19pp

OPPT-2002-0066-0001



(EPD) to Shaw Industries, Inc.—Plant No. 80 (Shaw) located in Dalton, Whitfield County, Georgia. This order constitutes final action on the petition submitted by the Georgia Center for Law in the Public Interest (GCLPI) on behalf of Georgia Forest Watch (Petitioner). Pursuant to section 505(b)(2) of the Clean Air Act (the Act) any person may seek judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of this notice under section 307 of the Act.

**ADDRESSES:** Copies of the final order, the petition, and all pertinent information relating thereto are on file at the following location: EPA Region 4, Air, Pesticides and Toxics Management Division, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The final order is also available electronically at the following address: *http://www.epa.gov/region07/programs/artd/air/title5/petitiondb/petitions/shaw80_decision2001.pdf.*

**FOR FURTHER INFORMATION CONTACT:** Art Hofmeister, Air Permits Section, EPA Region 4, at (404) 562–9115 or *hofmeister.art@epa.gov.*

**SUPPLEMENTARY INFORMATION:** The Act affords EPA a 45-day period to review and, as appropriate, to object to operating permits proposed by state permitting authorities under title V of the Act, 42 U.S.C. 7661–7661f. Section 505(b)(2) of the Act and 40 CFR 70.8(d) authorize any person to petition the EPA Administrator to object to a title V operating permit within 60 days after the expiration of EPA's 45-day review period if EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or the grounds for the issues arose after this period.

GCLPI submitted a petition on behalf of Georgia Forest Watch to the Administrator on November 26, 2001, requesting that EPA object to a state title V operating permit issued by EPD to Shaw. The Petitioner maintains that the Shaw permit is inconsistent with the Act because of: (1) The inadequacy of the public participation process and related public notice; (2) the permit's apparent limitation of enforcement authority and credible evidence; (3) the inadequacy of the monitoring and reporting requirements; and (4) the incompleteness of the permit itself as well as the corresponding narrative.

On November 15, 2002, the Administrator issued an order denying this petition. The order explains the reasons behind EPA's conclusion that the Petitioner has failed to demonstrate that the Shaw permit is not in compliance with the requirements of the Act on the grounds raised.

Dated: December 6, 2002.

**A. Stanley Meiburg,**

*Deputy Regional Administrator, Region 4.*

[FR Doc. 02–32905 Filed 12–27–02; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

**[Petition IV–2001–10; FRL–7432–3]**

### Clean Air Act Operating Permit Program; Petition for Objection to State Operating Permit for Shaw Industries, Inc.—Plant No. 2; Dalton (Whitfield County), GA

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of final order on petition to object to a state operating permit.

**SUMMARY:** Pursuant to Clean Air Act section 505(b)(2) and 40 CFR 70.8(d), the EPA Administrator signed an order, dated November 15, 2002, denying a petition to object to a state operating permit issued by the Georgia Environmental Protection Division (EPD) to Shaw Industries, Inc.—Plant No. 2 (Shaw) located in Dalton, Whitfield County, Georgia. This order constitutes final action on the petition submitted by the Georgia Center for Law in the Public Interest (GCLPI) on behalf of Georgia Forest Watch (Petitioner). Pursuant to section 505(b)(2) of the Clean Air Act (the Act) any person may seek judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of this notice under section 307 of the Act.

**ADDRESSES:** Copies of the final order, the petition, and all pertinent information relating thereto are on file at the following location: EPA Region 4, Air, Pesticides and Toxics Management Division, 61 Forsyth Street, SW., Atlanta, Georgia 30303–8960. The final order is also available electronically at the following address: *http://www.epa.gov/region07/programs/artd/air/title5/petitiondb/petitions/shaw2_decision2001.pdf.*

**FOR FURTHER INFORMATION CONTACT:** Art Hofmeister, Air Permits Section, EPA Region 4, at (404) 562–9115 or *hofmeister.art@epa.gov.*

**SUPPLEMENTARY INFORMATION:** The Act affords EPA a 45-day period to review and, as appropriate, to object to operating permits proposed by state permitting authorities under title V of the Act, 42 U.S.C. 7661–7661f. Section 505(b)(2) of the Act and 40 CFR 70.8(d) authorize any person to petition the EPA Administrator to object to a title V operating permit within 60 days after the expiration of EPA's 45-day review period if EPA has not objected on its own initiative. Petitions must be based only on objections to the permit that were raised with reasonable specificity during the public comment period provided by the state, unless the petitioner demonstrates that it was impracticable to raise these issues during the comment period or the grounds for the issues arose after this period.

GCLPI submitted a petition on behalf of Georgia Forest Watch to the Administrator on November 26, 2001, requesting that EPA object to a state title V operating permit issued by EPD to Shaw. The Petitioner maintains that the Shaw permit is inconsistent with the Act because of: (1) The inadequacy of the public participation process and related public notice; (2) the permit's apparent limitation of enforcement authority and credible evidence; (3) the inadequacy of the monitoring and reporting requirements; and (4) the incompleteness of the permit itself as well as the corresponding narrative.

On November 15, 2002, the Administrator issued an order denying this petition. The order explains the reasons behind EPA's conclusion that the Petitioner has failed to demonstrate that the Shaw permit is not in compliance with the requirements of the Act on the grounds raised.

Dated: December 6, 2002.

**A. Stanley Meiburg,**

*Deputy Regional Administrator, Region 4.*

[FR Doc. 02–32906 Filed 12–27–02; 8:45 am]

BILLING CODE 6560–50–P

## ENVIRONMENTAL PROTECTION AGENCY

**[OPPT–2002–0066; FRL–7286–6]**

### Endocrine Disruptor Screening Program, Proposed Chemical Selection Approach for Initial Round of Screening; Request for Comment

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice sets forth for public comment the approach EPA plans to use for selecting the first group of chemicals to be screened in the

2002 DEC 30 AM 10: 20

Agency's Endocrine Disruptor Screening Program (EDSP). Following consideration of comments on this draft approach, EPA will issue a second **Federal Register** notice setting forth its approach for selecting the first group of chemicals and the chemicals it proposes for this initial list. Following comment on the draft list of specific chemicals, EPA will issue the final list.

Because the list of chemicals produced using the proposed approach will be a list of chemicals that the Agency, in its discretion, has decided should be tested first, based primarily upon exposure potential, it should not be construed as a list of known or likely endocrine disruptors nor characterized as such. Nothing in the approach for selecting the initial list would provide a basis to infer that any of the chemicals selected for the list interferes with or is suspected to interfere with the endocrine systems of humans or other species.

EPA anticipates that it will modify its chemical selection approach for subsequent Tier 1 screening lists based on experience gained from the results of testing of chemicals on the initial list, the feasibility of incorporating different categories of chemicals (e.g., non-pesticide substances) and additional pathways of exposure, and the availability of new priority-setting tools (e.g., High Throughput Pre-screening (HTPS) or Quantitative Structure Activity Relationship (QSAR) models).

**DATES:** Comments, identified by docket ID number OPPT–2002–0066, must be received on or before March 1, 2003.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION.**

**FOR FURTHER INFORMATION CONTACT:** *For general information contact*: Barbara Cunningham, Acting Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: *TSCA-Hotline@epa.gov*.

*For technical information contact*: Greg Schweer, Exposure Assessment Coordination and Policy Division (7203M), Office of Science Coordination and Policy, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8469; e-mail address: *schweer.greg@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### *A. Does this Action Apply to Me?*

This action is directed to the public in general, and may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under the Toxic Substances Control Act (TSCA), the Federal Food, Drug and Cosmetic Act (FFDCA), the Safe Drinking Water Act (SDWA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

### *B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPPT–2002–0066. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

2

*C. How and To Whom Do I Submit Comments?*

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this Unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPPT–2002–0066. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to *oppt.ncic@epa.gov*, Attention: Docket ID Number OPPT–2002–0066. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

3. *By hand delivery or courier.* Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Building Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID Number OPPT–2002–0066. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930.

*D. How Should I Submit CBI To the Agency?*

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

*E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. Provide specific examples to illustrate your concerns.
5. Offer alternative ways to improve the proposed approach.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## II. Introduction

*A. What Action is the Agency Taking?*

In this notice, EPA is setting forth, and requesting public comment on, the approach EPA plans to use for selecting an initial group of chemicals to be screened in the Agency's EDSP. EPA anticipates that it will modify its chemical selection approach for subsequent Tier 1 screening lists based on experience gained from the results of testing of chemicals on the initial list, the feasibility of incorporating different categories of chemicals (e.g., non-pesticide substances) and additional pathways of exposure, and the availability of new priority-setting tools (e.g., HTPS or QSAR models). EPA developed its EDSP in response to a Congressional mandate in section 408(p) of FFDCA "to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other effects as [EPA] may designate" (21 U.S.C. 346a(p)). When carrying out the program, the statute requires EPA to "provide for the testing of all pesticide chemicals." The statute also provides EPA with discretionary authority to "provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such a substance." In addition, section 1457 of SDWA provides EPA with discretionary authority to provide

3

for testing, under the FFDCA section 408(p) screening program, "of any other substances that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance."

EPA is following a tiered approach in implementing the requirements of section 408(p) of FFDCA. The core elements of the tiered approach are priority setting, Tier 1 screening, and Tier 2 testing. Tier 1 will be comprised of a battery of screening assays to identify substances that have potential to interact with the estrogen, androgen, or thyroid hormone systems. The purpose of Tier 2 is to determine whether the substance may cause endocrine-mediated effects via or involving estrogen, androgen, or thyroid hormone systems, determine the consequences to the organism of the activities observed in Tier 1, and establish the relationship between doses of an endocrine-active substance administered in the test and the effects observed. (**Federal Register** issue of December 28, 1998 (63 FR 71542, FRL–6052–9, Docket Control Number OPPTS–42208).

At the request of EPA, a joint subcommittee of the EPA Science Advisory Board (SAB) and the FIFRA Scientific Advisory Panel (SAP) reviewed a set of scientific issues related to the development of the Agency's EDSP. One of the recommendations of the SAB/SAP Subcommittee (Ref. 1) was that EPA should initiate the Tier 1 screening program with a set of 50 to 100 chemicals and then convene a panel of independent scientists to review the screening data for the purpose of evaluating and optimizing the Tier 1 screening battery. EPA is proposing to adopt this SAB/SAP recommendation to initially select and screen approximately 50 to 100 chemicals to help the Agency further refine the EDSP. The Agency intends to submit the data received from the screening to an independent external panel of experts and request an evaluation of whether the program could be improved or optimized, and if so, how.

EPA has stated its intention to consider a broad universe of chemicals as potential candidates for testing under the EDSP including pesticide chemicals, non-pesticide commercial chemicals, mixtures, and environmental contaminants (63 FR 71542). However, for the first group of chemicals to be tested, EPA is intending to focus only on pesticide active ingredients and high production volume (HPV) chemicals with some pesticidal inert uses (i.e., the chemicals that are specifically mandated for testing under section 408(p) of FFDCA). The pesticide inerts to be considered are those with relatively large overall production volumes considering both pesticide and non-pesticide uses. This approach will allow EPA to focus its initial endocrine screening efforts on a smaller and more manageable universe of chemicals that emphasizes early attention to the pesticide chemicals that Congress specifically mandated EPA to test for possible endocrine effects.

The purpose of this notice is to describe the approach that EPA plans to use to select this initial set of chemicals to undergo Tier 1 screening. EPA is proposing to use an approach based in part on the compartment-based priority setting approach described in the December 28,1998, **Federal Register** notice (FRL–6052–9) in which EPA provided details about, and requested comment on, its EDSP. The proposed approach focuses on human exposure-related factors rather than using a combination of exposure- and effects-related factors. The approach would, however, exclude from the first group of chemicals to undergo Tier 1 screening any chemical for which the available effects information clearly shows an endocrine-mediated effect. Such chemicals would be considered for proposed Tier 2 tests, mechanistic or special studies, or hazard assessment. Similarly, the approach for this initial list also would exclude substances that EPA anticipates have low potential to cause endocrine disruption (e.g., certain FIFRA List 4 inerts, most polymers with number average molecular weight greater than 1,000 daltons, strong mineral acids, and strong mineral bases). Although EPA's general focus in this approach is on pesticide active ingredients and inerts with relatively greater potential human exposure, EPA believes that the proposed approach will also identify chemicals with high potential for exposure of humans from non-pesticide uses and/or chemicals with widespread environmental exposures to other organisms. EPA does not intend to develop an ordinal ranking of priorities of the chemicals within any list developed using the proposed approach.

Because the list of chemicals produced using the proposed approach will be a list of chemicals that the Agency, in its discretion, has decided should be tested first, based primarily upon exposure potential, it should not be construed as a list of known or likely endocrine disruptors nor characterized as such. Nothing in the approach for selecting the initial list would provide a basis to infer that any of the chemicals selected for the list interferes with or is suspected to interfere with the endocrine systems of humans or other species.

