docket and is made available in EPA's E-Docket.

You may submit public comments on a disk or CD ROM mailed to the OEI Docket mailing address. Files will be accepted in WordPerfect, Word, or PDF file format. Avoid the use of special characters and any form of encryption.

If you provide public comments in writing, please submit one unbound original, with pages numbered consecutively, and three copies. For attachments, provide an index, number pages consecutively with the main text, and submit an unbound original and three copies.

Dated: September 21, 2005.

**Peter W. Preuss,**

*Director, National Center for Environmental Assessment.*

[FR Doc. 05–19253 Filed 9–26–05; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7975–5]**

## Proposed CERCLA Administrative Cost Recovery Settlement; Town of Tilton and Tilton/Northfield Fire Department, Old Pillsbury Mill Superfund Site, Tilton, NH

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

**ACTION:** Notice of proposed settlement; request for public comment.

**SUMMARY:** In accordance with section 122(i) of the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past costs concerning the Old Pillsbury Mill Superfund Site in Tilton, New Hampshire with the following settling parties: Town of Tilton and the Tilton/Northfield Fire Department. The settlement requires the settling parties to pay $378,706.00 to the Hazardous Substance Superfund. The settlement includes a covenant not to sue the settling parties pursuant to section 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a). For thirty (30) days following the date of publication of this notice, the Agency will receive written comments relating to the settlement. The Agency will consider all comments received and may modify or withdraw its consent to the settlement if comments received disclose facts or considerations which indicate that the settlement is inappropriate, improper, or inadequate.

The Agency's response to any comments received will be available for public inspection at One Congress Street, Boston, MA 02214–2023 (Telephone No. 617–918–1440).

**DATES:** Comments must be submitted on or before October 27, 2005.

**ADDRESSES:** Comments should be addressed to Audrey Zucker, Enforcement Counsel, U.S. Environmental Protection Agency, Region I, One Congress Street, Suite 1100 (SES), Boston, Massachusetts 02114–2023 (Telephone No. 617–918–1778) and should refer to: In re: Old Pillsbury Mill Superfund Site, U.S. EPA Docket No. 01–2005–0016.

**FOR FURTHER INFORMATION CONTACT:** A copy of the proposed settlement may be obtained from Audrey Zucker, U.S. Environmental Protection Agency, Region I, Office of Environmental Stewardship, One Congress Street, Suite 1100 (SES), Boston, MA 02114–2023 (Telephone No. 617–918–1778; E-mail *zucker.audrey@epa.gov).*

Dated: September 12, 2005.

**Susan Studlien,**

*Director, Office of Site Remediation & Restoration, Region 1.*

[FR Doc. 05–19262 Filed 9–26–05; 8:45 am]

**BILLING CODE 6560–50–P**

## ENVIRONMENTAL PROTECTION AGENCY

**[OPPT–2004–0109 FRL–7716–9]**

## Endocrine Disruptor Screening Program; Chemical Selection Approach for Initial Round of Screening

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

**ACTION:** Notice.

**SUMMARY:** This notice describes the approach EPA plans to use for selecting the first group of chemicals to be screened in the Agency's Endocrine Disruptor Screening Program (EDSP). The Food Quality Protection Act of 1996 (FQPA) amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to direct EPA to develop a chemical screening program using appropriate validated test systems and other scientifically relevant information to determine whether certain substances may have hormonal effects. In December 2002, EPA sought comment on its approach for selecting the initial list of chemicals for which testing will be required under the EDSP. Following review and revision based on the public comments, EPA is now describing the approach that it intends to use for selecting the chemicals for the initial list. For this initial approach, as recommended by scientific advisory committees, EPA will select 50 to 100 chemicals. The chemicals will be selected based on their relatively high potential for human exposure rather than using a combination of exposure- and effects-related factors. The scope of this first group of chemicals to be tested includes pesticide active ingredients and High Production Volume (HPV) chemicals used as pesticide inerts. This will allow EPA to focus its initial screening efforts on a smaller and more manageable universe of chemicals that emphasizes the early attention to the pesticide chemicals that Congress specifically mandated EPA to test for possible endocrine effects. This notice does not identify the initial list of chemicals, nor does it describe other aspects of the EDSP such as the administrative procedures EPA will use to require testing, the validated tests and battery that will be included in the EDSP, or the timeframe for requiring the testing or receiving the data. The initial chemical list and the details of the EDSP process that will apply to the initial chemical list will be addressed in subsequent notices published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** *For general information contact*: Colby Lintner, Regulatory Coordinator, 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*: Mary Belefski, Office of Science Coordination and Policy (7201M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8461; e-mail address: *belefski.mary@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

This action is directed to the public in general. This action may, however, be of interest if you produce, manufacture, use, consume, work with, or import pesticide chemicals, substances that may have an effect cumulative to an effect of a pesticide, or substances found in sources of drinking water. To determine whether you or your business may be affected by this action, you should carefully examine section 408(p) of FFDCA, 21 U.S.C. 346a(p), and the Safe Drinking Water Act (SDWA), 42

U.S.C. 300j–17. 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 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–2004–0109. The official public docket consists of the documents specifically referenced in this action, including EPA's response to comments received and other information related to this action. In addition, documents are also in docket ID number OPPT–2002–0066 for the proposed approach. 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 view public comments, to 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.

## II. Introduction

*A. What Action is the Agency Taking?*

Following review of public comments received in response to the **Federal Register** notice of December 30, 2002 (67 FR 79611) (FRL–7286–6), EPA is describing the approach it plans to use for selecting an initial group of chemicals to be screened in the Agency's EDSP. This notice does not identify the initial list of chemicals, nor does it describe other aspects of the EDSP such as the administrative procedures EPA will use to require testing, the validated tests and battery that will be included in the EDSP, or the timeframe for requiring the testing or receiving the data. The initial chemical list and the details of the EDSP process that will apply to the initial chemical list will be addressed in subsequent notices published in the **Federal Register**.

EPA anticipates that it may modify its chemical selection approach for subsequent screening based on experience gained from the results of testing chemicals on the initial list, its needs to extend screening to additional 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).

