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Information concerning the involvement of the CSLC in the EIS/EIR process may be obtained from Tom Filler, Project Manager, at (916) 574-1938, or on the CSLC Internet website at <http://www.slc.ca.gov>.

Information concerning the proposed land use plan amendment and the involvement of the BLM in the EIS/EIR and plan amendment process may be obtained from Lynda Kastoll, Project Manager, at (760) 337-4421. The U.S. Environmental Protection Agency's publication of the Notice of Availability/Completion of the final EIS/EIR/plan amendment in the **Federal Register** initiates a 30-day protest period on the plan amendment. Instructions for filing a protest can be found in section 1.7.7 of the final EIS/EIR/plan amendment.

The CSLC is expected to consider certification of the final EIS/EIR/plan amendment and act on North Baja's application at a regularly scheduled meeting in mid-2007. Interested parties will be notified of the date, time, and location of the meeting. If you have any questions regarding the CSLC hearing,

or wish to testify, please contact Tom Filler at the number above.

Kimberly D. Bose,

Secretary.

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2004-0109; FRL-8129-3]

Draft List of Initial Pesticide Active Ingredients and Pesticide Inerts to be Considered for Screening under the Federal Food, Drug, and Cosmetic Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA) directs 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 September 2005, EPA published its approach for selecting the initial list of chemicals for which testing will be required under the Endocrine Disruptor Screening Program (EDSP). This document presents the draft list of the first group of chemicals that will be screened in the Agency's EDSP. The draft list was produced using the approach described in the September 2005 notice, and includes chemicals that the Agency, in its discretion, has decided should be tested first, based upon exposure potential. This list should not be construed as a list of known or likely endocrine disruptors. Nothing in the approach for generating the initial list provides a basis to infer that by simply being on this list these chemicals are suspected to interfere with the endocrine systems of humans or other species, and it would be inappropriate to do so. The first group of chemicals identified for testing includes pesticide active ingredients and High Production Volume (HPV) chemicals used as pesticide inerts. After considering comments on this draft list of chemicals, EPA will issue a second **Federal Register** notice containing the final list of chemicals. This document does not 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. These topics will be

addressed in subsequent notices published in the **Federal Register**.

DATES: Comments must be received on or before September 17, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2004-0109, by one of the following methods.

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery:* OPPT Document Control Office (DCO), EPA East Bldg., Rm. 6428, 1201 Constitution Ave., NW., Washington, DC. Attention: Docket ID number EPA-HQ-OPPT-2004-0109. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564-8930. Such deliveries are only accepted during the DCO's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to docket ID number EPA-HQ-OPPT-2004-0109. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [regulations.gov](http://www.regulations.gov) or e-mail. The [regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects

or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the docket index available in [regulations.gov](http://www.regulations.gov). To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the [regulations.gov](http://www.regulations.gov) web site to view the docket index or access available documents. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

FOR FURTHER INFORMATION CONTACT: Linda Phillips, Office of Science Coordination and Policy (7203M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-1264; e-mail address: phillips.linda@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. You may be potentially affected by this action if you produce, manufacture, use, consume, work with, or import pesticide chemicals. 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). Potentially affected entities, using the North

American Industrial Classification System (NAICS) codes to assist you and others in determining whether this action might apply to certain entities, may include, but are not limited to:

- Chemical manufacturers, importers and processors (NAICS code 325), e.g., persons who manufacture, import or process chemical substances.
- Pesticide, fertilizer, and other agricultural chemical manufacturers (NAICS code 3253), e.g., persons who manufacture, import or process pesticide, fertilizer and agricultural chemicals.
- Scientific research and development services (NAICS code 5417), e.g., persons who conduct testing of chemical substances for endocrine effects.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. 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. What Should I Consider as I Prepare My Comments for EPA?

1. *Scope of comments sought.* As discussed in more detail later in this document, the Agency has already sought and considered comments on the priority-setting approach before issuing the final approach in 2005 (70 FR 56449, September 27, 2005), which was used to identify the initial group of chemicals presented today. As such, the Agency is not seeking comment on the particulars of the approach used. Since FFDCA requires that all pesticides be screened under the EDSP, any suggestions to add a chemical to the list should be based on the application of the Agency's approach and supported with additional information. Should you have more recent information that affects the Agency's application of the approach, e.g., chemical is no longer manufactured or sold in the United States as a pesticide or used as an inert in pesticides, please provide the supporting information and data with your comment.

As indicated in the September 2005 **Federal Register** notice, any company subject to a testing requirement under Tier 1 may assert (supported by appropriate data) during the comment period for the draft list that the chemical is an endocrine disruptor and that the Tier 1 EDSP screening is unnecessary. EPA does not intend to permit chemicals on this list to bypass Tier 1 screening and move directly to Tier 2

testing without appropriate data to support such an action.

2. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

3. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at the estimate.
- vi. Provide specific examples to illustrate your concerns, and suggested alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

II. Introduction

A. What Action is the Agency Taking?

Based on the approach described in the **Federal Register** notice of September 27, 2005 (70 FR 56449) (FRL-7716-9), EPA is announcing the draft list of the first group of chemicals that will be screened in the Agency's Endocrine Disruptor Screening Program (EDSP). As required by FFDCA, all pesticides must eventually be screened under the EDSP, and this first group is simply a starting point. Because EPA developed this draft list of chemicals based upon exposure potential, it

should not be construed as a list of known or likely endocrine disruptors, and it would be inappropriate to do so. Nothing in the approach for generating the initial list provides a basis to infer that by simply being on this list these chemicals are suspected to interfere with the endocrine systems of humans or other species. The first group of chemicals to be tested consists of chemicals that section 408(p) requires be screened, i.e., pesticide active ingredients and chemicals used as pesticide inert ingredients that are also High Production Volume (HPV) chemicals. Following consideration of comments on this draft list of chemicals, EPA will issue a second **Federal Register** notice containing the final list of chemicals. This document does not 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. These topics will be addressed in subsequent notices published in the **Federal Register**.

EPA anticipates that it may, in the future, modify its approach to selecting chemicals for screening. Information and factors that EPA may consider in selecting chemicals could include: Public input; the results of testing chemicals on the initial list; management considerations to increase the integration of screening with other regulatory activities; implementation considerations flowing from a decision to extend screening to additional categories of chemicals (e.g., nonpesticide chemical substances); 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 the Safe

Drinking Water Act (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 document is to announce the draft initial list of chemicals to be screened in the Agency’s EDSP. EPA used an approach based on the priority-setting approach described in the September 2005 **Federal Register** notice. The approach focused on human exposure-related factors rather than using a combination of exposure- and effects-related factors. The approach did not include a literature search for or consideration of any data on potential endocrine effects. It is therefore inappropriate to infer that by simply being on this list, these chemicals are suspected to interfere with the endocrine systems of humans or other species. As described in detail in the September 2005 **Federal Register** notice, for the approach EPA:

- Focused chemical selection on the subset of chemicals for which testing is required (i.e., pesticide chemicals).
- Used exposure data as the basis for chemical selection.
- Deferred consideration of nominations from the public.
- Excluded mixtures.
- Excluded chemicals that are no longer produced or used in the U.S.

The approach described in the September 2005 **Federal Register** notice further indicated that the following would be excluded from the initial list of chemicals for screening.