EPA has decided to defer consideration of nominations from the public until subsequent testing lists in order to keep this initial effort administratively simpler and ensure that a set of test results can be obtained in a relatively prompt timeline to aid the Agency in a mid-course evaluation of the EDSP Tier 1 screening battery. In addition, EPA has decided that the prudent approach would be to gain experience with the Tier 1 screening battery on single chemicals before the tests are used with mixtures. EPA also is proposing to exclude from consideration for the initial Tier 1 screening list chemicals that are no longer produced or used in the United States. The Agency thinks that the added administrative complexity of determining who should be responsible for testing such chemicals could unnecessarily delay EPA's selection of an initial list for Tier 1 screening.

*B. What is the Agency's Authority for Taking this Action?*

In this notice, EPA is proposing an approach for selecting an initial set of chemicals to go through endocrine disruptor screening. EPA has a number of authorities at its disposal to require screening and testing for endocrine disrupting effects. As explained previously, FFDCA section 408(p) requires EPA "to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other effects as [EPA] may designate." (21 U.S.C. 346a(p)). The statute requires EPA to "provide for the testing of all pesticide chemicals." It defines "pesticide chemical" as "any substance that is a pesticide within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act, including all active and inert ingredients of such pesticide." (FFDCA section 201(q)(1) (21 U.S.C. 231(q)(1)). The statute also provides EPA with discretionary authority to "provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such a substance" (21 U.S.C. 346a(p)(3)). In addition, section 1457 of SDWA provides EPA with discretionary authority to provide for testing, under the FFDCA section 408(p) screening program, "of any other substances that may be found in sources of drinking water if the Administrator determines

4

that a substantial population may be exposed to such substance." (42 U.S.C. 300j–17). Several other Federal statutes also provide EPA with authority to require testing of certain substances, including FIFRA and TSCA. EPA may use any or all of these authorities to require testing of substances to determine whether a substance may cause endocrine effects.

## III. Background

### *A. EPA's Endocrine Disruptor Screening Program*

EPA initially set forth the EDSP in the **Federal Register** issue of August 11, 1998 (63 FR 42852, FRL–6021–3, Docket Control Number OPPTS–42206) and solicited public comment on the program in the December 28, 1998, **Federal Register** notice (FRL–6052–9). The program set forth in these notices was based on the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) which was a committee chartered under the Federal Advisory Committee Act. The Committee was comprised of members representing the commercial chemical and pesticides industries, Federal and State agencies, worker protection and labor organizations, environmental and public health groups, and research scientists. EPA charged EDSTAC to advise the Agency regarding:

1. Methods for chemical selection and priorities for screening,
2. A set of available, validated screening assays for early application,
3. Ways to identify new and existing screening assays and mechanisms for their validation,
4. Processes and criteria for deciding when additional tests beyond screening would be needed and how to validate such tests, and
5. Processes for communicating to the public about EDSTAC's agreements, recommendations, and information developed during priority setting, screening, and testing.

In response to this charge, EDSTAC recommended that EPA's EDSP address both potential human and ecological effects; examine effects on estrogen, androgen, and thyroid hormone-related processes; and include non-pesticide chemicals, contaminants, and mixtures in addition to pesticides (Ref. 2). Based on these recommendations, EPA developed a tiered approach for the EDSP. The core elements of the proposed approach are: Priority setting, Tier 1 screening, and Tier 2 testing. Tier 1 is envisioned as a battery of screening assays that would identify substances that have the potential to interact with the estrogen, androgen, and thyroid hormone systems. The purpose of Tier 2 is to determine whether the substance could, in fact, cause endocrine effects mediated by estrogen-, androgen-, and thyroid-related processes, and establish the relationship between doses of an endocrine-active substance administered in the test and any effects observed (December 28, 1998, **Federal Register** notice (FRL–6052–9)).

In addition, based on EDSTAC's recommendations, EPA proposed in the December 28, 1998, **Federal Register** notice (FRL–6052–9) an approach to establish the priority of chemicals for Tier 1 screening. The approach reflected the concern that the quantity and quality of exposure and effects information would be uneven across chemicals. EPA wanted to ensure that data-rich and data-poor chemicals were not directly compared in the priority setting process because data-poor chemicals might tend to be ranked low under such an approach. Thus, the approach set forth in the December 28, 1998, **Federal Register** notice (FRL–6052–9) was to set up categories of information relating to the production, release, exposure and hazard of chemicals and to group the chemicals according to what data were available. This approach was termed a "compartment-based approach." The compartment-based approach was based on exposure- and effects-related compartments even though it was recognized that effects or toxicity data relevant to endocrine disruption would be extremely limited for the majority of chemicals. To partly compensate for the lack of relevant toxicity data, EPA proposed to conduct a HTPS on all non-pesticide active ingredient chemicals with a production volume in excess of 10,000 pounds per year. HTPS activities are discussed more fully in Unit IV.C. EPA developed the Endocrine Disruptor Priority Setting Data Base (EDPSD) to assist in assigning chemicals to compartments and setting priorities. More information on the EDPSD is available at: *http://www.epa.gov/scipoly/oscpendo/prioritysetting/*.

EPA currently is implementing its EDSP in three major parts. The Agency is:

1. Developing and validating Tier 1 screening level assays, selecting the appropriate screening assays for the Tier 1 battery based on the validation data, and developing and validating Tier 2 tests.
2. Developing an approach for selecting an initial set of chemicals to go through Tier 1 screening.
3. Developing the procedures the Agency will use to require screening.

This notice deals only with the development of the approach that EPA will use to select the initial set of chemicals for Tier 1 screening.

### *B. SAB/SAP Review*

EPA asked the SAB and the SAP to review jointly the Agency's proposed EDSP as described in the December 28, 1998 **Federal Register** notice (FRL–6052–9). The Agency's charge to the SAB/SAP Subcommittee was broad and complex consisting of 18 questions in four broad areas:

1. Scope of the program.
2. Priority setting.
3. HTPS.
4. Screening and testing.

The Subcommittee met on March 30–April 1, 1999. Its report was published the following July (Ref. 1). In general, the SAB/SAP Subcommittee agreed with the program that EPA had developed for conducting endocrine disruptor screening. The following are recommendations from the Subcommittee with respect to the scope of the program and setting of priorities for Tier 1 screening.

In the December 28, 1998, **Federal Register** notice (FRL–6052–9), EPA explained that it was considering 87,000 substances as potential candidates for testing under the EDSP. The SAP/SAB Subcommittee expressed some reservations about the ambitious scope of the universe of chemicals that EPA envisioned as potentially being included in the Program. The Subcommittee felt that developing massive amounts of screening data on a large universe of chemicals would not necessarily expedite the development of the appropriate underpinning that the Agency needs before it proceeds with the screening of the large universe of chemicals that it anticipates will be included in the EDSP. The Subcommittee also expressed concern that it did not see a provision for mid-course correction or optimization of the Program. Thus, the Subcommittee recommended that the EPA implement the EDSP on 50 to 100 compounds and submit the data to independent review with an eye toward eliminating methods that do not work and optimizing the program.

The Subcommittee also recommended against including mixtures in the initial set of chemicals to be tested. The Subcommittee thought that the question of testing mixtures should be deferred until accepted single-compound methods had been successfully completed.

The Subcommittee also found that the compartment-based approach to priority setting was supportable when ranking is

5

based on both effect and exposure data. It suggested that the greatest weight should be given to chemicals for which there are data that indicate actual human or environmental exposure and effects. Lower weight should be given to agents for which the data are indicative of probable exposure (in food or drinking water) or probable effects (from animal studies). The lowest weight and priority should be given to chemicals for which the data are indicative of possible exposure (based on release or production volume) or possible effects (from *in vitro* or HTPS assays). The Subcommittee expressed concern that the lack of effects data on the universe of chemicals currently in commercial use would lead to a database that only identifies known problem chemicals that are already well studied. To overcome this obstacle, the Subcommittee encouraged the development of new techniques including QSAR and molecular modeling to help identify the bio-available, potentially active compounds for further testing in the EDSP. The Subcommittee supported the concept of nominations by citizens but recommended that the process needed further definition.

Finally, the Subcommittee agreed with EPA's assessment that the HTPS system, which EPA subjected to a demonstration project, was not ready for use but that the concept was still valuable. The Subcommittee encouraged EPA to be open to other types of assays for HTPS including receptor binding, gene chip and microassays, and computer modeling. The Subcommittee also gave some guidance regarding further development and employment of HTPS including the need for standardization and validation of any system to be used in priority setting.

*C. Previous Public Comments on Priority Setting*

In addition to comments provided by the SAB/SAP Subcommittee, comments provided by the public on priority setting in response to EPA's EDSP Proposed Statement of Policy in the December 28, 1998, **Federal Register** notice (63 FR 71542, FRL–6052–9, Docket Control Number OPPTS–42208) and at two public meetings on the Endocrine Disruptor Priority Setting Data Base held on January 20, 1999 (**Federal Register** issue of December 28, 1998 (63 FR 71568, FRL–6052–8, Docket Control Number OPPTS–42207)) and June 5–6, 2000 (**Federal Register** issue of May 19, 2000 (65 FR 31900, FRL–6559–9, Docket Control Number OPPTS–42212)) have been helpful to the Agency in developing the approach presented in this notice for selecting the first group of chemicals to be screened in the EDSP.

## IV. EPA's Approach to Selecting the Initial Set of Chemicals to Undergo Tier 1 Screening

On the basis of EPA's experience to date and comments received from the SAB/SAP Subcommittee and the public, EPA is setting forth its approach for selecting the first group of chemicals to be screened in the EDSP. Based on the SAB/SAP recommendations, EPA is proposing to select and screen approximately 50 to 100 chemicals drawn from pesticide active ingredients and HPV chemicals with some pesticidal inert uses (HPV/Inert chemicals) to help the Agency further refine the EDSP. As recommended by the SAP/SAB Subcommittee, the Agency intends to submit the data received from the screening to an independent external panel of experts and request an evaluation of whether the program could be improved or optimized, and if so, how. EPA does not intend to develop an ordinal ranking of priorities of the chemicals within this initial list.

EPA is proposing to use an approach based in part on the compartment-based priority setting approach described in the December 28, 1998, **Federal Register** notice (FRL–6052–9) that provided details about the EDSP. That document proposed approach focuses on exposure-related factors rather than using a combination of exposure- and effects-related factors. The approach would, however, exclude from the first group of chemicals to undergo Tier 1 screening any chemical for which the available effects information clearly shows an endocrine-mediated effect. Such chemicals would be considered for proposed Tier 2 tests, mechanistic or special studies, or hazard assessment. Similarly, the approach for this initial list also would exclude substances that EPA anticipates have low potential to cause endocrine disruption (e.g., certain FIFRA List 4 inerts, most polymers with number average molecular weight greater than 1,000 daltons, strong mineral acids, and strong mineral bases). Although EPA proposes to use in this approach many of the exposure-data sets previously identified for use in the EDPSD, EPA is not proposing to directly use the EDPSD itself at this time in light of the narrower scope and focus of this initial list. EPA anticipates that it will modify its chemical selection approach for subsequent Tier 1 screening lists based on experience gained from the results of testing of chemicals on the initial list, the feasibility of incorporating different categories of chemicals (e.g., non-pesticide substances), and the availability of new priority-setting tools (e.g., HTPS and QSAR models).

EPA is proposing to use several bodies of data to identify pesticide active ingredients for screening in the first use of the Tier 1 battery. These data focus on human exposure by different pathways:

1. As a consequence of consumption of food containing pesticide residues.
2. As a consequence of consumption of drinking water containing pesticide residues.
3. As a consequence of residential use of pesticide products.
4. Through occupational contact with pesticide-treated surfaces.

For each of the four pathways, EPA has identified existing data that it believes will help to identify active ingredients likely to be among those having either relatively more widespread or higher levels of human exposure than would be expected for other active ingredients. EPA proposes to give higher priority for inclusion on the list for initial screening to chemicals likely to have human exposure via multiple pathways, with the highest priority being given to substances having exposure through all four pathways, followed by those having exposure via three pathways, etc. Details on EPA's proposed approach for selecting pesticide active ingredients are presented in Unit V.

EPA is proposing to use a generally similar approach to identify HPV/Inert chemicals to be included in the initial list for screening in the Tier 1 battery. However, EPA generally has more extensive information of known quality available to assess potential exposure to pesticide active ingredients via food, water, occupational and residential exposure pathways than is available to assess exposure to HPV/Inert chemicals. In addition, EPA generally has more extensive information available on usage (including both agricultural and residential) of active ingredients than is available for HPV/Inert chemicals (including both pesticidal and non-pesticidal uses of those same substances). For these reasons, the specific data and approaches EPA has identified for selecting an initial set of HPV/Inert chemicals for endocrine disruptor screening differs somewhat from those proposed for selecting pesticide active ingredients.