EPA developed its EDSP in response to the Congressional mandate in section 408(p) of FFDCA to ''develop a screening program * * * 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 endocrine 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 for testing, under the FFDCA 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.''

The purpose of this notice is to describe the approach that EPA plans to use to select this initial set of chemicals to undergo screening. EPA will use an approach based in part on the compartment-based priority-setting approach described in the **Federal Register** notices of December 28, 1998 (63 FR 71542) (FRL–6052–9) and December 30, 2002. This approach focuses on human exposure-related factors rather than using a combination of exposure- and effects-related factors. However, in making selections for this exposure-based initial list, EPA does not plan to select substances it considers to be a low priority for early screening under the EDSP because they are anticipated to have low potential to cause endocrine disruption (e.g., certain Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) List 4 inerts, most polymers with number average molecular weight greater than 1,000 daltons, strong mineral acids, and strong mineral bases). Also, chemicals that are being used by EPA as ''positive controls'' to validate the screening assays will be excluded from its initial list.

Although EPA's general focus in this approach for the initial list is on pesticide active ingredients and inerts with relatively greater potential human exposure, EPA believes that the approach will also identify chemicals with high potential for exposure of humans from non-pesticide uses 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 this approach.

The Agency will use the approach set forth in this notice to select the initial list of chemicals to test first under the

EDSP based primarily on exposure data. Therefore, this initial list of chemicals 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.

In subsequent notices published in the **Federal Register**, EPA intends to issue the draft initial list of chemicals resulting from the implementation of this approach, and to describe the other aspects of the EDSP, including the procedures it will use to require the testing and the timeframe for the initial screening. EPA intends to provide time for review and comment on the draft initial list prior to the Agency's imposition of actual screening of the initial chemicals.

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

Section 408(p) of FFDCA requires EPA ''to develop a screening program 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 endocrine effect as [EPA] may designate.'' (FFDCA 21 U.S.C. 346a(p)). The statute generally requires EPA to ''provide for the testing of all pesticide chemicals.'' (FFDCA 21 U.S.C. 346a(p)(3)). However, EPA is authorized to exempt a chemical, by order upon a determination that ''the substance is anticipated not to produce any effect in humans similar to an effect produced by a naturally occurring estrogen.'' (FFDCA 21 U.S.C. 346a(p)(4)). ''Pesticide chemical'' is defined 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))).

**III. Background**

*A. EPA's Endocrine Disruptor Screening Program (EDSP)*

EPA initially set forth the EDSP in the August 11,1998 **Federal Register** notice (63 FR 42852) (FRL–6021–3) and solicited public comment on the program in the December 28, 1998 **Federal Register** notice. The program set forth in these notices was based on the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), which was chartered under the Federal Advisory Committee Act (FACA), 5 U.S.C. App.2, section 9(c). The EDSTAC 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 setting 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.
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 program 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. 1). Based on these recommendations, EPA developed a tiered approach for their program (referred to as the EDSP). The core elements of EDSP are: Priority setting, Tier 1 screening, and Tier 2 testing. Tier 1 is envisioned as a battery of screening assays (referred to as ''screening'') that would identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems. The purpose of Tier 2 testing (referred to as ''testing'') is to determine whether the substance could, in fact, cause endocrine effects mediated by estrogen-, androgen-, or thyroid-related processes, and to establish the relationship between doses of an endocrine-active substance administered in the test and any effects observed.

In addition, based on EDSTAC's recommendations, EPA proposed in the December 28, 1998 **Federal Register** notice 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, EPA proposed to develop categories of information relating to the production, release, exposure, and hazard of chemicals and to group the chemicals according to the available data. 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 study addressing all chemicals with a production volume in excess of 10,000 pounds per year, excluding pesticide active ingredients. EPA developed the Endocrine Disruptor Priority Setting Database (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 the screening level assays, selecting the appropriate screening assays for the screening battery based on the validation data, and developing and validating Tier 2 tests.
2. Finalizing the priority-setting chemical selection approach to be applied to select an initial list of chemicals to go through screening.
3. Developing the procedures the Agency will use to require screening.

This notice deals only with finalizing the priority-setting chemical selection approach to be applied to select an initial list of chemicals to go through screening. As indicated, EPA intends to address the other aspects of the EDSP in subsequent notices published in the **Federal Register**.

*B. Science Advisory Board/FIFRA Scientific Advisory Panel Review*

EPA asked its Science Advisory Board (SAB) and the FIFRA Scientific Advisory Panel (SAP), independent scientific review committees of non-EPA scientists, to review jointly the Agency's proposed EDSP. 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 SAB/SAP Subcommittee met on March 30–April 1, 1999. Its report was published the following July (Ref. 2). 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 SAB/SAP Subcommittee with respect to the scope of the program and setting of priorities for screening.

In the December 28, 1998 **Federal Register** notice, EPA explained that it was considering 87,000 substances as potential candidates for testing under 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 SAP/SAB 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 EDSP. The SAB/SAP Subcommittee also expressed concern that it did not see a provision for mid-course correction or optimization of the program. Thus, the SAB/SAP Subcommittee recommended that the EPA start by applying EDSP to 50 to 100 compounds and submit the data to independent review to consider eliminating methods that do not work, and also evaluate how to optimize the program.

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

The SAB/SAP Subcommittee also found that the compartment-based approach to priority setting was supportable when ranking is 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 chemicals 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 SAB/SAP 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 SAB/SAP 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 EDSP. The SAB/SAP Subcommittee supported the concept of nominations by citizens, but recommended that the process needed further definition.