- Substances 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).
- “Positive control” substances that are being used by EPA to validate screening assays proposed for the Tier 1 battery. See Unit IV.G. for more information.

EPA’s general focus in the approach for the initial list was on pesticide active ingredients and inerts with relatively greater potential for human exposure. The emphasis on human exposure does not necessarily mean that the list will not contain substances that may not also have potentially high levels of environmental exposure to ecological receptors. This **Federal Register** document presents the draft list of chemicals in alphabetical order. An

ordinal ranking of chemicals selected using the approach was not created.

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

Section 408(p) of FFDCA requires EPA to “develop a screening program, using appropriate validated test systems and other scientifically relevant information, 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.” (21 U.S.C. 346a(p)). The statute generally requires EPA to “provide for the testing of all pesticide chemicals.” (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.” (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.” (21 U.S.C. 321(q)(1)).

III. Background

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.

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 two-tiered approach, referred to as the EDSP. The purpose of the Tier 1 screening (referred to as “screening”) is to identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems using a battery of assays. The purpose of Tier 2 testing (referred to as “testing”)

is to identify and establish a dose-response relationship for any adverse effects that might result from the interactions identified through the Tier 1 assays. EDSTAC also recommended that EPA establish a priority-setting approach for choosing chemicals to undergo Tier 1 screening. EPA described this approach in the **Federal Register** of September 2005. More information on EPA's priority setting approach for the EDSP is available at <http://www.epa.gov/scipoly/oscpendo/prioritysetting>.

EPA currently is implementing its EDSP in three major parts that are being developed in parallel and with substantial work on each well underway.

1. *Assay validation.* Under FFDC section 408(p), EPA is required to use "appropriate validated test systems and other scientifically relevant information" to determine whether substances may have estrogenic effects in humans or other endocrine effects as the Administrator may designate. EPA is validating assays that are candidates for inclusion in the Tier 1 screening battery and Tier 2 tests, and will select the appropriate screening assays for the Tier 1 battery based on the validation data. Validation is defined as the process by which the reliability and relevance of test methods are evaluated for the purpose of supporting a specific use. The Tier 1 screening battery is expected to complete peer review and be ready for use early in 2008. The status of each assay can be viewed on the EDSP website in the Assay Status table: <http://www.epa.gov/scipoly/oscpendo/pubs/assayvalidation/status.htm>.

2. *Priority setting.* EPA described its priority setting approach for the first group of pesticide chemicals to be tested in the **Federal Register** of September 2005, and this document today announces the draft initial list of chemicals to undergo Tier 1 screening. The Agency expects to finalize this initial list of chemicals early in 2008. More information on EPA's priority setting approach for the EDSP is available at <http://www.epa.gov/scipoly/oscpendo/prioritysetting>.

3. *Procedures.* EPA intends to commence Tier 1 screening of the first group of pesticide chemicals by issuing test orders under FFDC section 408(p) to chemical companies identified as the manufacturer or processor of the identified chemicals, including the pesticide registrant. EPA is developing a draft implementation policy that will describe the procedures that EPA will use to issue orders, the procedures that order recipients would use to respond to the order, how data protection and

compensation will be addressed in the test orders, and other related procedures or policies. In addition, EPA is developing a draft template for the test order and a draft information collection request (ICR) to obtain the necessary clearances under the Paperwork Reduction Act (PRA). The Agency expects to seek public comment on the draft implementation policy and related documents late spring or early summer 2007, and after considering those comments, EPA expects to finalize the policy by the end of 2007.

Based on the current timing for each of the three major parts of the EDSP, the Agency intends to initiate the EDSP Tier 1 screening for the first group of pesticide chemicals early in 2008, at which time the final Tier 1 screening battery and the final procedures will be available. This document deals only with the draft list of chemicals initially selected to go through screening in the Tier 1 assays. As indicated in Unit II.A, EPA intends to address the other aspects of the EDSP in subsequent notices published in the **Federal Register**.

IV. Development of the Initial List of Chemicals

The following sections summarize the approach that was used to develop the draft initial list of chemicals, which is described in more detail in the September 2005 **Federal Register** notice. Again, it would be inappropriate to construe the draft initial list of chemicals as a list of known or likely endocrine disruptors. Nothing in the approach for generating the initial list provides a basis to infer that by simply being on this list, these chemicals are suspected to interfere with the endocrine systems of humans or other species.

A. Universe of Chemicals

EPA indicated in the September 27, 2005 (70 FR 56449) (FRL-7716-9) **Federal Register** notice that the universe of chemicals to be considered would include: (1) Pesticide active ingredients and (2) high production volume (HPV) chemicals that are also pesticide inerts.

1. *Pesticide active ingredients.* The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) defines a pesticide active ingredient as a chemical contained in pesticide products that prevents, destroys, repels, or mitigates any pest, or is a plant regulator, defoliant, desiccant, or nitrogen stabilizer. (7 U.S.C. 136(2)(u)). The universe of pesticide active ingredients which are required to be screened for their potential to adversely affect the endocrine system corresponds to the

active ingredients EPA has scheduled for review in its "registration review" program. (FIFRA requires EPA periodically to review the registration of all pesticide products, which the Office of Pesticide Programs (OPP) will implement through a program called "registration review." It should be noted that OPP may group similar active ingredients together, e.g., 2,4-D esters, salts, and amines, in "cases" that are evaluated at the same time. The EDSP, however, will focus on screening individual active ingredients.) The registration review schedule identifies all pesticide active ingredients that are used in currently registered products and indicates when they will be addressed in EPA's periodic registration review program. The draft registration review schedule was posted on EPA's website in August 2005 (Ref. 2). The draft schedule listed all registration review cases and pesticide active ingredients as of September 30, 2004. The draft schedule listed 666 registration review cases, comprising 1,056 active ingredients. Only those pesticide active ingredients that appear on this draft schedule were considered for generating the initial list of chemicals to undergo testing in the EDSP. The list is consistent with the final registration review schedule posted in October 2006. The principal difference between the draft and the final schedule is the inclusion of new active ingredients contained in newly registered pesticides as of September 30, 2005. The Agency does not expect any of the newly added active ingredients to be found in multiple exposure pathways. There are currently 678 registration review cases, comprising 1,077 active ingredients. These numbers will change annually as registration review schedule updates are announced.

2. *High production volume pesticide inerts.* HPV chemicals are those substances that are not pesticide active ingredients and that are produced or imported into the U.S. in amounts greater than or equal to one million pounds per year. The list of HPV chemicals is based on the non-confidential list of 2002 Toxic Substances Control Act (TSCA) Inventory Update Rule (IUR) chemicals (Ref. 3).

Pesticide inert chemicals are defined as any ingredients in pesticide product formulations other than the active ingredient. (7 U.S.C. 136(2)(m)). OPP maintains an inventory of pesticide inert chemicals that are categorized into the following four lists (Ref. 4):

- *List 1--Inert Ingredients of Toxicological Concern.* Any product

containing a List 1 ingredient must include the label statement:

This product contains the toxic inert ingredient (name of inert).

- *List 2--Potentially Toxic Inert Ingredients/High Priority for Testing Inerts.* The substances on this list may be structurally similar to chemicals known to be toxic; some have data suggesting a concern.