For HPV/Inert chemicals, EPA will focus on several indicators of the potential for human exposure, including production volume, specific pathways of exposure, and presence in human tissues. First, EPA will review existing

6

databases to identify chemicals that are both pesticide inerts and HPV (defined as chemicals that are manufactured or imported into the United States for all uses in amounts equal to or greater than 1 million pounds per year) chemicals (HPV/Inert). This first step will focus initial Tier 1 screening of pesticide inerts on chemicals with higher potential human exposure on the basis of large amounts produced or imported each year in the United States. Second, EPA will review existing data to identify HPV/Inert chemicals that have been found to be present in: Human tissue, ecological tissues that have human food uses (i.e., fish tissues), drinking water, and/or indoor air. Using this approach, an HPV/Inert chemical appearing in monitoring data from one or more of these media, would be a higher priority for testing than an HPV/Inert chemical that does not appear in monitoring data from any of the media. Details on this priority setting approach for HPV/Inert chemicals are presented in Unit VI.

While EPA's general focus in this approach is on pesticide active ingredients and HPV/Inert chemicals with relatively greater potential human exposure, this focus does not necessarily mean that the list developed using this approach will not contain substances which also have potentially high levels of environmental exposure to ecological receptors. As explained in Units V. and VI., EPA believes that the approach proposed to select an initial list of pesticide active ingredients and HPV/Inert chemicals for screening, while focused on human exposure, will also capture many chemicals with widespread environmental exposures to other organisms.

This proposed approach for selecting the initial list of chemicals to undergo Tier 1 screening differs from the more general EDSP priority setting approach outlined in EPA's December 28, 1998, **Federal Register** notice (FRL–6052–9) in several aspects: EPA would focus chemical selection for this initial list on the subset of chemicals subject to a statutory mandate for screening (i.e., pesticide chemicals); EPA would use exposure data as the primary basis for chemical selection rather than using HTPS, QSARs or other hazard data in conjunction with exposure data; EPA would defer consideration of nominations from the public; and EPA would not include mixtures in this initial list. The reasons for these proposed changes are as follows:

*A. Focusing on the Subset of Chemicals Subject to a Statutory Mandate for Screening*

For the initial Tier 1 screening list, EPA is proposing to focus only on pesticide active ingredients and HPV chemicals with some pesticidal inert uses (i.e., the chemicals that are specifically mandated for testing under section 408(p) of FFDCA) as candidates. The pesticide inerts to be considered are those with relatively large overall production volumes considering both pesticide and non-pesticide uses. This approach will allow EPA to focus its initial endocrine screening efforts on a smaller and more manageable universe of chemicals that emphasizes early attention to the pesticide chemicals that Congress specifically mandated EPA to test for possible endocrine effects.

*B. Using Exposure Data as the Primary Basis for Chemical Selection*

In response to the recommendations of EDSTAC, EPA had stated its intention to incorporate effects information into an overall chemical prioritization scheme in conjunction with exposure information for identifying chemicals to undergo screening and testing for endocrine disruption potential. However, in light of the limited availability of data for many chemicals that would indicate their relative potential for disrupting endocrine systems and the delays in identifying adequate HTPS or QSAR approaches that are discussed in Units IV.C. and IV.D., the Agency is proposing to use a simpler and narrower approach based primarily on exposure for this initial selection of a limited number of chemicals for screening under the EDSP.

A relatively broad range of toxicity data generally are available for pesticide active ingredients regulated under FIFRA, but in most cases it has not yet been established how the available data might be confidently used to predict the endocrine disruption potentials of these chemicals. This may be due, for example, to the non-specific nature of an effect or effects observed, questions related to whether the mode of action of a given effect or effects is or are endocrine system-mediated in whole or in part, or the lack of relevant data to make a judgement altogether. A more limited set of toxicity data generally is available for pesticide inert ingredients.

Nevertheless, for certain chemicals the available data may provide a sufficiently clear indication of an endocrine-mediated effect or perturbation to warrant exclusion from the first group of chemicals to undergo Tier 1 testing. Such chemicals would be considered for proposed Tier 2 tests, mechanistic or special studies, or hazard assessment. Similarly, based on a review of the available information, there are certain other substances which EPA anticipates have low potential to cause endocrine disruption (e.g., certain FIFRA List 4 inerts, most polymers with number average molecular weight greater than 1,000 daltons, strong mineral acids, and strong mineral bases). EPA anticipates also excluding certain of these substances from the first group of chemicals to undergo Tier 1 testing.

Therefore, except for purposes of exclusion (e.g., there are sufficient data to determine that a chemical has endocrine-mediating activity), effects data are not being considered in this approach for identifying the initial group of chemicals for Tier 1 screening. This does not necessarily mean, however, that toxicity data will not be used in identifying subsequent groups of chemicals for Tier 1 screening.

Because the list of chemicals produced using the proposed approach will be a list of chemicals that the Agency, in its discretion, has decided should be tested first based primarily upon exposure potential, it should not be construed as a list of known or likely endocrine disruptors nor characterized as such. Nothing in the approach for selecting the initial list would provide a basis to infer that any of the chemicals selected for the list interferes with or is suspected to interfere with the endocrine systems of humans or other species.

*C. HTPS*

Recognizing the limitations on existing hazard data, EPA proposed in the December 28, 1998, **Federal Register** notice (FRL–6052–9) the use of *in vitro* HTPS to assist in sorting and priority setting. The plan was to use HTPS to pre-screen up to 15,000 chemicals that are produced in quantities exceeding 10,000 pounds per year. HTPS data would define one of the compartments in the EDPSD and provide a criterion for identifying high priority chemicals. EPA sponsored a limited demonstration of an HTPS system utilizing reporter gene assays for the estrogen receptor (ER), androgen receptor (AR), and thyroid receptor (TR). The reporter gene assays used in this demonstration project employed a human cell line that naturally contains the receptor. A reporter element was then introduced into these cells so that when a substance binds to a receptor it would activate the genetic machinery in the cell. This activation could be detected in a quantitative manner. The SAB/SAP

7

Subcommittee agreed with EPA that the demonstration HTPS system did not work well enough in its present form to serve as a tool for priority setting (Ref. 1). The assays had too much variability and too low of a response to be useful without modifications to boost their sensitivity. EPA concluded that the HTPS approach still holds promise but that it has potential for success only after substantial additional research. EPA decided to defer its plans for using HTPS and to explore the potential for using QSAR models to address the problem of inadequate hazard data to prioritize chemicals. Nonetheless, the SAB/SAP Subcommittee believed that HTPS is a promising tool for priority setting and EPA agrees. EPA has issued a Request For Application (RFA) under its Science to Achieve Results (STAR) research grants program to solicit new approaches that may lead to the development of HTPS to assist in the prioritization of chemicals for screening for endocrine disrupting activity (*http://es.epa.gov/ncer/rfa/current/2003high_throughput.html*). EPA is also following the work being conducted in Japan on ER and AR transcriptional activation-based HTPS systems. EPA will consider the applicability of new HTPS approaches to future priority setting in the EDSP as those approaches are further developed and refined.

*D. QSAR Models*

At the time EPA decided to suspend its efforts under the EDSP on HTPS, it was aware of at least two QSAR models that were being developed to predict the potential of a chemical to bind to cellular ER. QSAR offers one important advantage over HTPS. It could provide data on thousands of chemicals without testing them in the laboratory. Such a tool could save millions of dollars in chemical testing costs, but still, if valid, be able to predict whether a new molecule that had never been synthesized or an untested existing chemical would be likely to interact with the ER or AR. EPA designed a program to validate two QSAR models within a defined chemical domain and activity range of interest to EPA. The comparative molecular field analysis (CoMFA) model developed by Federal Food and Drug Administration's (FDA) National Center for Toxicological Research and the common reactivity pattern (COREPA) model developed at the University of Bourgas were evaluated. EPA asked each of the modeling teams to predict the relative ER binding of 6,649 high production chemicals on the TSCA inventory. EPA selected 50 chemicals predicted to be positive by each model and approximately 200 chemicals selected from the 6,649 at random and tested almost all in an ER binding assay. Thus, a total of nearly 300 chemicals were tested to validate the models. Each model predicted about 300 of the 6,649 chemicals to be positive. There were 78 chemicals that were predicted to be positive by both models (Ref. 3). A comparison of model predictions with laboratory results did not meet EPA's expectations because, although both models demonstrated relatively high specificity, both models also demonstrated low sensitivity. EPA believes that the performance problems associated with the models are likely due to the chemical training set being significantly dissimilar in terms of structures and binding potency ranges compared to the TSCA HPV chemicals. EPA is continuing to encourage the development and refinement of QSARs and beginning in Fiscal Year 2002 redirected $4 million to a computational toxicology initiative to integrate modern computing and information technology, not limited to just QSARs, with the technology of molecular biology and chemistry to improve EPA's ability to prioritize chemicals for screening and testing, and its risk assessments.

*E. Deferring Consideration of Nominations From the Public*

For the initial Tier 1 screening list, EPA proposes to focus on pesticide active ingredients and HPV chemicals with some pesticidal inert uses (i.e., the chemicals that are specifically mandated for testing under section 408(p) of FFDCA) as candidates. EPA believes that nominations from the public are important because they provide a mechanism to identify chemicals which may result in high exposures in local communities but which would not otherwise receive national attention. However, EPA has decided to defer consideration of nominations from the public until subsequent testing lists in order to keep this initial effort administratively simpler and ensure that a set of test results can be obtained in a relatively prompt timeline to aid the Agency in a mid-course evaluation of the EDSP Tier 1 screening battery.

*F. Not Testing Mixtures*

EPA has decided that the prudent approach would be to gain experience with these tests on a variety of single chemicals before it addresses mixtures. This judgement is consistent with advice from the SAB/SAP Subcommittee (Ref. 1).

*G. Excluding Chemicals that are no Longer Produced or Used in the United States*

EPA also is proposing to exclude from the initial Tier 1 screening list any chemicals that are no longer produced or used in the United States. The Agency thinks that such chemicals would not warrant high priority for testing at this time. Although some of the databases that EPA proposes to consider may report past detections of such chemicals, the discontinuation of their use and manufacture means that exposure to these substances is likely declining. Moreover, EPA anticipates that it will have to resolve significant practical difficulties (such as determining who EPA could require to conduct the testing) before it attempts to require testing of these substances. This combination of reasons leads the Agency to propose excluding discontinued chemicals from the initial group of chemicals to undergo testing in the Tier 1 screening battery.

**V. Approach for Selecting Pesticide Active Ingredients**

EPA is proposing to use several sets of criteria for identifying pesticide active ingredients to be given priority for screening in EPA's initial application of the Tier 1 battery. These criteria would focus on human exposure by different pathways: As a consequence of consumption of food containing pesticide residues; as a consequence of consumption of drinking water containing pesticide residues; as a consequence of residential use of pesticide products; and through occupational contact with pesticide-treated surfaces. For each of the four pathways, EPA would review existing databases that can help the Agency to identify active ingredients generally expected to be among those having either widespread or high levels of human exposure.

While EPA's general focus is on pesticide active ingredients with relatively greater potential human exposure, this focus does not necessarily mean that the list of active ingredients will not contain substances which also have potentially high levels of environmental exposure to ecological receptors. Many of the pesticide active ingredients having greater potential for human exposure will also have greater potential for exposure to wildlife. For example, one pathway of human exposure, drinking water, is also a pathway through which aquatic life and many terrestrial species are exposed. Most of the databases that EPA will consider in evaluating active ingredients

8

for exposure through drinking water contain monitoring data collected on raw surface water, i.e., before the water enters a Community Water System. Thus, these monitoring data show the levels of pesticide residues which fish, amphibians, and other aquatic species will encounter. Similarly, when data show higher and more widely distributed levels of pesticide residues in food, EPA thinks that such residues generally tend to reflect greater usage and/or persistence of the pesticide on crops and thus, greater environmental loads. Accordingly, EPA believes that the approach proposed to evaluate pesticide active ingredients, while focused on human exposure, will also capture many active ingredients with widespread environmental exposures.

*A. The Food Pathway*

Every person eats food and a significant portion of food contains some amount of pesticide residues, although usually at very low levels. Therefore, pesticide residues in food have the potential to cause widespread human exposure. Pesticides have different use patterns and have different physical and chemical properties that affect how they move in the environment and how quickly they break down. As a result, there are often significant differences among pesticides in the proportion of food containing residues and in the levels of such residues. People also consume different amounts of different foods. All of these factors mean that people ingest greater quantities of some pesticide active ingredients than of others.