Finally, the SAB/SAP 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 SAB/SAP Subcommittee encouraged EPA to be open to other types of assays for HTPS including receptor binding, gene chip and microarrays, and computer modeling. The SAB/SAP 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. Public Comments on Priority Setting*

In addition to comments provided by the SAB/SAP Subcommittee, comments were also provided by the public on priority setting in response to EPA's EDSP Proposed Statement of Policy notice published in the December 28, 1998 **Federal Register**, at two public meetings held on the Endocrine Disruptor Priority Setting Database (EDPSD), and from the request for comment on the proposed approach in the December 30, 2002 **Federal Register** notice. The January 20, 1999 meeting was published in the **Federal Register** of December 28, 1998 (63 FR 71568) (FRL–6052–8) and the June 5–6, 2000 meeting was published in the **Federal Register** of May 19, 2000 (65 FR 31900) (FRL–6559–9). All of these comments were helpful to the Agency in developing the approach presented in this notice for selecting the initial list of chemicals to be screened in EDSP.

## IV. Summary of Comments Received on EPA's Proposed Approach to Selecting the Initial Set of Chemicals

After reviewing all of the comments received, EPA has decided to make some changes to the proposed approach. The priority-setting issues raised in the most recent comments on the proposed approach are addressed in the Comment Response Document for Endocrine Disruptor Chemical Selection/Priority Setting (Ref. 3), which can be found in the public docket. This unit addresses the major comments that caused EPA to revise its proposed approach.

### *A. Use of Effects Data for Chemical Selection*

In the proposed chemical selection approach in the December 30, 2002 **Federal Register** notice, EPA stated that, prior to publishing the draft initial list of chemicals for screening, the Agency intended to review the available effects information for those candidate chemicals identified using the exposure-based approach, in order to identify any chemical for which the effects information either clearly indicates an endocrine-mediated effect/perturbation or clearly indicates low potential to cause endocrine disruption. Such chemicals would then be excluded from the initial list. Most commenters urged EPA to utilize existing effects data to the greatest extent that is scientifically justifiable, and emphasized that an exposure-based approach should only be used, if at all, for the initial list.

Following review of the comments and further evaluation of the proposed approach, EPA has decided for the initial list to limit its review of effects data and primarily select chemical candidates based on exposure. With two exceptions where EPA believes that it has sufficient information of an appropriate quality, EPA generally believes that it lacks sufficient information and experience to determine whether a chemical should be designated as a ''potential endocrine disruptor.'' As a general matter, EPA will therefore not exclude chemicals from the initial list based on a finding of the chemical's endocrine disruption potential.

Generally, with respect to using additional existing effects data, given the current state of scientific understanding of endocrine system effects and the types of testing currently available for most pesticide chemicals, EPA has decided for this initial list that it would be impractical to establish criteria for judging whether a chemical should be designated as a ''potential endocrine disruptor'' and removed from the initial group for screening. Although a relatively broad range of toxicity data are available for pesticide active ingredients regulated under FIFRA, in most cases EPA has not yet established how the available data might be confidently used to predict the endocrine disruption potentials of these chemicals. This may be due to the non-specific nature of an effect or effects observed, questions related to whether the mode of action in producing 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. When the draft

initial list is published, any company subject to a testing requirement may request, during the comment period, a waiver (supported by appropriate data) on the grounds that the chemical is an endocrine disruptor and that EDSP screening is unnecessary.

EPA has identified two exceptions. First, chemicals that are being used by EPA as ''positive controls'' to validate the screening assays will be excluded from its initial list. Inclusion of these chemicals in the initial list would be to require companies to generate duplicative data unnecessarily. These chemicals were selected because they were expected to elicit positive responses in the assays proposed to identify estrogen-, androgen-, and/or thyroid-system disruptors. Second, EPA does not plan to select substances it anticipates as having 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), and considers these substances to be a low priority for early screening under the EDSP. High molecular weight substances are unlikely to reach molecular receptors or other target tissue; highly reactive chemicals will destroy tissue at the point of entry leading to toxicity other than through the endocrine system.

*B. Appropriateness of the Proposed Data Sources*

Many comments received on the appropriateness of the data sources identified in the December 30, 2002 **Federal Register** notice questioned the relevance and quality of the proposed data sources. Specific issues raised in these comments included: The inability to analyze and fully understand the data in some data sources because the raw data underlying the summary data are not accessible; several databases are very dated and may not be relevant to potential exposures today; several databases may not be relevant to or extrapolated to the U.S. population as a whole; some databases/data sources used biased sampling rather than random or probability design; although the data do indicate exposure, they do not fully characterize exposure in terms of time, duration, and level of exposure; and that the EPA review of the databases should comply with the Agency's policies provided in its December 2002 information quality guidelines (Ref. 4).

In accordance with EPA's information quality guidelines, EPA has reviewed the data sources described in this chemical selection approach for the initial round of screening in the EDSP. Following review of the proposed databases (Ref. 5), EPA made the determination to exclude the Heidelberg College's Monitoring Data at this time because it has limited public availability, at best, and because comparable data are available from two other sources that are publicly available. For the remainder of the data sources, EPA believes that the data sources are appropriate and relevant for the intended application and that the quality and transparency of the information is sufficient for the intended use. The most current versions of the databases will be used and evaluated when developing the initial list.

EPA acknowledges that many of the proposed data sources may be limited in their usefulness for certain applications but believes, nonetheless, that the data sources are of appropriate quality for their intended use and purpose for a number of reasons. First, the most current versions of the databases will be used and evaluated when developing the initial list. In addition, the limitations of 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 Units VI. and VII. are not as vulnerable to criticism as a particular individual data set. Finally, EPA generally determines the quality of data sources based on the Agency's intended use of the data. For the initial list, EPA will select 50 to 100 pesticide active ingredients and HPV chemicals used as pesticide inerts to which the public may be more highly exposed. EPA will use these data sources to help select just the first round of chemicals to be screened and does not intend to use these sources to create a definitive, scientifically rigorous list of chemicals with a high potential for exposure, nor to develop quantitative exposure estimates in this analysis. The chemicals identified under this approach belong to the group of chemicals that are required to be tested under FFDCA section 408(p)(3)(A)—pesticide chemicals. Because Congress specifically required that these chemicals be tested, the impact of EPA's assessments in this case is quite limited—merely determining the timing of the testing, rather than whether the testing is to be conducted. Consequently, EPA believes the proposed data sources are of sufficient quality for their intended use.