- *List 3--Inerts of Unknown Toxicity.* Inert ingredients on this list have not yet been determined to be of known potential toxicological concern nor have they been determined to be of minimal concern. These substances will continue to be evaluated to determine if they merit reclassification to List 1, 2, or 4.

- *List 4--Inerts of Minimal Concern.* This list is subdivided into List 4A (minimal risk inert ingredients) and List 4B (inerts which have sufficient data to substantiate that they can be used safely in pesticide products).

Table 1 presents the number of HPV and pesticide inert chemicals and the number of chemicals that are contained on both lists.

TABLE 1.—HPV AND PESTICIDE INERT CHEMICAL COUNTS

Chemical List	Number of Chemicals
High Production Volume Chemicals ¹	2,708
Pesticide Inert Chemicals	2,775 ²
Overlap of HPV/Pesticide Inert Chemicals	643

¹Based on the 2002 TSCA IUR.

²The number of inert ingredients contained in one or more registered pesticide products as of April 27, 2007. Note that as new products and formulations are registered, and as other products are canceled or reformulated, the number of inert ingredients contained in one or more registered pesticide products can change.

As shown in Table 1, there are a total of 643 chemicals that are both an HPV and pesticide inert chemical. This overlap was identified by matching Chemical Abstract Service (CAS) Registry numbers on each of the lists. Note that the list of pesticide inerts contains 109 chemicals without corresponding CAS numbers. This list of 109 pesticide inert chemicals was reviewed to determine whether any overlap could be identified based on chemical name. Table 2 presents chemical matches that were identified based on name, and also includes the CAS number provided on the HPV list. These chemicals shown in Table 2 were included in the universe of HPV/pesticide inert overlap chemicals considered for EDSP screening as shown in Table 1 (Ref. 5).

TABLE 2.—ADDITIONAL CHEMICALS INCLUDED IN THE UNIVERSE OF HPV/PESTICIDE INERT OVERLAP CHEMICALS

HPV CAS Number	HPV Name	Inert Name
67784901	Fatty acids, coco, reaction products with 2- [(2-aminoethyl) amino] ethanol	Fatty acids, coco, reaction products with 2-[(2-aminoethyl) amino] ethanol, alkylation products with methyl acrylate, sodium salts
68442091	Naphthalenesulfonic acid, sodium salt, isopropylated	Naphthalenesulfonic acid, isopropylisohexyl-, sodium salt

B. Approach for Selecting the Initial List of Chemicals to Undergo Screening

The following sections describe the approach that was used for selecting the initial list of chemicals to undergo screening, which is described in more detail in the September 2005 **Federal Register** notice. It is important to note that the approach did not include a literature search for or consideration of any data on potential endocrine effects. In fact, nothing in the approach for generating the initial list provides a basis to infer that by simply being on this list, these chemicals are suspected to interfere with the endocrine systems of humans or other species, and it would be inappropriate to make any such references.

1. *Pesticide active ingredients approach.* EPA applied the approach outlined below and described in detail in the September 2005 **Federal Register** notice. EPA used several groups of data to identify pesticide active ingredients to include on the initial list of chemicals for screening. These data focus on the potential for human exposure by

different pathways, including those resulting from:

- Consumption of food containing pesticide residues (i.e., food pathway);
- Consumption of drinking water containing pesticide residues (i.e., water pathway);
- Residential use of pesticide products (i.e., residential use pathway); and/or
- Occupational contact with pesticide-treated surfaces (i.e., occupational exposure pathway).

The data sources analyzed for each pathway are described in Unit IV.C. For each of the four pathways, EPA used the most current data available from each data source to identify active ingredients. As indicated in the September 2005 **Federal Register** notice, these data sources were selected to 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 believes that these data sources are suitable for identifying pesticide active ingredients

likely to be among those having either potentially widespread or relatively higher levels of human exposure than would be expected for other active ingredients. These data sources were not used to create a definitive, scientifically rigorous list of pesticide chemicals to which the public is the most highly exposed. Nor did EPA create quantitative exposure estimates for this analysis using these databases.

In accordance with the approach described in the September 2005 **Federal Register** notice, EPA considered pesticide active ingredients that indicated likely exposure via multiple pathways a higher priority for screening. Substances having potential exposure through all four pathways were considered the highest priority for inclusion on the draft list of chemicals for screening. Chemicals having potential exposure via three pathways were considered next highest in priority. For the purposes of further establishing priorities for pesticide active ingredients in three pathways, greater priority was given to chemicals

having potential exposure via the food pathway, followed by the occupational pathway (i.e., two of the three exposure pathways had to be food and occupational exposure to be included on the draft list of chemicals for screening). Specific details on EPA's approach for selecting pesticide active ingredients are presented in Unit VI. of the September 2005 **Federal Register** notice. In addition, a detailed summary of the analyses performed for each data source for pesticide active ingredients are available in the Docket (Ref. 6).

2. *High production volume pesticide inerts approach.* EPA used a similar approach to identify HPV/pesticide inert chemicals to be included in the initial list for screening. In general, EPA had more extensive information available to assess potential exposure to pesticide active ingredients than to assess HPV/pesticide inert chemical exposure. In addition, more extensive information was available on pesticide active ingredient usage (including both agricultural and residential) than was available for HPV/pesticide inert chemicals (including both pesticidal and nonpesticidal uses of those same substances). For these reasons, the specific pathways and data sources EPA identified for selecting an initial set of HPV/pesticide inert chemicals for endocrine disruptor screening differed somewhat from those for selecting pesticide active ingredients.

For HPV/pesticide inert chemicals, EPA applied the approach outlined below and described in detail in the September 2005 **Federal Register** notice. EPA used several groups of data to identify HPV/pesticide inert chemicals to include on the initial list of chemicals for screening. These data focus on indicators of potential human exposure using the following types of monitoring data:

- i. Human biological samples (i.e., human biological monitoring pathway);
- ii. Ecological tissues that have human food uses (e.g., fish tissues) (i.e., ecological biological pathway);
- iii. Drinking water (i.e., drinking water pathway); and/or
- iv. Indoor air (i.e., indoor air pathway).

The data sources analyzed for each pathway are described in Unit IV.D. For each of these four pathways, EPA reviewed the most current existing data available from each data source to identify HPV/pesticide inert chemicals. As with pesticide active ingredients, these data sources were selected to provide occurrence data on a broad range of HPV/pesticide inert chemicals across a wide geographical scope. Although the final selected data sources

do have limitations, EPA believes that these data sources are suitable for identifying HPV/pesticide inert chemicals likely to be among those having either potentially widespread or higher levels of human exposure than would be expected for other HPV/pesticide inert chemicals. These data sources were not used to create a definitive, scientifically rigorous list of HPV/pesticide inert chemicals to which the public is the most highly exposed. Nor did EPA use these databases to create quantitative exposure estimates in this analysis.

In accordance with the approach described in the September 2005 **Federal Register** notice, EPA considered HPV/pesticide inert chemicals present in multiple pathways a higher priority for screening. Substances having potential exposure through all four pathways were considered the highest priority for inclusion on the draft list of chemicals for screening. Chemicals having potential exposure via three pathways were considered next highest in priority. For the purposes of further establishing priorities for HPV/pesticide inert chemicals in three pathways, greater priority was given to chemicals observed in human biological monitoring data (i.e., one of the three exposure pathways had to be human biological monitoring to be included on the draft list of chemicals for screening). Specific details on EPA's priority setting approach for selecting HPV/pesticide inert chemicals are presented in Unit VII. of the September 2005 **Federal Register** notice. In addition, a detailed summary of the analyses performed for each data source for high production volume pesticide inerts are available in the Docket (Ref. 7).