To evaluate the interplay of these different variables, EPA proposes to identify the pesticide active ingredients which are most frequently found as residues on the top twenty foods that people consume. First, EPA will examine the most recent Continuing Survey of Food Intake by Individuals (CSFII) to determine the mean amount of each raw agricultural commodity consumed in the general population. The CSFII is a database derived from a survey performed by the U. S. Department of Agriculture (USDA) in 1994–1996 and supplemented with additional survey responses collected in 1998. USDA collected food diary information from over 20,000 individuals who were interviewed on two non-consecutive days, generally spaced 3 to 10 days apart. After appropriate statistical weighting, the survey, in the aggregate, is representative of the U. S. population in terms of age, gender, major ethnic groups, and socio-economic status. Moreover, sampling was representative of different days of the week, seasons of the year, and parts of the country. Extensive quality control procedures assured that the data collected in the survey were accurate and reliable. More information on USDA's food surveys and the CSFII ('94–'96) is available through *http://www.barc.usda.gov/bhnrc/foodsurvey.*

Using the CSFII information, EPA has converted the reported food consumption for each survey respondent into the constituent raw agricultural commodities. For example, if a person reported having eaten 6 ounces of beef stew, EPA estimated the amount of beef, carrot, potato, and each other raw agricultural commodity used in making that quantity of beef stew. EPA made similar conversions for each of the different finished foods reported in the CSFII—from apple pie to yogurt. Then EPA estimated the total amount of each of the various raw agricultural commodities eaten over the course of the day, for example summing the amount of apple consumed from drinking cider and eating apple sauce. This individual food consumption database provides the basis for identifying the top twenty foods consumed, in terms of mean daily consumption for the general population. List 1 of this unit lists these raw agricultural commodities.

**List 1.—Top Twenty Foods**
(Foods accounting for the largest quantity of food intake by individuals (arranged alphabetically))

1. Apple
2. Banana
3. Beef
4. Carrot
5. Chicken
6. Corn, Field
7. Corn, Sweet
8. Egg
9. Grape
10. Lettuce
11. Milk
12. Onion
13. Orange
14. Pork
15. Potato
16. Rice
17. Soybean, oil
18. Sugar
19. Tomato
20. Wheat

Having identified the top 20 foods, EPA would characterize the pesticide residue levels on these foods using information collected by two Federal agency monitoring programs, the USDA Pesticide Data Program (PDP) and the Surveillance Monitoring Program conducted by FDA's Center for Food Safety and Applied Nutrition. PDP has been collecting pesticide residue data since 1991. PDP is designed to provide a nationally representative database on the distribution of pesticide residues in food as close as possible to the actual time of consumption as practical. Using analytical methods that have been standardized and validated, and following strict quality control procedures, USDA has focused on foods highly consumed by children throughout the year. Over the years of operation, PDP has collected data on over 290 different pesticides and 50 different commodities. Additional information can be found at *http://www.ams.usda.gov/science/pdp/index.htm.* The FDA Surveillance Monitoring Program is designed primarily for enforcement of pesticide tolerances on imported foods and domestic foods shipped in interstate commerce. Domestic samples are collected as close as possible to the point that the food enters the distribution system. FDA samples imported food at the port of entry into the United States. Additional information on the FDA program appears at *http://www.cfsan.fda.gov/~dms/pesrpts.html.*

Because of the differences in how samples are collected and handled, EPA would rely on the PDP database when both sources cover the same pesticides and commodities. The FDA Surveillance data covers different pesticides and commodities in different years from the PDP monitoring. (For example, in 1999, FDA used analytical methods capable of detecting 366 different active ingredients.) Therefore, in making its weight-of-the-evidence judgment, EPA would consider the FDA information as a supplement to the information from the PDP database.

EPA proposes to examine the PDP and FDA Surveillance databases to identify the pesticide active ingredients which appear on the largest proportion of the samples, focusing on the twenty foods which make up the largest part of the U.S. diet. Generally, EPA would give higher weight to pesticides that appear frequently on multiple foods. In reviewing these data, EPA will take into account qualitatively any risk mitigation measures implemented since residues levels were monitored.

EPA recognizes that this approach would be more likely to give higher priority to the pesticides which are the subject of routine monitoring in either PDP or FDA's Surveillance program. Both programs rely primarily on "multi-residue methods" that are capable of detecting many different chemical substances using a single analytical procedure. Active ingredients which

9

require specialized analytical methodology may not be looked for and thus would be unlikely to be included for consideration in the food pathway. This limitation particularly applies to newer pesticide active ingredients. Notwithstanding these limitations, EPA believes that the approach described is a practicable approach for identifying pesticide active ingredients with widespread or high levels of exposure.

*B. The Water Pathway*

Significant portions of the general population may be exposed to pesticide residues in drinking water. Although monitoring data indicate that most pesticide active ingredients are rarely detected, analytical surveys in virtually every region of the country have detected a number of active ingredients in ground and surface water used as sources of drinking water. Monitoring also indicates that, even when found in water, residue levels vary significantly both seasonally and regionally for a single pesticide, as well as across pesticides. Particularly for surface water, residues tend to occur in pulses that can last days to weeks to months, depending on the type of water body and the pesticide. Because almost every person consumes some water every day, either in prepared foods or beverages (e.g., coffee, tea, or reconstituted juice) or simply by drinking water, exposure to pesticides through the drinking water pathway can be widespread and repeated. And, while such exposure is usually neither as widespread nor of the same magnitude as pesticide exposure through food, a significant portion of the population in a particular region of the country can be exposed.

To assess relative exposure to different pesticides in water, EPA would examine a number of different databases that contain the results of programs to monitor surface and ground water for the presence of pesticide residues. These databases, which contain data collected by Federal and State agencies, academicians, pesticide companies, and others, are summarized in this unit:

1. *EPA Pesticides in Ground Water Database (PGWDB).* The PGWDB was created to provide a more complete picture of ground-water monitoring for pesticides in the United States. It is a collection of ground-water monitoring studies conducted by Federal, State, and local governments; the pesticide industry; and private institutions between 1971–1991. The PGWDB compiles, in tabular format, data from monitoring of raw ground-water[1] and contains data only from studies in which pesticides were included as analytes. Some of the data limitations include: age of the data; differences in the design of studies; lack of historical pesticide use or hydrological information; and lack of information on well use, sampling practices, and laboratory procedures. Further details can be found in *EPA Pesticides in Ground Water Database, A Compilation of Monitoring Studies: 1971–1991 National Summary* (Ref. 4).

2. *EPA Chemical-Specific Monitoring Data.* Pesticide registrants have conducted and submitted to the Agency targeted surface water and ground water monitoring studies for approximately 50 pesticide active ingredients. The Agency decides whether to require monitoring of raw surface or ground water for a pesticide based on the environmental fate characteristics (persistence and mobility) of the pesticide; the current or proposed use patterns for the pesticide; and other information that would indicate potentially significant levels of the pesticide could be present in water. The design of monitoring studies takes into consideration application rate, crops, and the location of potentially more vulnerable use sites. These studies are performed under Good Laboratory Practice regulations, and contain internal quality assurance procedures. When submitted, the monitoring data undergo primary and secondary review by Agency scientists.

3. *Heidelberg College's Monitoring Data.* Heidelberg College's Water Quality Laboratory (WQL) conducts research, monitoring and educational programs that address the impacts of agricultural and urban land use on the water resources of Ohio, the Midwest, and the Lake Erie and Great Lakes ecosystems. The WQL began studying pesticides in 1981. These studies now provide the longest and most detailed record of pesticide residues in raw water available for any river system in the United States. The WQL maintains a modern, highly automated water chemistry laboratory with capabilities rarely found within academic research settings. While much of the WQL's program is organized within the context of a large-scale, long-term agricultural ecosystem study, the lab also conducts research related to public drinking water supplies (finished water), urban runoff, industrial and municipal pollution sources and changing biological communities in Lake Erie. Further details can be found on the web at: *http://www.heidelberg.edu/WQL/index.html.*

4. *U.S. Geological Survey (USGS)/EPA Reservoir Monitoring Study.* The USGS/EPA Reservoir Monitoring study was a pilot monitoring program initiated by USGS and EPA to provide information on pesticide concentrations in drinking water and to assist in the implementation of the Food Quality Protection Act (FQPA) of 1996. Drinking-water utilities that withdrew water from reservoirs were sampled in 1999 and 2000. Water samples were collected from raw water (at the intake point) and from finished drinking-water (at the tap prior to entering the distribution system). At some sites, samples were also collected at the reservoir outflow. Sampling frequencies were designed to measure long-term mean and short-term peak concentrations of pesticides in drinking water. The analytical methods used for analyzing the pesticides in the water samples included 178 different pesticides and degradation products. Additional information on the USGS/EPA Reservoir Monitoring Study can be found in *Pesticides in Select Water Supply Reservoirs and Finished Drinking Water, 1990–2000: Summary of Results from a Pilot Monitoring Program* (Ref. 5).

5. *Environmental Monitoring and Assessment Program (EMAP).* EMAP is an EPA research initiative designed to support the development of tools necessary to monitor and assess the status and trends of national ecological resources. Research is conducted on various ecosystems (e.g., estuaries, forests, rangelands, and lakes). Sediment samples were collected in 18 States at various times between 1990 and 1998. This data source provides information about the contaminants present in sediment/soil which humans and wildlife may contact. EMAP includes relevant data for over 170 chemicals and three separate data sets for estuary sediments. Extensive field and laboratory QA/QC procedures were performed during the collection and analysis of the samples. Further details can be found on the web at: *http://www.epa.gov/emap/.*

6. *National Sediment Inventory (NSI).* The Water Resources Development Act (WRDA) of 1992 directed EPA, in consultation with the National Oceanic and Atmospheric Administration (NOAA) and the U.S. Army Corps of Engineers (USACE), to conduct a national survey of data regarding the quality of sediments in the United States. To comply with the WRDA mandate, EPA's Office of Science and Technology initiated the NSI. The NSI

[1] "Raw" water refers to a water source that has not been treated in a drinking water facility. Water that has been treated is referred to as "finished" water.

is a database that documents the composition of sediment in rivers, lakes, oceans, and estuaries. The NSI tissue residues studies (primarily fish) help assess sediment quality and can be used to assess potential exposure of humans to these chemicals through the consumption of fish. Also, sediment chemistry data are evaluated for theoretical bioaccumulation potential. The NSI includes data collected by a variety of Federal, State, regional, local, and other monitoring programs from 1980 through 1999. It includes over 4.6 million analytical observations for over 50,000 monitoring stations across the country of sediment chemistry, tissue residues, and sediment toxicity data. NSI's minimum data requirements include monitoring program identification, sampling date, latitude and longitude coordinates, and measured units. EPA retains additional data such as QA/QC information, if available, but did not require that information for a data set to be included in NSI. Additional limitations of the compiled data include the mixture of data sets derived using different sampling strategies, incomplete sampling coverage, and the age and quality of the data. Because the data analyzed in this report were collected over a relatively long period of time, conditions may have changed since the sediment was sampled. Further details on the NSI database and the National Sediment Quality Survey, which the NSI was developed to support, can be found at: *http://www.epa.gov/waterscience/cs/nsidbase.html* and *http://www.epa.gov/waterscience/cs/draft/survey.html.*

7. *National Drinking Water Chemical Occurrence Database (NCOD).* NCOD is a repository of drinking water quality data, mandated by Congress in the 1996 SDWA Amendments. NCOD contains national occurrence data from public water systems and from ambient water from the USGS National Water Information System. It includes information on regulated and unregulated contaminants, containing physical, chemical, microbial, and radiological information for both detects and non-detects. NCOD-drinking water contains relevant data for over 120 chemicals, and includes samples from both raw and finished water. Currently, NCOD-drinking water contains occurrence only for those water systems that have been reported by States to EPA's Safe Drinking Water Information System. While data sets will be updated over time, they may reflect a lag time of at least six months. Further details can be found on the web at: *http://www.epa.gov/safewater/data/ncodgateway.html.*

8. *National Stream Quality Accounting Network (NASQAN) Data.* NASQAN, a monitoring and data-collection program conducted by the USGS, is designed to characterize raw surface water in large sub-basins of rivers, determine regional source areas for chemicals, and assess the effects of human influences on observed concentrations and amounts of chemicals. Since 1995, NASQAN has focused on monitoring the water quality of four of the nation's largest river systems: the Mississippi, the Columbia, the Colorado, and the Rio Grande. A network of 40 stations monitors the concentrations of a broad range of chemicals including pesticides, major ions, and trace elements. NASQAN contains relevant data for over 70 chemicals. NASQAN samplers collect quality control (QC) samples to evaluate the quality of sampling data. However, the data in NASQAN do not characterize ambient water quality throughout the United States, only for four river basins and sub-basins. Further details can be found on the web at: *http://water.usgs.gov/nasqan/.*