*C. Synchronization of the Endocrine Disruptor Screening Program's Components*

In response to comments and consistent with its intent to have the initial list drafted and finalized when the screening assays are available for testing, EPA plans on publishing the draft initial chemical list well in advance of when an appropriate screening test battery is ready for use. This interval is intended to allow adequate time for EPA to solicit and consider public comments on the draft list without delaying the initial round of testing.

## V. EPA's Approach to Selecting the Initial Set of Chemicals to Undergo Screening

On the basis of EPA's experience to date and comments received, EPA is setting forth its approach for selecting the first group of chemicals to be screened in the EDSP. Based on the SAB/SAP Subcommittee recommendations and public comments, EPA will select and screen approximately 50 to 100 chemicals drawn from pesticide active ingredients and pesticide inerts with relatively large overall production volumes considering both pesticide and non-pesticide uses (HPV/Inert chemicals) to help the Agency further refine the EDSP. EPA will list the chemicals alphabetically, or numerically by CAS number, to avoid the appearance of a specific ranking of the chemicals selected for initial screening.

As recommended by the SAP/SAB Subcommittee, the Agency intends to conduct a review of the data received from the screening to evaluate whether the program could be improved or optimized, and if so, how. In addition to Agency scientists, the review of the initial list screening results will be evaluated by an expert panel such as one under the SAP/SAB Subcommittee. Evaluation of the screening results for the initial 50 to 100 chemicals will add substantially to our understanding of the performance of the Tier I test battery. Thus, the evaluation may identify methodological issues encountered when this larger set of chemicals are tested by laboratories not involved in the assay validation effort that may lead to further optimization of the assays to improve performance. The evaluation may also identify interpretive issues such as a determination that a specific assay may not be needed because another assay in the screening battery adequately measures the same effect. Other information from the review process

may help identify potential issues or areas for improvement, such as whether there is sufficient laboratory capacity or problems with correctly performing the tests, whether there are issues with the industry's ability to test the identified chemicals, or whether there are any procedural changes that would improve the overall program.

EPA will use an approach based in part on the compartment-based priority-setting approach described in the December 28, 1998 **Federal Register** notice that provided details about the EDSP and that the SAB/SAP Subcommittee commented on in 1999. As explained in Unit IV.A., the approach focuses primarily on exposure-related factors rather than using a combination of exposure- and effects-related factors. Although EPA will use many of the exposure data sets previously identified for use in the EDPSD in this approach, EPA anticipates not directly using 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 screening lists based on experience gained from the results of testing 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 will use several groups of data to identify pesticide active ingredients to include on the initial list of chemicals for screening. These data focus on human exposure by different pathways:

1. As a consequence of consuming food containing pesticide residues.
2. As a consequence of consuming 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 will use the most current data available from each data source to identify active ingredients. To ensure, to the extent possible, that all pesticide chemicals are addressed using this approach based on comparable exposure potential, EPA is most interested in identifying and selecting data sources which provide occurrence/usage data on a broad range of pesticide chemicals and across a wide geographical scope. Although the final selected data sources do have limitations, EPA is confident that these data sources can be used to identify pesticide active ingredients likely to be among those having either potentially widespread or higher levels of human exposure than would be expected for other active ingredients. EPA does not plan to use these data sources to create a definitive, scientifically rigorous list of pesticide chemicals to which the public is the most highly exposed. Nor is EPA proposing to use these databases to create quantitative exposure estimates in this analysis.

EPA is giving higher priority to chemicals likely to have human exposure via multiple pathways, with the highest priority being given to substances having potential exposure through all four pathways, followed by those having potential exposure via three pathways, etc. for inclusion on the list for initial screening. Details on EPA's approach for selecting pesticide active ingredients are presented in Unit VI.

EPA will use a similar approach to identify HPV/Inert chemicals to be included in the initial list for screening in the screening battery. However, EPA generally has more extensive information 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 pathways and data sources EPA has identified for selecting an initial set of HPV/Inert chemicals for endocrine disruptor screening differ somewhat from those 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 use the most current databases available 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 one million pounds per year) chemicals. This first step will focus initial 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 the most current existing data available for its use to identify HPV/Inert chemicals that have been found to be present in: Human biological samples, 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 EPA's priority-setting approach for selecting HPV/Inert chemicals are presented in Unit VII.

While EPA's general focus in this approach is on pesticide active ingredients and HPV/Inert chemicals with relatively greater potential human exposure, this 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 VI. and VII., EPA believes that the approach 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 to which other organisms have potential for widespread environmental exposures. In addition, because the screening battery will likely include assays involving different species (e.g., amphibians and fish) whose results are relevant to both humans and wildlife, EPA will capture information relevant to ecological protection.

The approach is consistent with the proposed approach and many of the comments received on the December 30, 2002 **Federal Register** notice. For its approach EPA is:

1. Focusing chemical selection for this initial list on the subset of chemicals for which testing is required (i.e., pesticide chemicals).
2. Using exposure data as the primary basis for chemical selection rather than using HTPS, QSARs, or other hazard data in conjunction with exposure data.
3. Excluding substances for the initial list anticipated to 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).
4. Deferring consideration of nominations from the public.
5. Not including mixtures for the initial list.
6. Excluding chemicals that are no longer produced or used in the United States.
7. Excluding ''positive control'' chemicals used for the validation of the screening assays.

EPA will issue an additional **Federal Register** notice setting forth the draft initial list of chemicals it proposes for screening. EPA expects that low-priority designations will initially be made on a case-by-case basis. Therefore, the **Federal Register** notice in which EPA will publish for public comment the draft initial list of chemicals for screening will clearly identify any chemical, which was identified having priority for testing through the application of the exposure-based criteria, but was excluded because it is considered to be a low priority for one of the reasons listed in this unit. That **Federal Register** notice will explain the rationale underlying any decisions made for selection of chemicals in the draft initial list. The draft initial list of chemicals is expected to be published to allow sufficient time for review and comment prior to actual testing. After considering comment on the draft list of chemicals, EPA will issue the initial list of chemicals for which screening will be required.

