,000	2	2,000
Section 1.2110*	1,000	1	1,000
Section 1.2111	100	.50	50
Microfiche	13,400	2	26,800
FCC Form 175	13,400	.50	6,700
FCC Form 175-S	6,400	.25	675

* Recordkeeping requirement.

Total Annual Burden: 100,925 Hours.

Needs and Uses: In the Second Memorandum Opinion and Order the Commission modified and supplemented several of its generic rules governing the auctioning of all licenses subject to competitive bidding. Applicants are required to file certain information so that the Commission can determine whether the applicants are legally, technically and financially qualified to be licensed and also whether applicants are entitled to receive certain benefits. Affected public are any member of the public who wants to become or remain a licensee.

The foregoing estimates include the time for reviewing instructions,

searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimates or any other aspect of the collection of information, including suggestions for reducing the burden, to the Federal Communications Commission, Records Management Branch, Paperwork Reduction Project, Washington, D.C. 20554 and to the Office of Management and Budget Paperwork Reduction Project, Washington, D.C. 20503.

Federal Communications Commission.

Williams F. Caton,

Acting Secretary.

Subpart Q—Competitive Bidding Proceedings

Authority: 47 U.S.C. 309(j).

General Procedures

Section 1.2101 Purpose

The provisions of this subpart implement Section 309(j) of the Communications Act of 1934, as added by the Omnibus Budget Reconciliation Act of 1993 (P.L. 103-66), authorizing the Commission to employ competitive bidding procedures to choose from among two or more mutually exclusive applications for certain initial licenses.

Existing Chemicals

De SHAH

FYI

JE Bannell

ATSDR Chemicals Added to MTL

EPA is adding 12 chemicals to the Master Testing List in response to a request for testing by the Agency for Toxic Substances and Disease Registry (ATSDR). The chemicals are: benzene, beryllium, chloroethane, chromium, cyanide, di (2-ethylhexyl) phthalate, mercury, methylene chloride, tetrachloroethylene, toluene, trichloroethylene, and vinyl chloride.

ATSDR is required to identify the hazardous substances most commonly found at Superfund sites, prepare toxicological profiles, and identify priority data needs for those substances. ATSDR is also required to initiate a research program to meet the priority data needs it identifies.

In October 1992, ATSDR requested EPA to use its authorities under TSCA and FIFRA to fill some of the data needs it identified on 37 chemicals. In its response to ATSDR, EPA agreed to develop a test rule under section 4 of TSCA to obtain data on 12 of the chemicals, but noted that a TSCA test rule would not be an appropriate mechanism for obtaining data on the other 25 chemicals. Before initiating rulemaking, EPA is inviting manufacturers of the 12 chemicals listed in the following table to submit testing plans and enter into consent agreements for testing. EPA intends to issue a test rule in late 1994 for any of the 12 substances which are not covered by a consent order or a voluntary testing agreement.

Chemical	Testing to be Proposed
Mercury	Immunotoxicity oral Chronic oral Reproductive oral Acute oral
Vinyl chloride	Reproductive inhalation Developmental inhalation
Benzene	Subchronic oral Neurotoxicity oral
Trichloroethylene	Subchronic oral Neurotoxicity oral
Chromium	Acute oral Reproductive oral Immunotoxicity oral
Tetrachloroethylene	Reproductive inhalation Neurotoxicity inhalation Immunotoxicity inhalation Developmental inhalation
Cyanide	Acute inhalation Subchronic inhalation Developmental inhalation Fate in soil
Beryllium	Acute inhalation Subchronic inhalation with reproductive and pulmonary pathology Developmental inhalation Immunotoxicity inhalation Bioavailability Fate in air
Toluene	Comparative Pharmacokinetics Immunotoxicity oral
Methylene chloride	Subchronic oral Immunotoxicity oral Developmental oral Neurotoxicity oral
Chloroethane	Comparative Pharmacokinetics Immunotoxicity oral

CMA 115632