9. *The National Water Quality Assessment Program (NAWQA).* Congress appropriated funds in 1986 for the USGS to design and implement a program to address questions related to status and long-term trends in raw surface- and ground-water quality at national, regional, and local scales. The USGS began a pilot program in seven project areas to develop and refine a plan for the National Water-Quality Assessment (NAWQA) Program. In 1991, the USGS began full implementation of the program. The NAWQA program builds upon an existing base of water-quality studies of the USGS, as well as those of other Federal, State, and local agencies. The NAWQA Program was designed to study 60 of the Nation's most important river basins and aquifer systems, which are referred to as study units. A national map of these study units shows that they are distributed throughout the Nation and cover a diversity of hydrogeologic settings. More than two-thirds of the Nation's freshwater use occurs within the study units and more than two-thirds of the people served by public water-supply systems live within their boundaries. The 60 study units have been divided into groups of 20 study units each, and their intensive data-collection phases have been staggered to allow efficient and effective use of resources. The first 20 studies began in 1991, the second group began in 1994, and the third group began study in 1997. Due to funding constraints, only 14 of the original first group of 20 study units began a second cycle of study in the year 2000. The cycle is intended to continue into the future with a total of 52 study units so as to provide both short-term information necessary for today's water-resource management decisions, and the long-term information needed for policy decisions. Further details can be found on the web at: *http://wwwga.usgs.gov/nawqa/main.nawqa.html.*

EPA notes that most of the monitoring databases report results from samples of "raw," or untreated, water, rather than "finished" drinking water prepared by a drinking water facility for its customers. To the extent that treatment methodologies (such as flocculation, softening, filtration, chlorination, sedimentation, etc.) either remove or transform the pesticide residue in the source water, residues found in the raw water may not represent exposure of the public consuming the finished water. EPA has considered the impacts of various treatment methodologies on different classes of pesticides found in raw water and concluded that conventional water treatment processes (such as coagulation/flocculation, sedimentation, and filtration) can have little or no effect on the removal of certain pesticides (Ref. 6). Thus, the Agency regards the results of monitoring raw or ambient water as an appropriate indicator of potential human exposure.

Many other factors affect the interpretation of a set of water monitoring data. Monitoring is most likely to detect the presence of pesticide residues in water if it is conducted in an area where the pesticide has been used, and samples are collected at a time when residues are likely to occur. Moreover, the analysis must employ methods sensitive enough to detect any residue. Often, however, monitoring reports lack sufficient information to evaluate how well these factors were considered. Consequently, evaluation of water monitoring data requires considerable judgment. See the discussion of considerations affecting the evaluation of water monitoring data in *Estimating the Drinking Water Component of a Dietary Exposure Assessment* (Ref. 7) and the *EPA Background Paper for the FIFRA Scientific Advisory Panel Meeting on Monitoring Strategies for Pesticides in Surface-Derived Drinking Water* (Ref. 8).

The limitations on an individual data set can be overcome, to some extent, by consideration of multiple sets of data and multiple databases. EPA thinks that, when considered collectively, the databases discussed in Unit V.B. are not

11

as vulnerable to criticism as a single data set. Generally, all of these databases include studies with high levels of quality control, and together they provide wide temporal and spatial coverage for a large number of pesticides. Thus, the Agency believes the databases in Unit V.B. would provide a reliable basis for drawing conclusions about the relative potential of different active ingredients to leach into ground water or run off into surface water in different parts of the country.

In light of these considerations, EPA proposes to review the multiple databases to identify those active ingredients which appear relatively more frequently and/or in more geographical areas than other pesticides. Because the scope of monitoring varies from pesticide to pesticide, EPA would use a weight-of-the-evidence approach to assess the frequency and geographic distribution of pesticide residues in water.

EPA's reliance on these databases would necessarily have some limitations. For example, most monitoring looks only for the "parent" compound, i.e., the pesticide active ingredient, rather than for environmental degradation products or compounds formed by chemical reactions during the treatment of raw water sources in a drinking water facility. Further, like food residue monitoring programs, monitoring efforts rely on multi-residue methods that may not detect certain compounds or classes or compounds. Notwithstanding these limitations, EPA believes that the approach described is a practicable approach for identifying pesticide active ingredients generally expected to be among those having either widespread or high levels of human exposure.

*C. The Residential Use Pathway*

Human exposure to pesticides may occur as the result of use of pesticidal products in and around homes, schools, businesses, public areas, golf courses, and similar sites. Such use patterns, collectively referred to as "residential use," include: Lawn and garden treatments, insect repellants, termite, and other indoor insect control, fumigation products, products applied to pets for flea or tick control, household sanitizers and disinfectants, and many more.

EPA proposes to use pesticide product labeling information as the primary indicator of pesticides whose use involves potential human exposure by this pathway. EPA would review its databases and identify those active ingredients approved for residential use. Aside from products approved only for limited exposure uses, such as rodenticides applied in tamper resistant bait boxes, all currently registered residential use pesticides would be identified as having higher priority with respect to the residential use pathway.

The Agency recognizes that registration of a pesticide for residential use does not necessarily mean that it would be widely used or that its use would entail significant levels of human exposure. EPA, however, generally lacks information to compare the extent of application of different active ingredients for residential uses. Moreover, EPA does not have a basis for distinguishing among various residential use patterns on the basis of which consistently have potential for higher levels of human exposure. Thus, EPA does not regard its proposed basis for selecting priority chemicals for this pathway as being as effective in setting priorities among active ingredients as the criteria proposed for the other pathways. Nonetheless, residential use pesticides involve potential exposures to the general population, the Agency believes it would be appropriate to consider giving priority to some of these products.

*D. Occupational Exposure Pathways*

Occupational exposure can occur either as a person mixes, loads, or applies a pesticide product (i.e., during pesticide use), or as a person, during some other occupational activity, comes in direct, repeated contact with pesticide residues present on previously treated surfaces (i.e., post-application exposure). Although numerically smaller than the populations exposed to pesticides through food, drinking water, and residential use, individuals receiving occupational exposures generally experience significantly higher levels of exposure than the larger groups encounter by the other pathways. Based on available data and current agricultural practices, the number of workers exposed through post-application is greater than the number of workers exposed through mixing, loading, and applying pesticides. As a result, EPA proposes to focus on post-application exposures.

Many factors affect the post-application exposure of agricultural workers, most notably the type of work activity and the level of residue present on pesticide-treated surfaces. As will be discussed in more detail in Unit V.D., different activities involve differing levels of contact with pesticide-treated surfaces and therefore can lead to different levels of exposure. Exposure levels also depend on the amount of residue available on a treated surface. This, in turn, depends on the amount of pesticide initially applied, how quickly the material degrades or is taken up by the plant, and how soon after application the worker contacts the treated surface. Pesticides show a large range of variation in application rates, application timing, and environmental fate characteristics with the result that there are significant differences in the levels of dislodgeable residues on treated surfaces encountered by workers.

In identifying active ingredients for priority consideration by this pathway, EPA proposes to rank pesticides on the basis of their potential for post-application exposure of agricultural workers. This group includes farmers and farmworkers who reenter pesticide-treated fields and orchards to care for or harvest the crop. A relatively recent database developed by the Agricultural Reentry Task Force (ARTF) clearly indicates that certain work activities in particular crops lead to higher levels of exposure than other post-application work activities (Ref. 9). For example, harvesting fruit in orchards or pruning vines in a grape vineyard requires extensive contact with plant foliage that is likely to contain pesticide residues. When the worker touches the foliage, a certain amount of the residue transfers to the worker's skin or clothing. The greater the contact is, the higher the residue transferred and the higher the ensuing exposure.

EPA will review the ARTF's transfer coefficient studies to identify those work activities and crops which have the highest potential for post-application exposure. The ARTF is a consortium of pesticide companies that formed a joint venture to develop data for use in EPA assessments of worker risk. The ARTF conducted a series of carefully controlled studies that measured the amount of pesticide residue present on workers' clothing after a specific period of time working in a crop with known amounts of pesticide residue on the crop foliage. The ARTF set of data is very extensive, covering over 100 different crops —essentially all crops, including greenhouses and ornamental crops, in which workers might come into contact with pesticide-treated leaf surfaces. The studies permit the calculation of a standardized "transfer coefficient" for the crop and activity.[2] Activities having

[2] The transfer coefficient is calculated by dividing the amount of residue found on workers, expressed as milligrams (mg), by the amount of dislodgeable residue found on the crop foliage, expressed as mg per square centimeter (cm2), and dividing this value by the length of time spent in the activity, expressed in hours (hr). The resulting coefficient for

higher transfer coefficients should result in higher levels of worker exposure, all other factors being equal.

EPA proposes to identify the crops having approximately the dozen highest transfer coefficients and then to identify the pesticides having the highest levels of use on those crops. Specifically, EPA would estimate the total number of acre treatments for each pesticide on all of the top crops and then rank the pesticides on the basis of the highest totals.[3] The Agency would obtain information about the number of acre-treatments for each pesticide from a variety of public and private data sources including USDA's National Agriculture Statistics Service, California's Department of Pesticide Regulation, and Doane Marketing Research.

The USDA's National Agricultural Statistics Service (NASS) has, for more than 10 years, conducted annual surveys of pesticide use in a large number of crops, surveying thousands of agricultural producers in any given year. NASS conducts their use survey every year for a set of row crops. NASS also surveys pesticide usage on other crops, alternating every year between a group of fruit and nut crops and a group of vegetable crops (i.e., selected fruits/nuts were surveyed in 1997, 1999, 2001; selected vegetables were surveyed in 1996, 1998, and 2000). NASS surveys states representing a majority of national production for a crop and reports a number of statistics for insecticide, fungicide, and herbicide use including: percent crop treated, application rate, numbers of applications, acreage grown. Using these data, EPA can estimate the total acre-treatments for the pesticides used on crops with the highest transfer coefficients. More information on NASS pesticide use data can be found at: *http://www.pestmanagement.info/nass/.*

The State of California has reported annually on all agricultural pesticide usage in the State for almost 10 years. This data collection effort is managed by the California Department of Pesticide Regulation (CDPR), and includes an extensive array of treatment information on crops including timing, location, area, and rate. These data allow EPA to calculate acre-treatments for pesticides on crops grown in California. In cases where crops with high transfer coefficients are grown in California, but not reported by NASS, CDPR data would be extremely useful. For those crops reported by both CDPR and NASS, data from both sources would serve to validate estimates. More information on CDPR pesticide usage data can be found at:*http://www.cdpr.ca.gov/docs/pur/purmain.htm.*

EPA's third major source of pesticide use information is AgroTrak™, a product of Doane Marketing Research, Inc. (referred to here simply as Doane). Doane maintains a proprietary national database of agricultural pesticide use summarizing data from surveys of thousands of agricultural producers across a wide range of row and specialty crops. Doane has conducted an annual survey for more than 15 years, and among the statistics they publish for a given crop/chemical combination are acres grown, acres treated, and acre-treatments. These data represent an important source of data, and can be compared to NASS and CDPR data to fill data gaps, or serve as another point of validation. Doane's survey can be particularly useful because their national survey covers fruits and vegetables producers every year. More information on Doane Marketing Research can be found at: *http://www.doanemr.com/.*

Basing its priorities for this pathway on the number of acre-treatments of crops with worker activities having high transfer coefficients should identify pesticides that have potential for relatively higher worker exposure. The combined criteria of crops with high transfer coefficients and pesticides used on such crops should identify those active ingredients with potential for high worker exposures. The use of the additional criterion of total acre-treatments should identify pesticides with the widest use, and thus the potential for exposures for the largest number of workers.

The proposed criteria, however, would not account for any of the characteristics specific to the use of a particular pesticide on a crop that could decrease or increase the potential for exposure—application rate, application timing, and environmental fate characteristics. Consequently, the priority listing may not completely reflect where the highest post-application exposures exist.

Nevertheless, EPA believes that the approach described is a practicable approach for identifying those pesticide active ingredients with the potential for either widespread or high levels of exposure to post-application workers.