## VI. Approach for Selecting Pesticide Active Ingredients

As proposed, EPA will use several criteria to identify pesticide active ingredients for the initial round of the screening. These criteria would focus on human exposure by different pathways: As a consequence of consuming food containing pesticide residues, drinking water containing pesticide residues, and residential use of pesticide products; and through occupational contact with pesticide-treated surfaces. For each of the four pathways, EPA will review the most current existing databases available 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 for exposure through drinking water contain monitoring data collected on raw surface water (i.e., before the water enters a public water system). Thus, these monitoring data show the levels of pesticide residues that 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 to evaluate pesticide active ingredients, while focused on human exposure, will also capture many active ingredients with widespread environmental exposures.

### *A. 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 others.

To evaluate the interplay of these different variables, EPA will identify the pesticide active ingredients which are found most frequently as residues on the top 20 foods that people consume. First, EPA will use 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 2 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 (1994–1996) is available at *http://www.barc.usda.gov/bhnrc/foodsurvey*.

Using standard, scientifically peer-reviewed recipes, EPA has converted the reported food consumption for each CSFII survey respondent into the constituent raw agricultural commodities. For example, if a person reported eating six 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. EPA then 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. The results of these recipe translations appears in the revised Food Commodity Intake Database (FCID) (Ref. 6). Information on the FCID can be reviewed at *http://www.barc.usda.gov/bhnrc/foodsurvey/fcid.html*. This individual food consumption database provides the basis for identifying the top 20 foods consumed, in terms of mean daily consumption for the general population. Table 1 of this unit presents these raw agricultural commodities.

TABLE 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 raw agricultural foods, EPA will 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 will rely on the PDP database when both sources cover the same pesticides and commodities. The FDA Surveillance Monitoring Program data covers different pesticides and commodities in different years from the PDP monitoring (e.g., in 1999, FDA used analytical methods capable of detecting 366 different active ingredients). Therefore, in making its weight-of-the-evidence judgement, EPA will consider the FDA information as a supplement to the information from the PDP database.

EPA will review the two residue monitoring databases to identify the pesticide active ingredients which appear on the largest proportion of the samples, focusing on the 20 foods which make up the largest part of the U.S. diet. EPA will then review all of the information to make a judgment about whether the pesticide is likely to have relatively more widespread or higher levels of human exposure by the food pathway than other pesticides. This judgement involves consideration of such factors as the number of foods on which the residue is detected, the quantity of the diet represented by the food, and the overall number of detections and the frequency of detection.

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 Monitoring 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 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 the approach described is a practicable approach for identifying pesticide active ingredients with widespread or high levels of exposure.

*B. Water Pathway*

Portions of the general population may be exposed to pesticide residues in sources of 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. 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; therefore, water may be a significant source of exposure.

To assess relative exposure to different pesticides in water, EPA will examine a number of different databases that contain the results of programs to monitor surface and ground water for the presence of pesticide residues. The different media covered by these databases include, finished drinking water, ambient water, finished ground water, fish tissue, and sediment, all of which reflect the presence of a substance in water sources. The presence of a substance in these media establishes the potential for exposure via drinking water. All sources of drinking water exposure will be considered of equal priority.

As with the residue data for the food pathway, EPA will compile the information from the various databases concerning the detection of different pesticides in water. After compiling the information, EPA will examine the results to identify pesticides for which there appears to be greater potential for widespread human exposure, based on factors such as the number of samples and the geographic distribution of the detections. The presence of a single or only a few detections of a pesticide in a limited geographic area typically would not be a sufficient basis for concluding that the pesticide should be identified as potentially having either widespread or high levels of exposure by the water pathway.

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*. The Pesticides in Ground Water Database (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 untreated ground water and contains data only from studies in which pesticides were included as analytes. Some 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. 7).

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 untreated or ambient 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 that 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. In implementing its approach for selecting the initial list of chemicals for screening, EPA will review these chemical-specific monitoring data sources to determine if they contain information for pesticide active ingredients without data from other water monitoring data sources.

3. *United States Geological Survey/EPA Reservoir Monitoring Study*. The United States Geological Survey (USGS)/EPA Reservoir Monitoring Study was a pilot monitoring program initiated by the USGS and EPA to provide information on pesticide concentrations in drinking water and to assist in the implementation of FQPA. 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. 8).

4. *Environmental Monitoring and Assessment Program*. Environmental Monitoring and Assessment Program (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 that humans and wildlife may contact. EMAP includes relevant data for over 170 chemicals and three separate data sets for estuary sediments. In addition, six additional estuary data sets are now available that will also be considered. Extensive field and laboratory quality assurance/quality control (QA/QC) procedures were performed during the collection and analysis of the samples. Further details can be found at *http://www.epa.gov/emap*.

5. *National Sediment Inventory*. 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 National Sediment Inventory (NSI). The NSI 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 the NSI 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*.

6. *National Drinking Water Chemical Occurrence Database*. EPA developed the National Drinking Water Chemical Occurrence Database (NCOD) to satisfy the statutory requirements set forth by Congress in the 1996 amendments to SDWA to maintain a national drinking water contaminant occurrence database using occurrence data for both regulated and unregulated contaminants in public water systems. NCOD provides a library of water sample analytical data (or ''samples data'') that EPA is currently using and has used in the past for analysis, rulemaking, and rule evaluation. The drinking water sample data, collected at public water systems, are for both regulated and unregulated contaminants. The data have been extensively checked for data quality and analyzed for national representativeness.

Currently, NCOD provides links to the unregulated contaminant monitoring data (UCMR), which are being collected and added to NCOD, as well as to static data sets that have been used in published regulatory analyses. These latter (static) data sets have been extensively quality-checked, and their corresponding reports provide full descriptions (meta data) of the data. Further details can be found at *http://www.epa.gov/safewater/data/ncod.html*.

7. *National Stream Quality Accounting Network Data*. The National Stream Quality Accounting Network (NASQAN), a monitoring and data collection program conducted by the USGS, is designed to characterize raw surface water and sediment 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 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 at *http://water.usgs.gov/nasqan*.