C. Pesticide Active Ingredients Data Sources

The pesticide active ingredient data sources analyzed are briefly described below. Detailed data source summaries were prepared for each data source and are available in the Docket (Ref. 8). In addition, each of these data sources are described in the September 2005 **Federal Register** notice.

1. *Food pathway.* Relevant data were extracted from the following data sources to determine the presence of pesticide active ingredients in food containing pesticide residues that may be consumed:

- Continuing Survey of Food Intake by Individuals (CSFII).
- U.S. Department of Agriculture's Pesticide Data Program (USDA PDP).
- U.S. Food and Drug Administration (FDA) Pesticide Monitoring Database.

EPA used the most recent CSFII to develop a list of the top 20 foods consumed in the U.S., in terms of the mean daily consumption by the general population. The list was derived using CSFII data in conjunction with recipe translations that appear in the revised Food Commodity Intake Database (FCID) (Ref. 9). The FCID can be reviewed at <http://www.ars.usda.gov/Services/docs.htm?docid=14514>. The list of top 20 foods can be found in the September 2005 **Federal Register** notice. Having identified the top 20 raw agricultural foods, EPA identified the pesticide active ingredients detected on these foods using information collected by two Federal agency monitoring programs, the USDA PDP and the Surveillance Monitoring Program conducted by FDA's Center for Food Safety and Applied Nutrition. Additional information can be found at <http://www.ams.usda.gov/science/pdp/index.htm>. Additional information on the FDA program appears at <http://www.cfsan.fda.gov/~dms/pesrpts.html>. Pesticide active ingredients that were detected in any of the top foods, as reported by the PDP or FDA Surveillance Monitoring Program sources, were considered for priority setting purposes.

2. *Water pathway.* Relevant data were extracted from the following data sources to characterize the potential presence of pesticide active ingredients in drinking water:

- EPA Pesticides in Ground Water Database (PGWDB).
- EPA Chemical-Specific Monitoring Data.
- United States Geological Survey (USGS)/EPA Reservoir Monitoring Study.
- Environmental Monitoring and Assessment Program (EMAP).
- National Sediment Quality Database: 1980 to 1999 (or National Sediment Inventory (NSI)) Sediment Data.
- National Contaminant Occurrence Database (NCOD).
- National Stream Quality Accounting Network (NASQAN) Surface Water and Sediment Data.
- National Water Quality Assessment (NAWQA) Ground Water, Surface Water, and Sediment Data.
- USDA Pesticide Data Program (PDP) Water Data.

i. *EPA Pesticides in Ground Water Database (PGWDB).* The PGWDB 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 contains pesticide data from monitoring

of untreated ground water. Further details can be found in "EPA Pesticides in Ground Water Database, A Compilation of Monitoring Studies: 1971–1991 National Summary" (Ref. 10).

ii. *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. In implementing its approach for selecting the initial list of chemicals for screening, EPA reviewed these chemical-specific monitoring data sources to determine if they contain information for pesticide active ingredients for which data from other water monitoring data sources were not available.

iii. *United States Geological Survey (USGS)/EPA Reservoir Monitoring Study*. The USGS/EPA Reservoir Monitoring study contains information for 178 different pesticides and degradation products in samples of raw water (at the intake point) and from finished drinking water (at the tap prior to entering the distribution system) collected in 1999 and 2000. 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. 11).

iv. *Environmental Monitoring and Assessment Program (EMAP)*. EMAP is an EPA research initiative that collected sediment samples in 18 states at various times between 1990 and 1998. EMAP contains approximately 397 individual data sets. Applicable EMAP sediment data sets identified and included in the analysis are described in the Data Manipulation Summary for Pesticide Active Ingredients (Ref. 6). Further details can be found at: <http://www.epa.gov/emap/>.

v. *National Sediment Inventory (NSI)*. EPA's Office of Science and Technology (OST) initiated the NSI to document the composition of sediment in rivers, lakes, oceans, and estuaries. 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. EPA used both sediment and sub-sediment data from the NSI for the purpose of setting priorities for EDSP. 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/nsibase.html>.

vi. *National Drinking Water Chemical Occurrence Database (NCOD)*. NCOD provides a library of water sample analytical data (or "samples data") that EPA uses for analysis, rulemaking, and rule evaluation. The drinking water sample data, collected at Public Water Systems, are for both regulated and unregulated contaminants. Further details can be found at: <http://www.epa.gov/safewater/data/ncod/index.html>.

vii. *National Stream Quality Accounting Network (NASQAN) Data*. The NASQAN, a monitoring and data collection program conducted by the USGS, 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 since 1995. A network of over 50 stations monitors the concentrations of a broad range of chemicals including pesticides, major ions, and trace elements. NASQAN contains data for over 70 chemicals. EPA used both surface water and sediment data from the NASQAN for the purposes of setting priorities for EDSP. Further details can be found at: <http://water.usgs.gov/nasqan/>.

viii. *The National Water Quality Assessment Program (NAWQA)*. The NAWQA Program was designed to study 60 of the Nation's most important river basins and aquifer systems to provide both short-term information necessary for today's water-resource management decisions, and the long-term information needed for policy decisions. EPA used surface water, ground water, and sediment data from the NAWQA for the purposes of setting priorities for EDSP. Further details can be found at: <http://water.usgs.gov/nawqa/>.

ix. *USDA Pesticide Data Program (PDP) Water Data*. The USDA PDP was designed by USDA in 1991 to collect data on pesticide residues consumed in the U.S. PDP samples are collected as close as possible to the time of consumption. PDP has tested over 50 different commodities, including drinking water, for more than 290 pesticides. Further details can be found at: <http://www.ams.usda.gov/science/pdp/index.htm>.

Pesticide active ingredients that were detected in monitoring samples from any of the water data sources described in this section were considered for priority setting purposes for the water exposure pathway.

3. *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 repellents, 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 obtained pesticide product labeling information from EPA's Labeling and Use Information System (LUIS). These data were used as the primary indicator of pesticides whose use involves potential human exposure by this pathway. Except for products approved only for limited exposure uses, such as rodenticides applied in tamper resistant bait boxes, all currently registered residential use pesticides were considered as having priority with respect to the residential use pathway. The data from the LUIS reports were cross referenced by the Agency with recent Reregistration Eligibility Decisions (REDs). If the RED had recommended cancellation of residential uses, the pesticide was considered to not have residential uses. In such an instance, the pesticide was not included in the residential use pathway.

4. *Occupational exposure pathway*. Relevant data were extracted from the following data sources to identify the potential for post-application exposure to pesticide active ingredients:

- Agricultural Reentry Task Force (ARTF) – Science Advisory Council on Exposure, Policy Number 003.1, Agricultural Transfer Coefficients.
- USDA's National Agriculture Statistics Services (NASS).
- California's Department of Pesticide Regulation (CDPR).

EPA indicated in the approach published in the September 2005 **Federal Register** notice that another source of pesticide use information is AgroTrak™, a product of Doane Marketing Research. EPA did not need to rely on AgroTrak™ data because sufficient data were available from the other publicly available data sources (i.e., NASS and CDPR).