*E. Integration of Pathway Priorities for Pesticide Active Ingredients*

This unit addresses how EPA would integrate the information developed on priorities through the analysis of the four exposure pathways discussed in Units V.A. through V.D. As its first step, the Agency would apply the criteria proposed for each pathway to produce four lists of candidate chemicals for potential screening in the endocrine disruptor Tier 1 battery. EPA expects that a number of pesticide active ingredients would be identified for more than one pathway, and that some chemicals will appear only on the list for a single pathway. In choosing which active ingredients it would recommend for screening, EPA would give higher priority to chemicals that appeared on multiple lists, with the substances appearing on four lists receiving the highest priority, followed by the group of chemicals appearing on three lists, followed by chemicals on only two lists. To the extent necessary to establish priorities within these four groups, EPA would propose to give greater priority to chemicals which appear on the list for the food pathway (which generally involves the most widespread exposure of the four pathways), followed by the list for the occupational pathway (which generally involves the highest per capita levels of exposure of the different pathways). As a final step, EPA would review the available effects information to identify any chemical for which the information clearly indicates an endocrine-mediated effect/perturbation. Such chemicals would be considered for proposed Tier 2 tests, mechanistic or special studies, or hazard assessment. During this step, EPA also would identify substances that EPA anticipates would have low potential to cause endocrine disruption. EPA would consider excluding substances in either category from the first group of chemicals to undergo Tier 1 testing.

## VI. Approach for Selecting Pesticide HPV/Pesticide Inert Chemicals

EPA is proposing to use several sets of criteria for identifying HPV/Inert chemicals that should be given priority for screening in the Tier 1 battery. In general, the Agency is proposing an approach for HPV/Inert chemicals that is similar to that proposed for pesticide active ingredients. EPA will focus on several indicators of the potential for human exposure including production volume, specific pathways of exposure, and presence in human tissues. While EPA's general focus is on HPV/Inert chemicals with relatively greater potential human exposure, this focus

each activity is expressed as $cm^2/hr$ and quantitatively reflects the extent to which the activity involves contact with pesticide-treated surfaces in a manner that dislodges the residues present on the surface.

[3] Acre-treatments are measured as the number of times an acre of crop may have been treated with a pesticide. For example, if two acres were each treated one time in a season, that would represent two acre-treatments. If a single acre were treated two times in a season, that would also represent two acre-treatments.

13

does not necessarily mean that the list of chemicals produced will contain no substances which have potentially high levels of environmental exposure to ecological receptors. Many of the HPV/Inert chemicals having greater potential for human exposure will also have greater potential for exposure to wildlife. For example, the databases to be reviewed for ecological biological monitoring data will directly identify certain chemicals to which aquatic organisms have been exposed (see Unit VI.B.). Similarly, several of the monitoring databases that will be reviewed for the drinking water pathway contain monitoring data collected on raw surface water, i.e., before the water enters a Community Water System (see Unit VI.C.). Thus, these surface water monitoring data will show the levels of chemical to which fish, amphibians, and other aquatic species are exposed. Accordingly, EPA believes that the approach proposed to evaluate pesticide HPV/Inert chemicals, while focused on human exposure, will also capture HPV/Inert chemicals with widespread environmental exposures.

EPA generally has more extensive information of known quality available to assess potential exposure to pesticide active ingredients via food, water, occupational and residential exposure pathways than is available to assess exposure to HPV/Inert chemicals. In addition, EPA generally has more extensive information available on usage (including both agricultural and residential) of active ingredients than is available for HPV/Inert chemicals (including both pesticidal and non-pesticidal uses of inerts). For these reasons, the databases available to evaluate potential human exposure of the two classes also differ.

First, EPA will review existing databases to identify chemicals that are both pesticide inerts and HPV chemicals (HPV/Inert). HPV chemicals are those chemicals manufactured or imported into the United States in amounts equal to or greater than one million pounds per year. The HPV chemicals are identified through information collected under the TSCA Inventory Update Rule (IUR). Organic chemicals that are manufactured or imported into the United States in amounts equal to or greater than 10,000 pounds per year are subject to reporting under TSCA IUR every 4 years. Second, EPA will review existing data bases to identify HPV/Inert chemicals that are present in human tissue, or ecological tissues that have human food uses, or drinking water or indoor air. Third, EPA will prioritize these chemicals based on the number of data bases in which that the chemical was found. Thus, HPV/Inert chemicals appearing in four types of monitoring data would be given higher priority than those appearing in only one type of monitoring data. EPA may also give higher priority to those HPV/Inert chemicals that appear in human tissues than to those chemicals that only appear in water, air, or ecological tissues.

As a final step, EPA would review the available effects information to identify any chemical for which the information clearly indicates an endocrine-mediated effect/perturbation. Such chemicals would be considered for proposed Tier 2 tests, mechanistic or special studies, or hazard assessment. During this step, EPA also would identify substances that EPA anticipates would have low potential to cause endocrine disruption (e.g., certain FIFRA List 4 inerts, most polymers with number average molecular weight greater than 1,000 daltons, strong mineral acids, and strong mineral bases). EPA would consider excluding substances in either category from the first group of chemicals to undergo Tier 1 testing.

*A. HPV/Inert Chemicals in Human Biological Monitoring Data*

EPA proposes to review the following data sources to determine which HPV/Inert chemicals have been detected in human biological samples.

1. *Third National Health and Nutrition Examination Survey (NHANES III).* The Third National Health and Nutrition Examination Survey (NHANES III) was conducted between 1988 and 1994 on 33,994 people. The survey was designed to obtain nationally representative information on the health and nutritional status of the U.S. population through interviews and direct physical examinations. Several studies (e.g., high blood pressure, immunization status, nutritional blood measures, etc.) were conducted under NHANES III. One study relevant to this priority setting exercise is Ashley et al (1994) (Ref. 10). This NHANES volatile organic compound (VOC) article contains relevant human biomonitoring data for over 40 chemicals. Standard quality assurance/quality control (QA/QC) procedures such as sample duplicates and blanks were used in the NHANES III study. The study participants in the special study are not statistically representative of the U.S. population.

2. *National Report on Human Exposure to Environmental Chemicals.* The National Report on Human Exposure (Ref. 11) is a Centers for Disease Control and Prevention (CDC) report that provides exposure information about people participating in an ongoing national survey of the general U.S. population—the NHANES. This report provides information on concentrations of 27 environmental chemicals measured in blood and/or urine in the U.S. population. These chemicals include metals; organophosphate pesticide metabolites; phthalate metabolites and cotinine, a marker of exposure to tobacco smoke. This report will be updated with additional biomonitoring data for these same or different chemicals on an annual basis. It is anticipated that a second report will be issued in late 2002 with human biomonitoring information on an additional 75 chemicals.

3. *National Human Adipose Tissue Survey (NHATS).* The EPA's OPPT operated the National Human Monitoring Program (NHMP) until the early 1990s. The NHMP's primary activity was conducting NHATS, which analyzed human adipose tissue specimens to monitor human exposure to potentially toxic chemicals. A nationwide network of pathologists and medical examiners from 47 standard metropolitan statistical areas (SMSAs) collected tissue specimens from cadavers and surgical patients that were then analyzed for certain chemicals. Throughout the 1970s and early 1980s, the chemical residues of primary interest were organochlorine pesticides and polychlorinated biphenyls (PCBs). In 1982, VOCs and semivolatile organic compounds (SVOCs) were included in the survey. NHATS contains relevant human biomonitoring data for over 150 chemicals. Quality control samples, such as method and equipment blank samples, control samples, and spike samples, were collected to evaluate the quality of sampling data. Data are available for years 1970 through 1987; however, a standard set of summarized data parameters are not available. (Refs. 12–25).

4. *Total Exposure Assessment Methodology Study (TEAM Study).* The TEAM Study was designed to develop methods to measure individual total exposure (exposure through air, food, and water) and resulting body burden of toxic and carcinogenic chemicals, and to apply these methods within a probability-based sampling framework to estimate the exposures and body burdens of urban populations in several U.S. cities. The TEAM Study reports the results of eight monitoring studies performed in five communities during different seasons of the year. Breath, personal air, outdoor air, and water samples were collected for 30 VOCs. (Refs. 26–28).

Established methods were used to collect and analyze TEAM Study data.

Quality control and quality assurance samples collected and analyzed include reagent blanks, field blanks, duplicate samples, and spiked samples. Data were reported for water using units of measure different than those used for air and breath samples. Environmental and biological data are generally lognormally distributed; thus, the data's central tendency is generally best represented using a geometric mean. Geometric means are provided for all compounds that were measured in 50% or more of the samples. For most of the compounds that were measured in less than 50% of the samples, a minimum quantifiable limit that can be used for ranking the data was provided.

*B. HPV/Inert Chemicals in Ecological Biological Monitoring Data Relevant to Human Exposure*

EPA proposes to review the following data sources to determine which HPV/Inert chemicals have been detected in non-human tissues potentially relevant to human ingestion exposure.

1. *National Sediment Inventory Fish Tissue Data (NSI Fish Tissue Data).* This database is described in Unit V.B.

2. *National Fish Tissue Study.* EPA is conducting a screening-level study to estimate the national distribution of selected persistent, bioaccumulative and toxic chemical residues in fish tissue from lakes and reservoirs of the continental United States. This 4-year study will define the national background levels for 265 chemicals in fish, establish a baseline to track the progress of pollution control activities, and identify areas where contaminant levels are high enough to warrant further investigation. The national fish tissue survey is the first survey of fish tissue to be based on a random sampling design. This sampling design will allow EPA to develop national estimates of the mean levels of persistent, bioaccumulative, and toxic chemicals in fish tissue. It will also provide data on the largest set of persistent, bioaccumulative, and toxic chemicals ever studied in fish. More details can be found at: *http://www.epa.gov/waterscience/fishstudy/results.htm.*

*C. HPV/Inert Chemicals in Drinking Water Monitoring Data*

EPA proposes to review the following data sources to determine which HPV/Inert chemicals have been detected in drinking water and in potential sources of drinking water.

1. *National Drinking Water Chemical Occurrence Data Base (NCOD Data Base).* This database is described in Unit V.B.

2. *National Human Exposure Assessment Survey (NHEXAS).* EPA designed the NHEXAS program to address some of the limitations of single-chemical and single-media exposure route studies. The purpose of NHEXAS is to evaluate comprehensive human exposure to multiple chemicals from multiple routes on both a community and regional scale, as well as its association with environmental concentrations and personal activities. EPA completed Phase 1 field sample collection and laboratory analyses of NHEXAS in 1998. EPA used established methods to collect and analyze NHEXAS data. Quality control and quality assurance samples collected and analyzed include reagent blanks, field blanks, duplicate samples, and spiked samples. Samples were split and analyzed in multiple laboratories; when appropriate audit samples were available, they were also analyzed. Data are reported for different media using different units of measure and different measures of central tendency. For example, arsenic concentrations are reported in micrograms per kilogram (µg/Kg) for beverages and food and in micrograms per liter (µg/L) for water. Sometimes the central tendency value is reported as an arithmetic mean, sometimes as a median, and sometimes as a 90th percentile. (Refs. 29–32).

3. *Total Exposure Assessment Methodology Water Data (TEAM Water Data).* The TEAM Study is described in Unit VI.A.

4. *National Stream Quality Accounting Network (NASQAN) Data.* This database, which contains information on surface water monitoring studies, is described in Unit V.B.

5. *The National Water Quality Assessment Program (NAWQA).* This database, which contains information on surface water and ground water monitoring studies, is described in Unit V.B.

*D. HPV/Inert Chemicals in Indoor Air Monitoring Data*

EPA proposes to review the following data sources to determine which HPV/Inert chemicals have been detected in residential indoor air.

1. *Office of Research and Development Published Literature.* The following eight EPA/ORD-authored journal articles and reports provide indoor air monitoring data: Brown et al. (1994), Daisey et al. (1994), Kelly et al. (1994), Immerman and Schaum. (1990), Samfield (1992), Shah et al. (1988), Sheldon et al. (1992), and Shields et al. (1996). (Refs. 33–40).

2. *NHEXAS.* The NHEXAS program was designed to evaluate comprehensive human exposure via indoor and outdoor air to multiple chemicals on a community and regional scale. Samples were collected of both the indoor and outdoor air that people breathe. Preliminary results of Phase I of NHEXAS were reported in 15 journal articles published in 1999. Four of these 15 journal articles provided information that is applicable to indoor air monitoring. (Refs. 30–32, 41).

3. *Total Exposure Assessment Methodology (TEAM).* The TEAM Study is described in Unit VI.A.