EPA will use the most current NASQAN data available. Following a brief review of current NASQAN data, EPA determined that no sediment data exists and only surface water data were available for pesticide active ingredients. NASQAN data may be updated prior to selecting the initial list of chemicals for screening and it is possible that sediment data may be made available and used for pesticide active ingredients for screening.

8. *National Water Quality Assessment Program*. 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 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 at *http://water.usgs.gov/nawqa*.

9. *USDA Pesticide Data Program Water Data*. The Pesticide Data Program (PDP) was designed by USDA in 1991 to collect data on pesticide residues consumed in the United States. PDP samples are collected as close as possible to the time of consumption, and are also designed to provide better pesticide residue data for the foods most consumed by children. PDP is a Federal-State partnership with program operations carried out with the support of 10 States that collectively represent 50% of the U.S. population. Samples are collected using a statistically reliable, random sampling protocol, and the number of samples collected is apportioned according to State population or commodity production figures. PDP has tested over 50 different commodities, including drinking water, for more than 290 pesticides.

EPA recognizes that most of the monitoring databases just described report results from samples of ambient or untreated water, rather than treated 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 untreated 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 untreated water and concluded that while conventional water treatment processes (such as coagulation/flocculation, sedimentation, and filtration) can reduce or remove some pesticides, there may be little or no effect on the removal of other pesticides (Ref. 9). Thus, the Agency regards the results of monitoring untreated or ambient water as a plausible and appropriate indicator of potential human exposure.

Other factors affect the interpretation of water monitoring data. These data sources represent compilations of data to support a variety of regulatory and surveillance programs. 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 the above conditions were met. 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. 10) and the *EPA Background Paper for the FIFRA Scientific Advisory Panel Meeting on Monitoring Strategies for Pesticides in Surface-Derived Drinking Water* (Ref. 11).

The limitations of 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 VI.B. are not 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 VI.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 will review the databases described 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 will 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 of 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. 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 will use pesticide product labeling information as the primary indicator of pesticides whose use involves potential human exposure by this pathway. EPA will 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 will be identified as having higher priority with respect to the residential use pathway. EPA may also consider the number of residential uses for which each pesticide active ingredient is approved in selecting the initial list of chemicals for screening.

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 those which consistently have potential for higher levels of human exposure. Thus, EPA does not regard its basis for selecting priority chemicals for this pathway as being as effective in setting priorities among active ingredients as the criteria used for the other pathways. Nonetheless, residential use pesticides involve potential exposures to the general population, and the Agency believes it is 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 will 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 this unit, 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 will rank pesticides on the basis of their potential for post-application exposure to agricultural workers. This group includes farmers and farm workers who reenter pesticide-treated fields and orchards to care for or harvest the crop. These agriculture transfer coefficients developed by the Agricultural Reentry Task Force (ARTF) clearly indicate that certain work activities in particular crops lead to higher levels of exposure than other post-application work activities (Ref. 12). 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.[1] Activities having higher transfer coefficients should result in higher levels of worker exposure, all other factors being equal.

EPA will identify those work activities and specific crops and crop categories (e.g., tree fruit crops) having approximately the dozen highest transfer coefficients to identify the pesticides having the highest levels of use on those crops. EPA will then identify specific crops associated with the highest transfer coefficients to obtain information from the data sources described in this unit. Specifically, EPA will estimate the total number of acre treatments for each pesticide on all of the top crops and then array the pesticides on the basis of the highest totals.[2] The Agency will 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 (NASS) and California's Department of Pesticide Regulation (CDPR).

The USDA's 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 average 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 CDPR, and includes an extensive array of treatment information on crops including timing, location, area, and rate. These data allow EPA to calculate average pounds of pesticides applied for 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

[1] 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 ($cm^2$), and dividing this value by the length of time spent in the activity, expressed in hours (hr). The resulting coefficient for 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.

[2] 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.

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. Although the database is proprietary, 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 can be found at *http://www.doanemr.com/row-specialty-turf/index.html*.

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 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, such as 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 will integrate the information developed on priorities through the analysis of the four exposure pathways discussed Units VI.A. through VI.D. As its first step, the Agency will apply the criteria for each pathway to produce four lists of candidate chemicals for potential screening in the endocrine disruptor screening battery. EPA expects that a number of pesticide active ingredients will 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 will recommend for screening, EPA will give higher priority to chemicals that appear 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 will 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).

EPA will review the candidate list to exclude the chemicals which are being used as ''positive controls'' to validate the screening assays. Also, in making selections for this exposure-based initial list, EPA does not plan to select substances it anticipates as having 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), and considers these substances to be a low priority for early screening under the EDSP. EPA will also exclude any chemicals that are no longer used or produced in the United States.

## VII. Approach for Selecting High Production Volume Pesticide Inerts

EPA will use several sets of criteria for identifying High Production Volume Pesticide Inerts (HPV/Inerts) that will be given priority for screening in the screening battery. In general, the Agency is using an approach for HPV/Inerts that is similar to that used 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 biological samples. While EPA's general focus is on HPV/Inerts with relatively greater potential human exposure, this focus 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/Inerts 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 VII.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 public water system) (see Unit VII.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 to evaluate HPV/Inerts, while focused on human exposure, will also capture HPV/Inerts with potentially widespread environmental exposures.

EPA generally has more extensive information 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/Inerts. In addition, EPA generally has more extensive information available on usage (including both agricultural and residential) of active ingredients than is available for HPV/Inerts (including both pesticidal and non-pesticidal uses of those same substances). For these reasons, the specific data sources and pathways EPA has identified for selecting an initial set of HPV/Inerts for endocrine disruptor screening differs somewhat from those for selecting pesticide active ingredients.