Using the ARTF data, EPA identified 14 work activities/crop categories (e.g., tree fruit crops) having the highest transfer coefficients. EPA then identified specific crops associated with the crop categories to use in conjunction with data available from the USDA's NASS and CDPR data to identify the pesticides used on those crops. More information on NASS pesticide use data can be found at <http://www.pestmanagement.info/nass>. More information on CDPR pesticide usage

data can be found at <http://www.cdpr.ca.gov/docs/pur/purmain.htm>. Pesticide active ingredients that were used on crops having the highest transfer coefficients were considered for priority setting purposes for the occupational exposure pathway.

D. High Production Volume Pesticide Inert Data Sources

The HPV/pesticide inert chemical data sources analyzed are briefly described below. Detailed data source summaries were prepared for each data source and are available in the Docket (Ref. 8). In addition, each of these data sources are described in the September 2005 **Federal Register** notice.

1. *Human biomonitoring exposure pathway*. Relevant data were extracted from the following data sources to determine the presence of HPV/pesticide inert chemicals in human tissues:

- National Health and Nutrition Examination Survey III (NHANES III) Priority Toxicant Reference Range Study for Volatile Organic Compounds.
- Centers for Disease Control and Prevention's National Reports on Human Exposure to Environmental Chemicals (NHANES 1999 to 2002).
- National Human Adipose Tissue Survey (NHATS).
- Total Exposure Assessment Methodology (TEAM) Breath Study.

i. *National Health and Nutrition Examination Survey III (NHANES III) Priority Toxicant Reference Range Study for Volatile Organic Compounds*. The Third NHANES (NHANES III) was conducted between 1988 and 1994 on 33,994 people. Several studies (e.g., high blood pressure, immunization status, nutritional blood measures) were conducted under NHANES III. One study relevant to priority setting was the Priority Toxicant Reference Range Study, previously referenced as Ashley *et al.* (1994) (Ref. 12). This NHANES III article contains relevant human biomonitoring data for over 40 volatile organic compounds (VOCs).

ii. *Centers for Disease Control (CDC) and Prevention's National Reports on Human Exposure to Environmental Chemicals (NHANES 1999 to 2002)*. The U.S. Department of Health and Human Services (HHS), CDC published three reports summarizing NHANES sampling data:

a. First National Report on Human Exposure to Environmental Chemicals (issued in March 2001, Ref. 13).

b. Second National Report on Human Exposure to Environmental Chemicals (issued in March 2003, Ref. 14).

c. Third National Report on Human Exposure to Environmental Chemicals (issued in July 2005, Ref. 15). Each year's report presents data from prior years, in addition to exposure data collected for current and additional chemicals studied. Overall, these reports provide data for 148 environmental chemicals for the survey years 1999 through 2002. These data were used for EDSP priority setting purposes.

iii. *National Human Adipose Tissue Survey (NHATS)*. NHATS collected and analyzed human adipose tissue specimens to monitor human exposure to potentially toxic chemicals. NHATS provides relevant human biomonitoring data for over 150 chemicals. Data are available for years 1970 through 1987 in 14 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. (See <http://www.epa.gov/scipoly/oscpendo/prioritysetting/database.htm>.) In implementing its approach for selecting the initial list of chemicals for screening, EPA considered chemicals for which geometric means were calculated.

iv. *Total Exposure Assessment Methodology (TEAM) Breath Study*. The TEAM study measured individual exposure through air, food, and water in 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).

HPV/pesticide inert chemicals that were detected in monitoring samples from any of the human biomonitoring databases described in this section were considered for priority setting purposes for the human biomonitoring pathway.

2. *Ecological biomonitoring exposure pathway*. Relevant data were extracted from the following data sources to determine the presence of HPV/pesticide inert chemicals in ecological tissues:

- National Sediment Inventory (NSI) Fish Tissue Data.
- National Fish Tissue Study (NFTS) Data.
- National Water Quality Assessment (NAWQA) Program Aquatic Animal Tissue Data.

i. *National Sediment Inventory (NSI) Fish Tissue Data (NSI Fish Tissue Data)*. This database is described in Unit IV.C.2.v. In implementing its approach for selecting the initial list of chemicals for screening, EPA considered the

analytical results for fish tissue samples collected after 1989.

ii. *National Fish Tissue Study (NFTS) Data*. EPA initiated this 4-year study in 2000 to 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. More details can be found at: <http://www.epa.gov/waterscience/fishstudy/results.htm>.

iii. *National Water Quality Assessment (NAWQA) Program Aquatic Animal Tissue Data*. This database, which also contains information on surface water and ground water monitoring studies, is described in Unit IV.C.2.viii. NAWQA has recently made aquatic organism tissue data available for a variety of species and tissues. EPA considered NAWQA tissue data for all species and tissue types for EDSP priority setting purposes.

HPV/pesticide inert chemicals that were detected in monitoring samples from any of the ecological biomonitoring databases described in this section were considered for priority setting purposes for the ecological biomonitoring pathway.

3. *Drinking Water Data Exposure Pathway*. Relevant data were extracted from the following data sources to determine the presence of HPV/pesticide inert chemicals in drinking water.

- National Contaminant Occurrence Database (NCOD).
- National Human Exposure Assessment Survey (NHEXAS) Drinking and Tap Water.
- TEAM Drinking Water Data.
- National Stream Quality Accounting Network (NASQAN) Surface Water and Sediment Data.
- National Water Quality Assessment (NAWQA) Ground Water, Surface Water, and Sediment Data.

i. *National Contaminant Occurrence Database (NCOD)*. This database is described in Unit IV.C.2.vi.

ii. *National Human Exposure Assessment Survey (NHEXAS) Drinking and Tap Water*. EPA designed the NHEXAS program 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 (Refs. 33–36, 45). Drinking water data and tap water from NHEXAS were used for priority setting purposes for this pathway.

iii. *TEAM Drinking Water Data*. The TEAM study is described in Unit IV.D.1.iv.

iv. *National Stream Quality Accounting Network (NASQAN) Data.* This database, which contains information on surface water monitoring studies, is described in Unit IV.C.2.vii.

v. *National Water Quality Assessment Program (NAWQA).* This database, which contains information on surface water and ground water monitoring studies, is described in Unit IV.C.2.viii.

HPV/pesticide inert chemicals that were detected in monitoring samples from any of the drinking water databases described in this section were considered for priority setting purposes for the drinking water exposure pathway.

4. *Indoor Air Exposure Pathway.*

Relevant data were extracted from the following data sources to determine the presence of HPV/pesticide inert chemicals in indoor air:

- EPA/Office of Research and Development (ORD) Journal Articles.
- NHEXAS – Indoor and Personal Air Data.
- TEAM Air Data.

i. *EPA/Office of Research and Development (ORD) Journal Articles.*

The following eight EPA/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) (Ref. 37–44). In implementing its approach for selecting the initial list of chemicals for screening, EPA excluded the Kelly *et al.* (1994) article, as this article only provides outdoor air data.

ii. *NHEXAS–Indoor and Personal Air Data.* The NHEXAS program was designed to evaluate comprehensive human exposure via indoor and outdoor air to multiple chemicals on a community and regional scale. Samples were collected of both the indoor and outdoor air that people breathe. Preliminary results of Phase I of NHEXAS were reported in 15 journal articles published in 1999. Four of these 15 journal articles provided information that is applicable to indoor air monitoring (Refs. 33–36, 45). In implementing its approach for selecting the initial list of chemicals for screening, EPA considered both NHEXAS indoor and/or personal air samples for EDSP priority setting purposes.

iii. *TEAM Air Data.* The TEAM study is described in Unit IV.D.1.iv. The ORD literature (see Unit IV.D.4.i.) includes all of the indoor air data collected in the TEAM study; therefore, EPA considered TEAM 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.