*E. Integration of Pathway Priorities for HPV/Inert Chemicals*

This unit addresses how EPA would integrate the information developed on priorities through the analysis of the four types of exposure monitoring data discussed in Units VI.A through VI.D (human biological data, ecological biological data relevant to human exposure, drinking water data, and indoor air data). As its first step, the Agency would produce four lists of candidate chemicals, one for each type of monitoring data, for potential screening in the endocrine disruptor Tier 1 battery. EPA expects that a number of chemicals will be identified in more than one type of monitoring data and that some chemicals will appear only in a single type of monitoring data. In choosing which HPV/Inert chemicals it would recommend for screening, EPA would give higher priority to chemicals that appeared in multiple types of monitoring data, with the HPV/Inerts appearing in four types receiving the highest priority, three types the next highest priority, etc. To the extent it becomes necessary to establish priorities within these four types of monitoring data, EPA would propose to give greater priority to HPV/Inerts which appear in human biological monitoring data followed by drinking water/indoor air monitoring data (weighted equally), followed by ecological biological monitoring data relevant to human exposure. As a final step, EPA would review the available effects information to identify any chemical for which the information clearly indicates an endocrine-mediated effect/perturbation. Such chemicals would be considered for proposed Tier 2 tests, mechanistic or special studies, or hazard assessment. During this step, EPA also would identify substances that EPA anticipates would have low potential to cause endocrine disruption (e.g., certain FIFRA List 4 inerts, most polymers with number average molecular weight greater than 1,000 daltons, strong mineral acids, and strong mineral

bases). EPA would consider excluding substances in either category from the first group of chemicals to undergo Tier 1 testing.

## VII. Issues for Comment

In developing this proposed approach for selecting the first group of chemicals to be screened in the Agency's EDSP, EPA discussed a number of alternative approaches and identified a series of questions to elicit information from the public that would help in the evaluation of alternative approaches. In addition to the specific questions in this unit, EPA invites comment on additional alternative approaches.

### *A. Overall Approach for Selecting the Initial Set of Chemicals to Undergo Tier 1 Screening*

1. *Focusing on the subset of chemicals subject to a statutory mandate for screening.* EPA is intending to focus only on pesticide active ingredients and HPV chemicals with some pesticidal inert uses (i.e., the chemicals that are specifically mandated for testing under section 408(p) of FFDCA) as candidates for the first group of chemicals to be screened. The pesticide inerts to be considered are those with relatively large overall production volumes considering both pesticide and non-pesticide uses. This approach will allow EPA to focus its initial endocrine screening efforts on a smaller and more manageable universe of chemicals that emphasizes early attention to the pesticide chemicals that Congress specifically mandated EPA to test for possible endocrine effects. Please comment on this proposed decision.

2. *Limited use of effects information.* Because the amount and type of toxicological data available to identify or characterize endocrine-related human health or ecological effects is not considered by the Agency to be adequate to support determinations of the endocrine disruption potential of most pesticide chemicals, EPA has proposed an approach that would use effects information only to exclude certain chemicals from the first group of chemicals to undergo Tier 1 screening. The approach would exclude from the first group of chemicals to undergo Tier 1 screening any chemical for which the available effects information is determined by EPA to clearly shows an endocrine-mediated effect. Such chemicals would be considered for proposed Tier 2 tests, mechanistic or special studies, or hazard assessment. Similarly, the approach for this initial list also would exclude substances that EPA anticipates have low potential to cause endocrine disruption (e.g., certain FIFRA List 4 inerts, most polymers with number average molecular weight greater than 1,000 daltons, strong mineral acids, and strong mineral bases). Please comment on this proposed decision and comment on the types of studies/data which could be evaluated by the Agency to aid in making exclusion decisions.

3. *Focus on human exposure; no separate criteria pertaining to exposure of ecological receptors.* While EPA's general focus in this approach is on pesticide active ingredients and HPV/Inerts with relatively greater potential for human exposure, this focus does not necessarily mean that the list developed using this approach will not contain substances which have potentially high levels of environmental exposure to ecological receptors. EPA believes that the proposed approach, while focused on human exposure, will also identify many chemicals with widespread environmental exposures to other organisms. If EPA should consider such exposures separately, please identify databases and criteria appropriate for setting priorities.

4. *Deferring consideration of nominations from the public.* For the initial Tier 1 screening list, EPA proposes to focus on pesticide active ingredients and HPV chemicals with some pesticidal inert uses. EPA believes that nominations from the public are important because they provide a mechanism to identify chemicals which may result in high exposures in local communities but which would not otherwise receive national attention. However, EPA has decided to defer consideration of nominations from the public until subsequent testing lists are proposed by EPA to keep this initial effort administratively simpler and ensure that a set of test results can be obtained in a relatively prompt timeline to aid the Agency in a mid-course evaluation of the EDSP Tier 1 screening battery. Please comment on this proposed decision.

5. *Defer testing of mixtures.* EPA believes that experience with the Tier 1 tests on a variety of single chemicals needs to be attained before the tests are used with mixtures. Therefore, EPA is proposing to defer consideration of testing of mixtures until subsequent testing lists are proposed by EPA. This judgement is consistent with advice from the SAB/SAP Subcommittee. Please comment on this proposed decision.

6. *Excluding chemicals that are no longer produced or used in the United States.* EPA also is proposing to exclude from the initial Tier 1 screening list any chemicals that are no longer produced or used in the United States. The Agency thinks that the added administrative complexity of determining who should be responsible for testing such chemicals could unnecessarily delay EPA's selection of an initial list for Tier 1 screening. Please comment on this proposed decision.

7. *Number of chemicals to be selected for the initial testing list.* The SAB/SAP Joint Subcommittee which reviewed EPA's proposed EDSP in 1999 felt that developing massive amounts of screening data on a large universe of chemicals would not necessarily expedite the development of the appropriate underpinning that the Agency needs to broaden this effort. The Subcommittee also expressed concern that it did not see a provision that would allow for mid-course correction or optimization of the Program. Thus, the Subcommittee recommended that EPA should initiate the Tier 1 testing program with a set of 50 to 100 chemicals and then convene an external panel of independent scientists to review the screening data for the purpose of evaluating whether the Tier 1 screening program could be improved or optimized, and if so, how. EPA is proposing to adopt this SAB/SAP recommendation. Please comment on this proposed decision.

8. *Integration of lists generated by the pesticide active ingredient approach and the pesticide inert approach.* As discussed in Unit IV, EPA is proposing to use similar but somewhat different sets of criteria for identifying pesticide active ingredients and inerts that should be given priority for screening in the Tier 1 battery. EPA generally has more extensive information of known quality available to assess usage and potential exposure to pesticide active ingredients than is available to assess exposure to HPV/Inert chemicals. Thus, the databases available to evaluate potential human exposure of the two classes also differ. EPA has not yet decided on the method to use to select the initial list of chemicals for screening from the separate lists that will be generated by the proposed approaches for pesticide active ingredients and HPV/Inert chemicals. Several alternative methods are being considered including the following. After looking at the separate lists, once they are generated, there may be natural break points. For example, if the top category for pesticide active ingredients (i.e., those chemicals which appear on lists for each of the four pathways) yields 60 actives and the top category for HPV/Inert chemicals (i.e., those chemicals which appear on lists for each of the three pathways and in human biomonitoring samples) yields

30, the Agency may select these 90 chemicals. Another approach being considered is a simple ratio approach. Because there are approximately an equal number of pesticide actives as HPV/Inerts, one way to produce a combined list would be to select approximately 50% of the chemicals from the active list and 50% from the HPV/Inert chemicals list. Please comment on these and other approaches that EPA could use to integrate the lists.

*B. Approach for Selecting Pesticide Active Ingredients*

1. The Agency considered approaches that did not focus on the four separate pathways of human exposure. Please comment on the following issues.

i. The advantages and disadvantages of setting priorities based on the overall extent of pesticide use, for example total pounds applied or total acres treated.

ii. Should all four pathways be considered? If not, please comment on which pathways should and should not be included.

2. Within separate pathways, EPA considered a variety of alternative approaches. Please comment on the following issues.

i. Food pathway. Would ranking pesticides by the extent of use on the top 20 crops be appropriate, given that it would be simpler and more quantitative than the approach proposed in this Notice?

ii. Water pathway. With regards to the proposed databases, should other databases be included, and should any be dropped?

iii. Residential use pathway. Should any additional criteria be used to set priorities within the universe of active ingredients with residential uses? For example, should EPA give higher or lower priority to particular use patterns because they are consistently likely to lead to greater or lesser levels of human exposure? Are there databases that could provide information on the extent of residential use of pesticides that would support setting priorities within this group?

iv. Occupational pathway. Are there criteria that would recognize how the differences in rate and timing of application of a pesticide or its environmental fate properties might affect levels of post-application exposure? Also, please comment on whether EPA should employ criteria to set priorities for active ingredients based on their levels of exposure for mixers, loaders, and applicators. If EPA should consider such exposure in setting priorities for the occupational pathway, please identify databases and criteria appropriate for setting priorities. Also, please comment on whether EPA should consider criteria for the occupational pathway that employs data from reports on the incidence of adverse effects among workers, such as data collected by the California's Pesticide Illness Surveillance Program (PISP) (see, for example, the PISP report for 2000, *http://www.cdpr.ca.gov/docs/dprdocs/pisp/2000pisp.htm*) or the National Institute of Occupational Safety and Health's Sentinel Event Notification System for Occupational Risk (see *http://www.cdc.gov/niosh/pestsurv/default.html*).

3. EPA's proposed approach to setting its overall priority for pesticide active ingredients that combines the analysis for each of the four pathways generally gives each pathway equal weight. Alternative approaches are also possible. Please comment on the following issues.

i. Should a different approach be used to integrate the information from the four different pathways, for example by assigning different weights to the pathways?

ii. Should there be any limit on the number of active ingredients included on the list for a single pathway?

iii. Should any factors other than the pathway lists and the hazard-based considerations be included in the integrative step?

iv. Should EPA attempt to explicitly consider magnitude of the environmental concentrations of chemicals in this approach and, if so, how?

*C. Approach for Selecting Pesticide HPVolume/Pesticide Inert Chemicals*

1. EPA's proposed approach for setting screening priorities for pesticide inert ingredients that are also HPV chemicals uses four types of monitoring data. These are human biomonitoring data, ecological biomonitoring data relevant to human exposure, water monitoring data and indoor air monitoring data. Please comment on the following issues.

i. Should the selection of priority HPV/Inert chemicals be based upon all four types of monitoring data? If not, please comment on which type of monitoring data should and should not be included.

ii. Should other types of exposure information be used instead of or in addition to monitoring data?

2. Within the four separate types of monitoring data, EPA identified and selected sources of monitoring data for use in priority setting for HPV/Inert chemicals. Please comment on the following issues.

i. The appropriateness of the data sources identified in this proposed approach.

ii. For human biological monitoring data, are there additional sources of data that EPA should consider?

iii. For ecological biological monitoring data relevant to human exposure, are there additional sources of data that EPA should consider?

iv. For water monitoring data, are there additional sources of data that EPA should consider?

v. For indoor air monitoring data, are there additional sources of data that EPA should consider?

3. EPA's proposed approach to setting its priorities for HPV/Inert chemicals combines the analysis for each of the four types of monitoring data and generally gives each type of monitoring data equal weight. However, if necessary to establish priorities within these four types of monitoring data, higher weight would be assigned to human biomonitoring data than to the other three types of monitoring data. Alternative approaches are also possible. Please comment on the following issues.

i. Should a different approach be used to integrate the information from the four different types of monitoring data, for example by assigning different weights initially to all types of monitoring data?

ii. Should there be any limit on the number of HPV/Inert chemicals included on the list for a single type of monitoring data?

iii. Should any factors other than the lists of HPV/Inert chemicals found in the four types of monitoring data and the hazard-based considerations be included in the integrative step?

## VIII. References

The Agency's actions are supported by the references listed in this unit and cited in this notice. These references are available in the public record for this notice under docket ID number OPPT–2002–0066. (See Unit I.B. for information on how to access this docket).

1. EPA, Science Advisory Board. Review of EPA's Proposed Environmental Endocrine Disruptor Screening Program. July 1999. EPA-SAB-EC-99-013. Available at: *http://www.epa.gov/science1/pdf/ec13.pdf.*

2. EPA. Endocrine Disruptor Screening and Testing Advisory Committee Final Report. August 1998. Available at: *http://www.epa.gov/scipoly/oscpendo/history/finalrpt.htm.*

3. EPA. Evaluation of SAR Predictions of Estrogen Receptor Binding Affinity. EPA Contract No. 68-W-01-023, Work

Assignment No. 2–3, Battelle Memorial Institute. August 1, 2002.

4. EPA. EPA Pesticides in Ground Water Database, A Compilation of Monitoring Studies: 1971–1991 National Summary, EPA 734-12-92-001. September 1992.

5. USGS. Pesticides in Select Water Supply Reservoirs and Finished Drinking Water, 1999–2000: Summary of Results from a Pilot Monitoring Program. 2001. USGS Open File Report 01–456.