First, EPA will review existing databases to identify chemicals that are both pesticide inerts and HPV chemicals. 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 Toxic Substances Control Act's (TSCA) Inventory Update Rule (IUR). IUR provides for periodic updating of production volume and other information pertaining to selected Inventory chemicals currently in commerce. Second, EPA will review existing databases to identify HPV/Inerts that are present in four types of environmental media or monitoring

data: Human biological samples, ecological tissues that have human food uses (i.e., fish tissues), drinking water, and indoor air. Third, EPA will prioritize these chemicals based on the number of monitoring data types in which the chemicals have been detected. Thus, HPV/Inerts appearing in four types of monitoring data would be given higher priority than those appearing in only one type of monitoring data. To the extent it becomes necessary to establish priorities within these four types of monitoring data, EPA will give higher priority to those HPV/Inerts that appear in human biological monitoring data, followed by drinking water/indoor air monitoring data (weighted equally), followed by ecological biological data relevant to human exposure.

*A. High Production Volume/Inerts in Human Biological Monitoring Data*

EPA will review the following data sources to determine which HPV/Inerts have been detected in human biological samples and to identify HPV/Inerts for which there appears to be widespread human exposure, based on factors such as the number of samples and number of detections. The presence of a single or only a few detections of a HPV/Inert chemical typically would not be a sufficient basis for concluding that the chemical should be identified as having significant exposure.

1. *Third National Health and Nutrition Examination Survey*. 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 the Priority Toxicant Reference Range Study, previously referenced as Ashley et al (1994) (Ref. 13). This NHANES III article contains relevant human biomonitoring data for over 40 volatile organic compounds (VOCs). Standard 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 for 2001 (Ref. 14) was a U.S. Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) report that provided 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. The most current 2003 Report (Ref. 15) presents exposure data for 116 chemicals (including the 27 chemicals presented in the 2001 Report) during NHANES 1999 and 2000. VOCs are not included in the 2003 Report. Chemicals and their metabolites were measured in blood, urine, and blood serum samples from selected NHANES participants. 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.

3. *National Human Adipose Tissue Survey*. The EPA's Office of Pollution Prevention and Toxics (OPPT) operated the National Human Monitoring Program (NHMP) until the early 1990s. The NHMP's primary activity was conducting a National Human Adipose Tissue Survey (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 in 13 journal articles and reports (Refs. 16–29). However, because a standard set of summarized data parameters has not been published, the NHATS data were previously compiled into a database by EPA, and this database was incorporated into the EDPSD (version 2). (See *http://www.epa.gov/scipoly/oscpendo/prioritysetting/database.htm*) In implementing its approach for selecting the initial list of chemicals for screening, EPA will consider chemicals contained in the database compiled for EDPSD and include those chemicals for which geometric means were calculated for EDSP priority-setting purposes.

4. *Total Exposure Assessment Methodology Study*. The Total Exposure Assessment Methodology (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. 30–32).

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. High Production Volume/Inerts in Ecological Biological Monitoring Data Relevant to Human Exposure*

EPA will review the following data sources to determine which HPV/Inerts have been detected in non-human tissues potentially relevant to human ingestion exposure and to identify HPV/Inerts for which there appears to be widespread human exposure, based on factors such as the number of samples and number of detections. The presence of a single or only a few detections of a HPV/Inert chemical typically would not be a sufficient basis for concluding that the chemical should be identified as having significant exposure.

1. *National Sediment Inventory Fish Tissue Data (NSI Fish Tissue Data)*. This database is described in Unit VI.B.5. In implementing its approach for selecting the initial list of chemicals for screening, EPA will consider fish species tissues for samples collected

after 1989 in NSI for EDSP priority-setting purposes.

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, which was initiated in 2000, 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 Study 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*.

3. *National Water Quality Assessment Program Aquatic Animal Tissue Data*. This database, which also contains information on surface water and ground water monitoring studies, is described in Unit VI.B.8. The National Water Quality Assessment (NAWQA) has recently made aquatic organism tissue data available for a variety of species and tissues. EPA will consider NAWQA tissue data for all species and tissue types for the ecological biological monitoring exposure pathway.

### *C. High Production Volume/Inerts in Drinking Water Monitoring Data*

EPA will review the following data sources to determine which HPV/Inerts have been detected in drinking water and in potential sources of drinking water and identify HPV/Inerts for which there appears to be widespread human exposure, based on factors such as the number of samples and number of detections. The presence of a single or only a few detections of a HPV/Inert chemical typically would not be a sufficient basis for concluding that the chemical should be identified as having significant exposure.

1. *National Contaminant Occurrence Data Base (NCOD Database)*. This database is described in Unit VI.B.6.

2. *National Human Exposure Assessment Survey*. EPA designed the National Human Exposure Assessment Survey (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 90$^{th}$ percentile. (Refs. 33–36).

3. *Total Exposure Assessment Methodology Water Data (TEAM Water Data)*. This study is described in Unit VII.A.4.

4. *National Stream Quality Accounting Network (NASQAN) Data*. This database, which contains information on surface water monitoring studies, is described in Unit VI.B.7.

5. *National Water Quality Assessment Program (NAWQA)*. This database, which contains information on surface water and ground water monitoring studies, is described in Unit VI.B.8.

### *D. High Production Volume/Inerts in Indoor Air Monitoring Data*

EPA will review the following data sources to determine which HPV/Inerts have been detected in residential indoor air and to identify HPV/Inerts for which there appears to be widespread human exposure, based on factors such as the number of samples and number of detections. The presence of a single or only a few detections of a HPV/Inert typically would not be a sufficient basis for concluding that the chemical should be identified as having significant exposure.

1. *Office of Research and Development published literature*. The following eight EPA/Office of Research and Development (ORD)-authored journal articles and reports provide indoor and personal 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. 37–44). In implementing its approach for selecting the initial list of chemicals for screening, EPA will exclude the Kelly et al. (1994) article, as this article only provides outdoor air data.

2. *National Human Exposure Assessment Survey*. The National Human Exposure Assessment Survey (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. 34–36, 44). In implementing its approach for selecting the initial list of chemicals for screening, EPA will consider both NHEXAS indoor and/or personal air samples for EDSP priority-setting purposes.

3. *Total Exposure Assessment Methodology Study*. The Total Exposure Assessment Methodology (TEAM) Study is described in Unit VII.A.4. The ORD literature (see Unit VII.D.1.) includes all of the indoor air data collected in the TEAM Study; therefore, EPA will consider TEAM Study data in implementing its approach for selecting the initial list of chemicals along with the ORD data rather than as a separate source of information.