HPV/pesticide inert chemicals that were detected in monitoring samples from any of the indoor air databases described in this section were considered for priority setting purposes for the indoor air exposure pathway.

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

The Agency analyzed the data sources for each pathway to produce four candidate lists of chemicals for potential screening using the endocrine disruptor screening battery. A number of pesticide active ingredients were identified for more than one pathway, and some chemicals appeared only in a single pathway. Table 3 presents the number of unique pesticide active ingredients included on each list.

TABLE 3.—NUMBER OF PESTICIDE ACTIVE INGREDIENTS ON EACH PATHWAY LIST

Exposure Pathway	Number of Unique Pesticide Active Ingredients
Overall Pesticides Combined List	690 ¹
Food Pathway	92
Water Pathway	130
Residential Use Pathway	381 ²
Occupational Exposure Pathway	564

¹One active ingredient was excluded because its registration was recently canceled; three active ingredients were excluded because they only have import tolerances (i.e., there are no domestic registrations for these active ingredients).

²Three hundred and eighty-one active ingredients were identified with residential uses based on the output of the LUIS report. These data were used to generate the list of active ingredients listed in Table 5. EPA performed a quality assurance review of the 64 chemicals presented in Table 5 to verify residential use.

Table 4 presents the number of pesticide active ingredients according to the number and types of pathways in which they were observed.

TABLE 4.—NUMBER OF PESTICIDE ACTIVE INGREDIENTS ACCORDING TO THE NUMBER OF PATHWAYS IN WHICH THEY WERE OBSERVED

Number (Type) of Pathways	Number of Pesticide Active Ingredients
4 (Food, Water, Residential, Occupational)	28

TABLE 4.—NUMBER OF PESTICIDE ACTIVE INGREDIENTS ACCORDING TO THE NUMBER OF PATHWAYS IN WHICH THEY WERE OBSERVED—Continued

Number (Type) of Pathways	Number of Pesticide Active Ingredients
3 (Food, Water, Occupational)	19

TABLE 4.—NUMBER OF PESTICIDE ACTIVE INGREDIENTS ACCORDING TO THE NUMBER OF PATHWAYS IN WHICH THEY WERE OBSERVED—Continued

Number (Type) of Pathways	Number of Pesticide Active Ingredients
3 (Food, Water, Residential)	0
3 (Food, Residential, Occupational)	17
3 (Water, Residential, Occupational)	33
2 (Food, Water)	1
2 (Food, Residential)	1
2 (Food, Occupational)	22

TABLE 4.—NUMBER OF PESTICIDE ACTIVE INGREDIENTS ACCORDING TO THE NUMBER OF PATHWAYS IN WHICH THEY WERE OBSERVED—Continued

Number (Type) of Pathways	Number of Pesticide Active Ingredients
2 (Water, Residential)	3
2 (Water, Occupational)	40
2 (Residential, Occupational)	175
1 (Food)	4
1 (Water)	6
1 (Residential)	111
1 (Occupational)	230
Total	690

Because there were a large number of chemicals from which to select, it was

necessary to establish priorities within the pathways. EPA gave priority to those pesticide active ingredients that appeared in four exposure pathways, followed by those that appeared in three pathways. Further, for pesticide active ingredients appearing in three pathways, EPA gave priority to those where the food pathway was represented because of the potential for widespread exposure to the general population, followed by those where the occupational exposure pathway was represented due to the potential for workers to be highly exposed.

Table 5 presents the draft initial list of 64 pesticide active ingredients to undergo screening in the Tier 1 assays under the EDSP, along with an indication of the pathways in which they appeared. Because this list of pesticide active ingredients was selected on the basis of exposure potential only, it should not be construed as a list of known or likely endocrine disruptors.

TABLE 5.—PESTICIDE ACTIVE INGREDIENTS

Chemical Name	CAS Number	Total Pathways	Food	Water	Residential	Occupational
Chemicals in 4 Pathways						
2,4-D	94757	4	x	x	x	x
Atrazine	1912249	4	x	x	x	x
Benfluralin	1861401	4	x	x	x	x
Bifenthrin	82657043	4	x	x	x	x
Captan	133062	4	x	x	x	x
Carbamoithioic acid, dipropyl-, S-ethyl ester	759944	4	x	x	x	x
Carbaryl	63252	4	x	x	x	x
Chlorothalonil	1897456	4	x	x	x	x
Chlorpyrifos	2921882	4	x	x	x	x
Dichlobenil	1194656	4	x	x	x	x
Disulfoton	298044	4	x	x	x	x
Fenvalerate	51630581	4	x	x	x	x
Glyphosate	1071836	4	x	x	x	x
Imidacloprid	138261413	4	x	x	x	x
Malathion	121755	4	x	x	x	x

TABLE 5.—PESTICIDE ACTIVE INGREDIENTS—Continued

Chemical Name	CAS Number	Total Pathways	Food	Water	Residential	Occupational
Metalaxyl	57837191	4	x	x	x	x
Methiocarb	2032657	4	x	x	x	x
Metolachlor	51218452	4	x	x	x	x
Metribuzin	21087649	4	x	x	x	x
Myclobutanil	88671890	4	x	x	x	x
Norflurazon	27314132	4	x	x	x	x
Permethrin	52645531	4	x	x	x	x
Propiconazole	60207901	4	x	x	x	x
Propyzamide	23950585	4	x	x	x	x
Quintozene	82688	4	x	x	x	x
Simazine	122349	4	x	x	x	x
Triadimefon	43121433	4	x	x	x	x
Trifluralin	1582098	4	x	x	x	x
Chemicals in 3 Pathways						
4,7-Methano-1H-isoindole-1,3(2H)-dione, 2-(2-ethylhexyl)-3a,4,7,7a-tetrahydro-	113484	3	x		x	x
Abamectin	71751412	3	x		x	x
Acephate	30560191	3	x		x	x
Aldicarb	116063	3	x	x		x
Allethrin	584792	3	x		x	x
Azinphos-Methyl	86500	3	x	x		x
Carbofuran	1563662	3	x	x		x
Cyfluthrin	68359375	3	x		x	x
Cypermethrin	52315078	3	x		x	x
DCPA (or chlorthal-dimethyl)	1861321	3	x	x		x
Diazinon	333415	3	x	x		x
Dichlorvos	62737	3	x		x	x
Dicofol	115322	3	x	x		x
Dimethoate	60515	3	x	x		x
Endosulfan	115297	3	x	x		x
Esfenvalerate	66230044	3	x		x	x
Ethoprop	13194484	3	x	x		x
Fenbutatin oxide	13356086	3	x		x	x
Flutolanil	66332965	3	x		x	x
Folpet	133073	3	x		x	x
Gardona (cis-isomer)	22248799	3	x		x	x

TABLE 5.—PESTICIDE ACTIVE INGREDIENTS—Continued

Chemical Name	CAS Number	Total Pathways	Food	Water	Residential	Occupational
Iprodione	36734197	3	x	x		x
Linuron	330552	3	x	x		x
Methamidophos	10265926	3	x	x		x
Methidathion	950378	3	x	x		x
Methomyl	16752775	3	x	x		x
Methyl parathion	298000	3	x	x		x
o-Phenylphenol	90437	3	x		x	x
Oxamyl	23135220	3	x	x		x
Phosmet	732116	3	x	x		x
Piperonyl butoxide	51036	3	x		x	x
Propachlor	1918167	3	x	x		x
Propargite	2312358	3	x	x		x
Pyridine, 2-(1-methyl-2-(4-phenoxyphenoxy) ethoxy)-	95737681	3	x		x	x
Resmethrin	10453868	3	x		x	x
Tebuconazole Total = 64 Pesticide Active Ingredients).	107534963	3	x		x	x

F. Integration of Pathway Priorities for High Production Volume/Pesticide Inerts

The Agency analyzed the data sources for each HPV/pesticide inert exposure pathway to produce four candidate lists of chemicals for potential screening using the endocrine disruptor screening battery. A number of HPV/pesticide inerts were identified for more than one pathway, and some chemicals appeared only in a single pathway. Table 6 presents the number of unique high production volume pesticide inerts included on each list.

TABLE 6.—NUMBER OF HIGH PRODUCTION VOLUME PESTICIDE INERTS ON EACH PATHWAY LIST

Exposure Pathway	Number of Unique HPV/Inert Chemicals
Overall Combined List	62
Human Biological Monitoring Exposure Pathway	14

TABLE 6.—NUMBER OF HIGH PRODUCTION VOLUME PESTICIDE INERTS ON EACH PATHWAY LIST—Continued

Exposure Pathway	Number of Unique HPV/Inert Chemicals
Ecological Biological Monitoring Exposure Pathway	17
Chemicals in Drinking Water Exposure Pathway	19
Indoor Air Monitoring Exposure Pathway	48

Table 7 presents the number of HPV/pesticide inert chemicals according to the number and types of pathways in which they were observed.

TABLE 7.—NUMBER OF HPV/PESTICIDE INERT CHEMICALS ACCORDING TO THE NUMBER OF PATHWAYS IN WHICH THEY WERE OBSERVED

Number (Type) of Pathways	Number of HPV/ Pesticide Inert Chemicals
4 (Human, Eco, Water, Air)	8
3 (Human, Eco, Water)	1
3 (Human, Eco, Air)	0
3 (Human, Water, Air)	0
3 (Eco, Water, Air)	3
2 (Human, Eco)	0
2 (Human, Water)	1

TABLE 7.—NUMBER OF HPV/PES-
TICIDE INERT CHEMICALS ACCORD-
ING TO THE NUMBER OF PATHWAYS
IN WHICH THEY WERE OBSERVED—
Continued

Number (Type) of Pathways	Number of HPV/ Pesticide Inert Chemicals
2 (Human, Air)	2
2 (Eco, Water)	0
2 (Eco, Air)	0
2 (Water, Air)	1

TABLE 7.—NUMBER OF HPV/PES-
TICIDE INERT CHEMICALS ACCORD-
ING TO THE NUMBER OF PATHWAYS
IN WHICH THEY WERE OBSERVED—
Continued

Number (Type) of Pathways	Number of HPV/ Pesticide Inert Chemicals
1 (Human)	2
1 (Eco)	5
1 (Water)	5
1 (Air)	34

Because there were a large number of chemicals from which to select, it was necessary to establish priorities within

the pathways. In choosing which HPV/pesticide inert chemicals to propose for the initial screening list, EPA gave highest priority to chemicals that appeared in four exposure pathways, followed by chemicals that appeared in three pathways. For those chemicals that appeared in three pathways, EPA gave highest priority to those chemicals appearing in human biological monitoring exposure data.

Table 8 presents the draft initial list of nine HPV/pesticide inert chemicals to undergo screening in the EDSP. Because this list of HPV/pesticide inert chemicals was selected on the basis of exposure potential only, it should not be construed as a list of known or likely endocrine disruptors.

TABLE 8.—HIGH PRODUCTION VOLUME PESTICIDE INERTS

Chemical Name	CAS Number	Total Pathways	Human	Eco	Water	Air
Chemicals in 4 Pathways						
Acetone	67641	4	x	x	x	x
Butyl benzyl phthalate	85687	4	x	x	x	x
Dibutyl phthalate	84742	4	x	x	x	x
Diethyl phthalate	84662	4	x	x	x	x
Dimethyl phthalate	131113	4	x	x	x	x
Di-sec-octyl phthalate	117817	4	x	x	x	x
Methyl ethyl ketone	78933	4	x	x	x	x
Toluene	108883	4	x	x	x	x
Chemical in 3 Pathways						
Isophorone	78591	3	x	x	x	

G. Chemical Substances Deferred from Screening

EPA previously indicated that the following types of chemical substances may be deferred from the initial list of chemicals to undergo screening:

- Certain FIFRA List 4 pesticide inerts (i.e., List 4 inerts are described as “Inerts of minimal concern”).
- Most polymers with number average molecular weight greater than 1,000 daltons.
- Strong mineral acids and bases.
- Chemicals that are being used as a “positive controls” to validate the screening assays.

EPA has examined the 73 chemicals identified by the selection process in light of the criteria for deferral. None of the chemicals selected for initial screening using the approach described in this **Federal Register** notice were

categorized as List 4 inerts, high molecular weight polymers, or strong mineral acids or bases. Several have been used as “positive controls” in the validation of individual assays by the EDSP. However, none of the chemicals identified as EDSP “positive controls” on the draft chemical lists were used in a full battery of Tier 1 screening assays. As a result, none of the chemicals qualify as “positive controls” for Tier 1 screening, as a whole. Use of these chemicals in the validation of individual assays by the EDSP does not mean that these chemicals should be characterized as endocrine disruptors at this time. EPA intends to use the results of the battery of Tier 1 assays on this initial list to make a “weight of the evidence” determination about a chemical’s potential to interact with the endocrine system. Excluding “positive

controls” used in individual assays from the list of chemicals for initial Tier 1 screening would mean that EPA would not have data for the remainder of the assays in the Tier 1 battery and would not be able to evaluate these chemicals’ potential interaction with the endocrine system in the same manner as for all other chemicals, and would not be able to properly evaluate whether these chemicals should proceed to Tier 2 testing. Thus, these chemicals were retained on the list of 73 chemicals for initial screening.

H. Bypassing Tier 1 Screening

As indicated in the September 2005 **Federal Register** notice, any company subject to a testing requirement under Tier 1 may assert (supported by appropriate data) during the comment period for the draft list that the chemical

is an endocrine disruptor and that the Tier 1 EDSP screening is unnecessary. EPA does not intend to permit chemicals on this list to bypass Tier 1 screening and move directly to Tier 2 testing without appropriate data to support such an action.

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

Table 9 presents an alphabetized draft list of the 73 pesticide active ingredients and HPV/pesticide inert chemicals for

screening in the EDSP. Because this list of chemicals was selected on the basis of exposure potential only, it should neither be construed as a list of known or likely endocrine disruptors nor characterized as such.

TABLE 9.—DRAFT LIST OF CHEMICALS FOR TIER 1 SCREENING IN THE EDSP

Chemical Name	CAS Number	Pesticide Active Ingredient	HPV/Inert
2,4-D	94757	x	
4,7-Methano-1H-isoindole-1,3(2H)-dione, 2-(2-ethylhexyl)-3a,4,7,7a-tetrahydro-	113484	x	
Abamectin	71751412	x	
Acephate	30560191	x	
Acetone	67641		x
Aldicarb	116063	x	
Allethrin	584792	x	
Atrazine	1912249	x	
Azinphos-Methyl	86500	x	
Benfluralin	1861401	x	
Bifenthrin	82657043	x	
Butyl benzyl phthalate	85687		x
Captan	133062	x	
Carbamothioic acid, dipropyl-, S-ethyl ester	759944	x	
Carbaryl	63252	x	
Carbofuran	1563662	x	
Chlorothalonil	1897456	x	
Chlorpyrifos	2921882	x	
Cyfluthrin	68359375	x	
Cypermethrin	52315078	x	
DCPA (or chlorthal-dimethyl)	1861321	x	
Diazinon	333415	x	
Dibutyl phthalate	84742		x
Dichlobenil	1194656	x	
Dichlorvos	62737	x	
Dicofol	115322	x	
Diethyl phthalate	84662		x
Dimethoate	60515	x	
Dimethyl phthalate	131113		x
Di-sec-octyl phthalate	117817		x
Disulfoton	298044	x	

TABLE 9.—DRAFT LIST OF CHEMICALS FOR TIER 1 SCREENING IN THE EDSP—Continued

Chemical Name	CAS Number	Pesticide Active Ingredient	HPV/Inert
Endosulfan	115297	x	
Esfenvalerate	66230044	x	
Ethoprop	13194484	x	
Fenbutatin oxide	13356086	x	
Fenvalerate	51630581	x	
Flutolanil	66332965	x	
Folpet	133073	x	
Gardona (cis-isomer)	22248799	x	
Glyphosate	1071836	x	
Imidacloprid	138261413	x	
Iprodione	36734197	x	
Isophorone	78591		x
Linuron	330552	x	
Malathion	121755	x	
Metalaxyl	57837191	x	
Methamidophos	10265926	x	
Methidathion	950378	x	
Methiocarb	2032657	x	
Methomyl	16752775	x	
Methyl ethyl ketone	78933		x
Methyl parathion	298000	x	
Metolachlor	51218452	x	
Metribuzin	21087649	x	
Myclobutanil	88671890	x	
Norflurazon	27314132	x	
o-Phenylphenol	90437	x	
Oxamyl	23135220	x	
Permethrin	52645531	x	
Phosmet	732116	x	
Piperonyl butoxide	51036	x	
Propachlor	1918167	x	
Propargite	2312358	x	
Propiconazole	60207901	x	
Propyzamide	23950585	x	
Pyridine, 2-(1-methyl-2-(4-phenoxyphenoxy)ethoxy)-	95737681	x	
Quintozene	82688	x	

TABLE 9.—DRAFT LIST OF CHEMICALS FOR TIER 1 SCREENING IN THE EDSP—Continued

Chemical Name	CAS Number	Pesticide Active Ingredient	HPV/Inert
Resmethrin	10453868	x	
Simazine	122349	x	
Tebuconazole	107534963	x	
Toluene	108883		x
Triadimefon	43121433	x	
Trifluralin	1582098	x	

V. Other Related Future Actions

EPA anticipates that it may, in the future, modify its approach to selecting chemicals for screening. Information and factors that EPA may consider in selecting chemicals could include: Public input; the results of testing chemicals on the initial list; management considerations to increase the integration of screening with other regulatory activities; implementation considerations flowing from a decision to extend screening to additional categories of chemicals (e.g., nonpesticide chemical substances); and the availability of new priority-setting tools (e.g., High Throughput Pre-Screening (HTPS) or Quantitative Structure Activity Relationship (QSAR) models).

As discussed in Unit III., EPA also expects to address other aspects of the EDSP such as the information collection request, the administrative procedures EPA will use to require testing, the validated tests and battery that will be included in the EDSP, and the timeframe for requiring the testing and receiving the data in subsequent notices published in the **Federal Register**.

The Agency intends to conduct a review of the data received from Tier 1 screening both to evaluate individual chemicals and to evaluate whether the EDSP could be improved or optimized, and if so, how. In addition to its own scientists, the Agency will ask an independent expert panel, such as one under the Scientific Advisory Panel (SAP)/Scientific Advisory Board (SAB) to review the results from the Tier 1 screening of the initial group of chemicals. The review 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 refinements in the protocols for the Tier 1 assays to improve their performance for a wider range of chemicals. The evaluation may also identify interpretive issues, such as a

determination that two assays 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 difficulties performing tests in strict adherence with the validated protocols, 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.

VI. References

The following is a list of the documents that are specifically referenced in this document. These references are available in the docket as identified under **ADDRESSES**, which is the same docket that was used for the final chemical selection approach described in the September 2005 **Federal Register** notice. In addition, some documents referenced are only available in docket ID number EPA-HQ-OPPT-2002-0066, which is the docket used for the proposed chemical selection approach described in the **Federal Register** notice of December 30, 2002 (67 FR 79611) (FRL-7286-6). These dockets are cross referenced, 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.

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List of Subjects

Environmental protection, Chemicals, Endocrine disruptors, Pesticides.

Dated: May 24, 2007.

James B. Gulliford,

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

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ENVIRONMENTAL PROTECTION AGENCY

[Docket# EPA-RO4-SFUND-2007-0473; FRL-8328-1]

Holmes Scrap Yard Site; East Spencer, Rowan County, NC; Notice of Settlement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of settlement.

SUMMARY: Under Section 122(h)(1) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the United States Environmental Protection Agency has entered into a settlement for reimbursement of past response concerning the Holmes Scrap Yard Site located in East Spencer, Rowan County, North Carolina.

DATES: The Agency will consider public comments on the settlement until July 18, 2007. 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.

ADDRESSES: Copies of the settlement are available from Ms. Paula V. Batchelor. Submit your comments, identified by Docket ID No. EPA-RO4-SFUND-2007-0473 or Site name Holmes Scrap Yard Superfund Site by one of the following methods:

- www.regulations.gov: Follow the on-line instructions for submitting comments.

- *E-mail:* Batchelor.Paula@epa.gov.

- *Fax:* 404/562-8842/Attn Paula V. Batchelor.

Mail: Ms. Paula V. Batchelor, U.S. EPA Region 4, SD-SEIMB, 61 Forsyth Street, SW., Atlanta, Georgia 30303. "In addition, please mail a copy of your comments on the information collection

provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Desk Officer for EPA, 725 17th St., NW., Washington, DC 20503."

Instructions: Direct your comments to Docket ID No. EPA-RO4-SFUND-2007-0473. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through www.regulations.gov or e-mail. The www.regulations.gov Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

Docket: All documents in the docket are listed in the www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in www.regulations.gov or in hard copy at the U.S. EPA Region 4 office located at 61 Forsyth Street, SW., Atlanta, Georgia 30303. Regional office is open from 7 a.m. until 6:30 p.m. Monday through Friday, excluding legal holidays.

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of this publication.