6. EPA. The Incorporation of Water Treatment Effects on Pesticide Removal and Transformation in Food Quality Protection Act Drinking Water Assessments. November 21, 2001. Available at: *http://www.epa.gov/pesticides/trac/science/#drinking.*

7. EPA. Estimating the Drinking Water Component of a Dietary Exposure Assessment. Revised November 2, 1999. Available at: *http://www.epa.gov/pesticides/trac/science/#drinking.*

8. EPA. EPA Background Paper for the FIFRA Scientific Advisory Panel Meeting on Monitoring Strategies for Pesticides in Surface-Derived Drinking Water. June 2002. Available at: *http://www.epa.gov/scipoly/sap/2000/june/drinkingwatersurvey.pdf.*

9. EPA. Science Advisory Council on Exposure, Policy Number 003.1, Agricultural Transfer Coefficients.

10. Ashley, David L.; Bonin, Michael A.; Cardinall, Frederick L.; McCraw, Joan M.; and Wootan, Joe V. Blood Concentrations of Volatile Organic Compounds (VOCs) in a Nonoccupationally Exposed U.S. Population and in Groups with Suspected Exposure. *Clinical Chemistry* (1994) 40: 1401–1404.

11. CDC. National Report on Human Exposure to Environmental Chemicals. March 2001. *http://www.cdc.gov/nceh/dls/report/reportsummary.htm.*

12. EPA. Chlorinated Dioxins and Furans in the General U.S. Population: NHATS FY87 Results—Executive Summary. EPA-560/5-91-003. May 1991.

13. Cramer, Paul H.; Stanley, John S.; Bauer, Karin; Ayling, Randy E.; Thornburg, Kelly R.; and Schwemberger, John. Brominated Dioxins and Furans in Human Adipose Tissue: Final Report. EPA-560/5-90-005 (NTIS PB91–103507). April 11, 1990.

14. Cramer, Paul H.; Stanley, John S.; and Thornburg, Kelly R. Mass Spectral Confirmation of Chlorinated and Brominated Diphenylethers in Human Adipose Tissues: Final Report. EPA-560/5-90-012 (NTIS PB91–159699). June 15, 1990.

15. Mack, Gregory A. and Mohadjer, Leyla. Baseline Estimates and Time Trends for Beta-benzene hexachloride, Hexachlorobenzene, and Polychlorinated Biphenyls in Human Adipose Tissue 1970–1983. EPA-560/5-85-025. September 30, 1985.

16. Onstot, J.D.; Ayling, R.E.; and Stanley, J.S. Characterization of HRGC/MS Unidentified Peaks from the Analysis of Human Adipose Tissue: Volume I—Technical Approach. EPA-560/5-87-002A (NTIS PB88–100367). May 1987.

17. Onstot, J.D.; Ayling, R.E.; and Stanley, J.S. Characterization of HRGC/MS Unidentified Peaks from the Analysis of Human Adipose Tissue: Volume II —Appendices. EPA-560/5-87-002B (NTIS PB88–100375). May 1987.

18. Onstot, J.D. and Stanley, J.S. Identification of SARA Compounds in Adipose Tissue. EPA-260/5-89-003 (NTIS PB90–132564). August 1989.

19. Orban, John E.; Stanley, John S.; Schwemberger, John G.; and Remmers, Janet C. Dioxins and Dibenzofurans in Adipose Tissue of the General US Population and Selected Subpopulations. *American Journal of Public Health.* (1994) 84: 439–445.

20. EPA. Semivolatile Organic Compounds in the General U.S. Population: NHATS FY86 Results—Volume I. EPA-747-R-94-001. July 1994.

21. Stanley, John S. Broad Scan Analysis of the FY82 National Human Adipose Tissue Survey Specimens: Volume I—Executive Summary. EPA-560/5-86-035 (NTIS PB87–177218). December 1986.

22. Stanley, John S. Broad Scan Analysis of the FY82 National Human Adipose Tissue Survey Specimens: Volume II—Volatile Organic Compounds. EPA-560/5-86-036 (NTIS PB87–177226). December 1986.

23. Stanley, John S. Broad Scan Analysis of Human Adipose Tissue: Volume III—Semivolatile Organic Compounds: Final Report. EPA-560/5-86-037 (NTIS PB87–180519). December 1986.

24. Stanley, John S. Broad Scan Analysis of Human Adipose Tissue: Volume IV— Polychlorinated Dibenzo-p-Dioxins (PCDDs) and Polychlorinated Dibenzofurans (PCDFs): Final Report. EPA-560/5-86-038 (NTIS PB87–177234). December 1986.

25. Stanley, John S. and Stockton, Rodney A. Broad Scan Analysis of the FY82 National Human Adipose Tissue Survey Specimens: Volume V—Trace Elements. EPA-560/5-86-039 (NTIS PB87–180527). December 1986.

26. EPA. The Total Exposure Assessment Methodology (TEAM) Study: Elizabeth and Bayonne, New Jersey, Devils Lake, North Dakota, and Greensboro, North Carolina: Volume II. Part 2. EPA-600/6-87/002b (NTIS PB88–100078). June 1987.

27. EPA. The Total Exposure Assessment Methodology (TEAM) Study: Selected Communities in Northern and Southern California: Volume III. EPA-600/6-87/002c (NTIS PB88–00086). June 1987.

28. Wallace, Lance. Project Summary: The Total Exposure Assessment Methodology (TEAM) Study. EPA/600/S6-87/002. September 1987.

29. Thomas, Kent W.; Pelizzari, Edo D.; and Berry, Maurice R. Population-based dietary intakes and tap water concentrations for selected elements in EPA Region V National Human Exposure Assessment Survey (NHEXAS). *Journal of Exposure Analysis and Environmental Epidemiology.* (1999) 9: 402–413.

30. Clayton, C.A.; Pellizzari, E.D.; Whitmore, R.W.; Perritt, R.L.; and J.J. Quackenboss. National Human Exposure Assessment Survey (NHEXAS): distributions and associations of lead, arsenic and volatile organic compounds in EPA Region 5. *Journal of Exposure Analysis and Environmental Epidemiology.* (1999) 9: 381-392.

31. O'Rourke, Mary Kay; Van de Water, Peter K.; Jin, Shan; Rogan, Seumas P.; Weiss, Aaron D.; Gordon, Sydney M.; Moschandreas, Demetrios M.; and Lebowitz, Michael D. Evaluations of primary metals from NHEXAS Arizona: distributions and preliminary exposures. *Journal of Exposure Analysis and Environmental Epidemiology.* (1999) 9: 435–445.

32. Robertson, Gary L.; Lebowitz, Michael D.; O'Rourke, Mary Kay; Gordon, Sydney; and Moschandreas, Demetrios. The National Human Exposure Assessment Survey (NHEXAS) study in Arizona—introduction and preliminary results. *Journal of Exposure Analysis and Environmental Epidemiology.* (1999) 9: 427–434.

33. Brown, S.K.; Sim, M.R.; Abramson, M.J.; and Gray, C.N. Concentrations of Volatile Organic Compounds in Indoor Air—A Review. *Indoor Air.* (1994) 4: 123–124.

34. Daisey, J.M.; Hodgson, A.T.; Fisk, W.J.; Mendell, M.J.; and Brinke, J. Ten. Volatile Organic Compounds In Twelve California Office Buildings: Classes, Concentrations and Sources. *Atmospheric Environment.* (1994) 28: 3557–3562.

35. Kelly, Thomas J.; Mukund, R.; Spicer, Chester W.; and Pollack, Albert J. Concentrations and Transformations of Hazardous Air Pollutants. *Environmental Science and Technology.* (1994) 28: 378A–387A.

36. Immerman, Frederick W. and Schaum, John L. Final Report of the Nonoccupational Pesticide Exposure Study (NOPES). EPA/600/3-90/003 (NTIS PB90–152224). January 1990.
37. Samfield, Max M. Indoor Air Quality Data Base for Organic Compounds. EPA-600-R-92-025 (NTIS PB92–158468). February 1992.
38. Shah, Jitendra J. and Singh, Hanwant B. Distribution of Volatile Organic Chemicals in Outdoor and Indoor Air. A National VOCs Data Base. *Environmental Science and Technology.* (1988) 22: 1381–1388.
39. Sheldon, L.; Clayton, A.; Jones, B.; Keever, J.; Perritt, R.; Smith, D.; Whitaker, D.; and Whitmore, R. Indoor Pollutant Concentrations and Exposures: Final Report. California Air Resources Board, Contract A833–156. January 1992.
40. Shields, Helen C.; Fleischer, Daniel M.; and Weschler, Charles J. Comparisons among VOCs Measured in Three Types of U.S. Commercial Buildings with Different Occupant Densities. *Indoor Air.* (1996) 6: 2–17.
41. Gordon, Sydney M.; Callahan, Patrick J.; Nishioka, Marcia G.; Brinkman, Marielle C.; O'Rourke, Mary Kay; Lebowitz, Michael D.; and Moschandreas, Demetrios J. Residential Environmental Measurements in the National Human Exposure Assessment Survey (NHEXAS) Pilot Study in Arizona: Preliminary Results for Pesticides and VOCs. *Journal of Exposure Analysis and Environmental Epidemiology.* (1999) 9: 546–470.

## IX. Statutory and Executive Order Reviews

This notice is not subject to review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Nevertheless, OMB participated in an interagency review of this notice and any comments or suggestions received during that review, have been addressed.

Since this notice does not impose any requirements, and instead seeks comments and suggestions for the Agency to consider in developing its approach for selecting the first group of chemicals to be screened in the Agency's EDSP, the various other review requirements that apply when an agency imposes requirements do not apply to this notice. As a part of your comments on this document, however, you may include any comments or information that would facilitate the Agency's consideration of approaches for selecting the first group of chemicals to be screened in the Agency's EDSP, including but not limited to potential impacts on small entities covered by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the availability of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), and potential paperwork burden and costs, as well as any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, related to the collection of this information as described by the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). The Agency will consider such comments during the development of the approach and will take appropriate steps to address any applicable requirements.

### List of Subjects

Environmental protection, Chemicals, Endocrine disruptors, Pesticides and pests.

Dated: December 23, 2002.

**Stephen L. Johnson,**

*Assistant Administrator for Prevention, Pesticides and Toxic Substances.*

[FR Doc. 02–32853 Filed 12–24–02; 11:49 am]

BILLING CODE 6560–50–S

---

## ENVIRONMENTAL PROTECTION AGENCY

**FRL–7432–2]**

## State Program Requirements; Approval of Application by Arizona To Administer the National Pollutant Discharge Elimination System (NPDES) Program; Arizona

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** On December 5, 2002, the Regional Administrator for the Environmental Protection Agency, Region IX (EPA), approved the application by the State of Arizona to administer and enforce the Arizona Pollutant Discharge Elimination System (AZPDES) Program, for all areas within the State, other than Indian country. The authority to approve State programs is provided to EPA in section 402(b) of the Clean Water Act (CWA). The State will administer the approved program through the Arizona Department of Environmental Quality (ADEQ), subject to continuing EPA oversight and enforcement authority, in place of the National Pollutant Discharge Elimination System (NPDES) program previously administered by EPA in Arizona. The program is a partial program to the extent described in the section of this Notice entitled National Pollutant Discharge Elimination System (NPDES) program "Scope of the AZPDES Program." In making its decision, EPA considered and addressed all comments and issues raised during the public comment period.

**DATES:** Pursuant to 40 CFR 123.61(c), the AZPDES program was approved and became effective on December 5, 2002.

**FOR FURTHER INFORMATION CONTACT:** Matthew Mitchell, USEPA Region IX (WTR–5), 75 Hawthorne Street, San Francisco, CA, 94105, (415) 972–3508 or Chris Varga, Federal Permits Unit, Arizona Department of Environmental Quality, 1110 W. Washington St., Phoenix, AZ, 85007, (602) 771–4665. Part of the State's program submission and supporting documentation is available electronically at the following Internet address: *http://www.adeq.state.az.us/environ/water/permits/federal.html*

**SUPPLEMENTARY INFORMATION:** Arizona's application was described in the **Federal Register** (67 FR 49916) on August 1, 2002, in which EPA requested comments. Notice of Arizona's application was published in the Arizona Republic on August 13, 2002. A public hearing on the application was held on September 4, 2002, in Phoenix, AZ.

Section 402 (c)(1) of the CWA provides that ninety days after a State has submitted an application to administer the NPDES program, EPA's authority to issue such permits is suspended unless EPA disapproves or approves the State's application. 40 CFR 123.21(b)(1). This ninety day statutory review period ended on October 8, 2002. However, because of the many complex issues that were raised with respect to the State's program and the need to address them in a comprehensive manner, EPA was unable to make a final decision by October 8, 2002. Thus, EPA suspended issuance of NPDES permits in Arizona on October 8, 2002. However, failure to make a decision by the October 8, 2002 deadline did not mean that the State automatically gained NPDES authority. It is EPA's interpretation that a State agency does not gain NPDES authority unless and until EPA approves the State program, consistent with CWA section 402(b) and 40 CFR 123.1. As of December 5, 2002, the ADEQ is now authorized to issue AZPDES permits under the CWA in all areas within the State, except for in Indian country.