### *E. Integration of Pathway Priorities for High Production Volume/Inerts*

This unit addresses how EPA will integrate the information developed on priorities through the analysis of the four types of exposure monitoring data discussed in Units VII.A. through VII.D. (human biological data, ecological biological data relevant to human exposure, drinking water data, and indoor air data). As its first step, the Agency will produce four lists of candidate chemicals, one for each type of monitoring data, for potential screening in the endocrine disruptor screening 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/Inerts to propose for the initial screening list, EPA will give higher priority to chemicals that appear 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 will 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. EPA will also exclude any chemicals that are no longer produced or used in the United States.

EPA will review the candidate list to exclude the chemicals which are being used as ''positive controls'' to validate the screening assays. Also, in making selections for this exposure-based initial list, EPA does not plan to select substances it anticipates as having 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), and considers these substances to be a low priority for early screening under the EDSP.

## VIII. Integration of the Pesticide Active Ingredients and High Production Volume/Inerts Lists

EPA will use similar but somewhat different sets of criteria for identifying pesticide active ingredients and HPV/Inerts that should be given priority consideration for inclusion in the initial round of screening.

EPA will generate four lists of candidate pesticide active ingredients (one for each exposure pathway) and four lists of candidate HPV/Inerts (one for each type of exposure monitoring data). Because EPA generally has more extensive exposure information for pesticide active ingredients than for HPV/Inerts, the Agency does not think it would be appropriate to integrate the eight lists. Instead, EPA will separately select pesticide active ingredients and HPV/Inerts giving higher priority to pesticide active ingredients and HPV/Inerts that appear in multiple lists of exposure pathways and exposure monitoring data types, respectively. Thus, the selected pesticide active ingredients may be those that appear in three or more pathways whereas the selected HPV/Inerts may be those that appear in one or more pathways. Finally, EPA will review the lists for chemical class representation (e.g., as a tie breaker). EPA's intent is to select a total of 50 to 100 chemicals to initiate the screening program, but will not treat that overall target as a rigid quota. In addition, EPA may sponsor Tier 1 screening of some of the positive control chemicals used for validation of the assays, and other chemicals, to provide data for comparison purposes and to test the performance of the battery. This would be in addition to the 50 to 100 chemicals selected using the approach described in this notice.

## IX. References

The following is a list of the documents that are specifically referenced in this notice. These references are available in the docket for this notice as described in Unit 1.B.1., under docket ID number OPPT–2004–0109. In addition, some documents referenced are only available in docket ID number OPPT–2002–0066, which is the docket used for the proposed approach. These dockets are linked in EDOCKET, but to simplify identifying the specific documents that can be found only in docket ID number OPPT–2002–0066, those references include the appropriate document ID number. (See Unit I.B.1. for information on how to access these dockets).

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## X. Statutory and Executive Order Reviews

This notice describes the approach that EPA intends to use to identify the first 50 to 100 chemicals to be screened under the EDSP. It represents a statement of Agency policy in this respect, but does not impose any requirements. As a policy statement related to a new program and the potential for novel policy issues to arise during this initial implementation of the statutory mandate in section 408(p) of FFDCA, the Office of Management and Budget (OMB) has designated this notice as ''significant'' under section 3(f) of Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). The Agency therefore submitted this notice to OMB for review under this Executive order, and any changes made in response to recommendations or comments received from OMB during that review have been documented in the public docket as required by the Executive order.

Since this notice is not a regulation and does not otherwise impose any requirements, it does not qualify as an economically significant action under section 3(f)(1) of Executive Order 12866. As such, this action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), or Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). Nor does this notice contain any information collection requirements that require review and approval by OMB pursuant to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*).

Since this type of action does not require any proposal, no action is needed under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), and since this action does not involve any technical standards, 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), does not apply.

For the same reason, this action will not have substantial direct effects on State or tribal governments, on the relationship between the Federal Government and States or Indian tribes, or on the distribution of power and responsibilities between the Federal Government and States or Indian tribes. As a result, this action does not require any action under Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999), or under Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Nor does it impose any enforceable duty or contain any unfunded mandate or otherwise require any action under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

Nor does this action require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

In addition, although not a final action that requires action under the Congressional Review Act, 5 U.S.C. 801 *et seq.*, which generally provides that before a final action may take effect, the issuing Agency must submit a report to each House of the Congress and the Comptroller General of the United States, EPA has submitted a courtesy copy of this notice to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to its publication in the **Federal Register**.

## List of Subjects

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

Dated: August 8, 2005.

**Susan B. Hazen,**

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

[FR Doc. 05–19260 Filed 9–26–05; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

**[FRL–7975–3]**

## New Hampshire Sanitation Device Standard; Notice of Determination

This Notice of Determination is for all New Hampshire coastal waters.

On July 8, 2005 notice was published that the State of New Hampshire had petitioned the Regional Administrator, Environmental Protection Agency, to determine that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for all coastal waters of New Hampshire. The petition was filed pursuant to section 312(f)(3) of Public Law 92–500, as amended by Public laws 95–217 and 100–4, for the purpose of declaring these waters a ''No Discharge Area'' (NDA).

Section 312(f)(3) states: After the effective date of the initial standards and regulations promulgated under this section, if any State determines that the protection and enhancement of the quality of some or all of the waters within such States require greater environmental protection, such State may completely prohibit the discharge from all vessels of any sewage, whether treated or not, into such waters, except that no such prohibition shall apply until the Administrator determines that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for such water to which such prohibition would apply.

The information submitted to me by the State of New Hampshire certified that there are six disposal facilities available to service vessels operating in the coastal waters of New Hampshire. A list of the facilities, phone numbers, locations, and hours of operation is appended at the end of the determination.

Based on the examination of the petition and its supporting information, which included site visits by EPA New England staff, I have determined that adequate facilities for the safe and sanitary removal and treatment of sewage from all vessels are reasonably available for the area covered under this determination.

The area covered under this determination is: