OPPT-2002-0066-0367

RECEIVED
OPPT CBIC
2003 APR -2 AM 11:38

"Liroff, Rich" <rich.liroff@wwfus.org> on 04/01/2003 04:55:22 PM

To: "Internet:" <oppt.ncic@epamail.epa.gov>
cc:

Subject: Docket No. OPPT-2002-0066 Endocrine Disruptor Screening Program

World Wildlife Fund submits the following comments, in the text of this message and also attached.

RECEIVED
OPPT NCIC
2003 APR -7 AM 7:48

April 1, 2003

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington D.C. 20460-0001
By e-mail: oppt.ncic@epa.gov

Re: Docket No. OPPT-2002-0066, Endocrine Disruptor Screening Program, Proposed Chemical Selection Approach for Initial Round of Screening

I. Introduction

World Wildlife Fund (WWF) submits the following comments regarding EPA's proposed approach for selecting the initial chemicals to be screened for endocrine disruption properties. WWF is a non-profit conservation organization with over 1.2 million members in the United States. Our involvement in the endocrine disruptor issue stems from the well-documented threats to millions of animals, and to potentially thousands of species, including humans, from these chemicals. WWF believes there is an urgent need to eliminate the endocrine threat to wildlife and humans, by identifying the chemicals responsible and ending their release into the environment as soon as possible.

Need to limit scope of EDSP Program

Although WWF played a key role in first identifying the endocrine threat to wildlife and humans and in urging EPA and world governments to act, we believe efforts to do so must be sharply focused on a relatively small number of the highest risk chemicals. As such, we believe the figure of 87,000 chemicals listed recently on EPA's website vastly overstates the desirable or likely scope of the EDSP. Instead, we think the program should focus on a sharply reduced number of chemicals that could be on the order of 1-2 percent of that figure

Moving to End Reliance on Animal Testing

To avoid unnecessary use of laboratory animals in endocrine disruptor screening and testing, WWF urges EPA to rely to the fullest extent possible on validated non-animal screens and tests. In vitro screens and tests, in addition to being more humane, promise to be quicker and less expensive. Where such tests are not yet available, WWF believes EPA ought to invest in their development as a matter of priority, and that Congress should increase funding to speed this important transition.

Need to avoid redundant testing

We underscore that, although some chemicals in use today--mainly pesticides--have been tested for acute toxicity or carcinogenicity, many may nonetheless still be potent endocrine disruptors and thus pose a threat to wildlife and people. These earlier tests, which typically relied on relatively high doses aimed at detecting cancer and other gross or readily-visible effects, do not capture the insidious endocrine damage which often occurs at much lower doses during specific stages of development. The results of this damage often show up later in life, in the form of compromised potential that includes reproductive abnormalities, increased susceptibility to various diseases, changes in behavior, and learning disorders.

Although earlier testing regimes have not adequately captured endocrine effects in humans and wildlife, WWF believes a number of chemicals have been shown to be sufficiently harmful to warrant imposing bans or severe restrictions on their use now, without need for further tests. These include pesticides such as atrazine and endosulfan.

II. **Specific Comments on EPA's Proposal**

1. EPA should clarify and narrow the scope of the EDSP, focusing its efforts on a much smaller number of chemicals than has to date been suggested.

When it publishes its next notice describing its proposed priority setting process, EPA should take the opportunity to clarify and downsize the likely scope of the EDSP. In the EDSP, EPA ought to focus on a number of chemicals on the order of 1-2 percent of EPA's list of 87,000 chemicals. These 87,000 chemicals include thousands of polymers that are not likely to be of biological concern, or which for other reasons are not likely to be a hazard to human health or the environment. On this point, EPA's own EDSTAC advisory panel suggested that approximately 20,000 to 25,000 polymers (with some exceptions) be placed "on hold", which in practice means that they are not likely to be subject to any immediate screening.

2. EPA's initial emphasis on pesticides and High Production Volume (HPV) inerts must not lead the Agency to exclude other chemicals of urgent concern which it can address using other statutory authorities. (EPA Issue for Comment A.1)

EPA has focused on pesticides and HPV inerts as the categories from which to select 50-100 of the initial chemicals for screening because these are categories it is directly mandated to address

under the FQPA. Nevertheless, the Agency should not hesitate to use its authority under other statutes to address chemicals of concern. This need not and should not significantly expand the number of chemicals EPA screens and tests, but it should ensure that potentially dangerous non-pesticide chemicals are not simply omitted from the program.

Under existing EPA authority, plastic and construction material components and brominated and fluorinated compounds merit the Agency's urgent attention. For example, evidence is accumulating of hazards from the plastic component bisphenol A, which is found in human reproductive fluid. Fluorinated compounds are accumulating globally in wildlife and humans as well, and measured concentrations of brominated compounds in Europeans and Americans have risen dramatically in recent years. Studies suggest these compounds impact the reproductive, thyroid, and other endocrine systems. Brominated and fluorinated compounds should be included in the initial screening, *unless they have otherwise been regulated or banned prior to the creation of the EDSP screening and testing battery.* (WWF notes that penta- and octa-brominated diphenyl ethers are banned in the European Union effective August 15, 2004.)

3. Although the FQPA specifies estrogen effects as one endpoint for the endocrine testing program, EPA must exercise its discretion to identify other key endpoints of concern.

In addition to estrogenic effects, EPA's screening program should look at thyroid, pancreatic, and adrenal effects, since these hormonal systems have been insufficiently addressed in the past. In particular, thyroid hormones play a critical role in early brain development. Interference with thyroid hormones during development can lead to irreversible damage such as changes in behavior and intellectual impairment.

4. EPA ought to clarify how the scope and timing of the EDSP relates to other agency testing programs, most notably the HPV program.

In prioritizing pesticides and HPV inerts for screening, EPA should take into account data already developed for the HPV program, which is off to a faster start than the EDSP program. WWF recognizes that the limited health end points addressed in the HPV program cannot substitute for the more sensitive endocrine endpoints of the EDSP program. *Yet these other effects may provide a sufficient basis for voluntary or regulatory action on specific chemicals so that screening under the EDSP will prove not to be necessary.*

5. WWF is concerned that EPA's proposed prioritizing process is too complex and may lead to unnecessary delays in devising the list of chemicals for initial screening.

(EPA Issues for Comment B1, B2, C1)

EPA's conceptual framework wisely recognizes the incompleteness of most government data sets on environmental exposures. Consequently, EPA proposes to rely on multiple sources of data. Many of these data sources, however, suffer from limited scope or are old. For example, the TEAM studies were path-breaking when conducted, but should not now be used for priority-setting.

By attempting to draw on too many incomplete exposure data bases with numerous limitations, EPA risks getting bogged down in an unwieldy analytical process. EPA should instead "keep it simple" by dramatically narrowing down the number of data bases on which it relies. We suggest a pragmatic focus on pesticides and household chemicals found in human blood, urine, and reproductive fluids in recent studies, and on pesticides most heavily used on foods most likely to be consumed by children and pregnant women. A clear benefit of this approach is that these two strategies, supplemented by information on occupational exposures and exposures of farm families and children, place the highest priority on actual measurements and on especially vulnerable populations. This is the right approach to address the primary health-related concerns about sensitive populations that underpin the FQPA.

Pesticides that are still heavily used in and around homes should be placed high on the priority list. In its rulemaking, EPA expressed reservations about the adequacy of its database for assessing the extent of residential uses. In WWF's view, even though these data are uncertain, they are preferable to data from some of the other data bases mentioned in EPA's notice. EPA should consider how it might develop some expert judgment systems to identify those chemicals of greatest concern in residential settings.

To make the database on actual exposures more robust in the coming years, WWF urges EPA to nominate pesticides and HPV inerts for analysis by the Centers for Disease Prevention and Control in future expansions of CDC's annual toxic report card on human exposures. *In the interest of reducing animal testing, EPA should not test chemicals which it has already banned or strictly regulated, except as part of suspect mixtures.*

6. **The need to continue taking account of effects on wildlife (EPA Issue for Comment A.3)**

   WWF commends EPA's proposal to examine data on contaminant concentrations in fish and sediments. It was wildlife populations that first signaled many endocrine-related effects were occurring in nature. EPA has authority under existing law to take environmental effects into account in its regulatory decisions on pesticides. In taking account of measurements of contaminants in fish and sediments, and subjecting suspect chemicals to the EDSP, EPA can help reduce the hazards to wildlife populations caused by currently-used pesticides and HPV inerts.

7. **WWF believes EPA *must* consider data on effects, and not confine its assessment to data on exposure.**

In an attempt to simplify its task, EPA has unwisely deviated from EDSTAC's recommendation that priorities be set on the basis of both exposures and effects. The Agency has proposed to focus exclusively on exposure data bases. WWF believes that the agency must not ignore effects completely, especially when its notice indicates that when enough is known about endocrine-mediating effects of a chemical, the substance will bypass screening and go directly to more detailed testing.

The pesticide atrazine highlights the hazard of minimizing effects information in setting priorities. In recent rule-makings, EPA has been reluctant to declare atrazine and other pesticides endocrine disruptors, pending the outcome of further analysis in the EDSP. In such rulemakings, e.g., for atrazine and endosulfan, WWF has argued that enough is known about endocrine disrupting effects that these data and data on other health end points are sufficient justification for outright bans. *For these chemicals, WWF urges that EPA act now and that no additional testing therefore is necessary.*

Waiting instead for the EDSP will have the perverse effect of keeping on the marketplace chemicals that ought to be banned, while promoting unnecessary tests on laboratory animals. If EPA insists that the existing endocrine data on atrazine and other pesticides are insufficient to allow it to act now, these chemicals should be placed at the very top of EPA's priority list for screening or else passed directly to Tier 2 for testing. They should be given the highest priority without resorting to complicated mathematical calculations based on multiple data bases.

WWF recommends that EPA review the data underlying its regulatory rulemakings for pesticides during the last three years. EPA should focus on each pesticide for which there is evidence of endocrine disruption (including thyroid effects) and for which there is sizeable exposure, especially of children, pregnant women, the unborn, and other vulnerable populations. If the chemical is unlikely to be banned or phased out prior to implementation of the EDSP, these chemicals should be placed at the top of the EDSP priority list for screening or else immediately be placed in Tier 2 for testing.

8. EPA's short-term emphasis on assessing individual chemicals cannot justify the Agency ignoring the most common combinations of chemicals that threaten humans and wildlife. (EPA Issue for Comment A-5)

WWF strongly disagrees with EPA's decision to avoid completely addressing the threat of chemical mixtures in the initial phase of the EDSP. While testing all the theoretical combinations of chemicals is, of course, impossible, this cannot acquit the Agency of its responsibility to test some of the more common and potentially dangerous mixtures. To this end, the EDSTAC identified specific candidate mixtures for analysis which EPA could consider, among them contaminants in human breast milk, phytoestrogens in soy-based infant formulas, and pesticide/fertilizer mixtures. Since residential exposure to commonly occurring pesticide mixtures in the U.S. is likely to be high, EPA should select the most common formulations of mixtures as determined by retail sales figures, and screen several of them simultaneously in its first round.

The need for EPA to address mixtures of chemicals is underscored by a number of recent studies showing that, when in combination with one another, groups of chemicals have endocrine effects that would not be expressed by individual chemicals alone at the same concentrations. Virtually no pesticide is used singly.

9. WWF supports EPA's short-term decision not to employ a nominations process for

selecting this initial round of chemicals for the EDSP, but we urge EPA to establish such a process expeditiously for subsequent priority-setting exercises.

WWF appreciates this opportunity to provide comment.

Richard A. Liroff, Ph.D
Policy Director
Wildlife and Contaminants Program
World Wildlife Fund
1250 24th St NW
Washington DC 20037
202 778-9644
Rich.Liroff@wwfus.org

Theo Colborn, Ph.D
Senior Scientist and Director
Wildlife and Contaminants Program
World Wildlife Fund
Washington DC

<<PrioritySettingCommentsfinal040103.doc>>
Richard A. Liroff, Ph.D
Policy Director
Wildlife and Contaminants Program
WWF Global Toxic Chemicals Program
World Wildlife Fund
1250 24th Street NW
Washington DC 20037
phone: 202 778-9644
fax: 202 530 0743

e-mail: Rich.Liroff@wwfus.org

PrioritySettingCommentsfinal040

April 1, 2003

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington D.C. 20460-0001
By e-mail: oppt.ncic@epa.gov

Re: Docket No. OPPT-2002-0066, Endocrine Disruptor Screening Program, Proposed Chemical Selection Approach for Initial Round of Screening

I. Introduction

World Wildlife Fund (WWF) submits the following comments regarding EPA's proposed approach for selecting the initial chemicals to be screened for endocrine disruption properties. WWF is a non-profit conservation organization with over 1.2 million members in the United States. Our involvement in the endocrine disruptor issue stems from the well-documented threats to millions of animals, and to potentially thousands of species, including humans, from these chemicals. WWF believes there is an urgent need to eliminate the endocrine threat to wildlife and humans, by identifying the chemicals responsible and ending their release into the environment as soon as possible.

Need to limit scope of EDSP Program

Although WWF played a key role in first identifying the endocrine threat to wildlife and humans and in urging EPA and world governments to act, we believe efforts to do so must be sharply focused on a relatively small number of the highest risk chemicals. As such, we believe the figure of 87,000 chemicals listed recently on EPA's website vastly overstates the desirable or likely scope of the EDSP. Instead, we think the program should focus on a sharply reduced number of chemicals that could be on the order of 1-2 percent of that figure

Moving to End Reliance on Animal Testing

To avoid unnecessary use of laboratory animals in endocrine disruptor screening and testing, WWF urges EPA to rely to the fullest extent possible on validated non-animal screens and tests. In vitro screens and tests, in addition to being more humane, promise to be quicker and less expensive. Where such tests are not yet available, WWF believes EPA ought to invest in their development as a matter of priority, and that Congress should increase funding to speed this important transition.

Need to avoid redundant testing

We underscore that, although some chemicals in use today--mainly pesticides--have been tested for acute toxicity or carcinogenicity, many may nonetheless still be potent endocrine disruptors

and thus pose a threat to wildlife and people. These earlier tests, which typically relied on relatively high doses aimed at detecting cancer and other gross or readily-visible effects, do not capture the insidious endocrine damage which often occurs at much lower doses during specific stages of development. The results of this damage often show up later in life, in the form of compromised potential that includes reproductive abnormalities, increased susceptibility to various diseases, changes in behavior, and learning disorders.

Although earlier testing regimes have not adequately captured endocrine effects in humans and wildlife, WWF believes a number of chemicals have been shown to be sufficiently harmful to warrant imposing bans or severe restrictions on their use now, without need for further tests. These include pesticides such as atrazine and endosulfan.

II. Specific Comments on EPA's Proposal

1. EPA should clarify and narrow the scope of the EDSP, focusing its efforts on a much smaller number of chemicals than has to date been suggested.

When it publishes its next notice describing its proposed priority setting process, EPA should take the opportunity to clarify and downsize the likely scope of the EDSP. In the EDSP, EPA ought to focus on a number of chemicals on the order of 1-2 percent of EPA's list of 87,000 chemicals. These 87,000 chemicals include thousands of polymers that are not likely to be of biological concern, or which for other reasons are not likely to be a hazard to human health or the environment. On this point, EPA's own EDSTAC advisory panel suggested that approximately 20,000 to 25,000 polymers (with some exceptions) be placed "on hold", which in practice means that they are not likely to be subject to any immediate screening.

2. EPA's initial emphasis on pesticides and High Production Volume (HPV) inerts must not lead the Agency to exclude other chemicals of urgent concern which it can address using other statutory authorities. (EPA Issue for Comment A.1)

EPA has focused on pesticides and HPV inerts as the categories from which to select 50-100 of the initial chemicals for screening because these are categories it is directly mandated to address under the FQPA. Nevertheless, the Agency should not hesitate to use its authority under other statutes to address chemicals of concern. This need not and should not significantly expand the number of chemicals EPA screens and tests, but it should ensure that potentially dangerous non-pesticide chemicals are not simply omitted from the program.

Under existing EPA authority, plastic and construction material components and brominated and fluorinated compounds merit the Agency's urgent attention. For example, evidence is accumulating of hazards from the plastic component bisphenol A, which is found in human reproductive fluid. Fluorinated compounds are accumulating globally in wildlife and humans as well, and measured concentrations of brominated compounds in Europeans and Americans have risen dramatically in recent years. Studies suggest these compounds impact the reproductive, thyroid, and other endocrine systems. Brominated and fluorinated compounds should be included in the initial screening, *unless they have otherwise been regulated or banned prior to*

the creation of the EDSP screening and testing battery. (WWF notes that penta- and octa-brominated diphenyl ethers are banned in the European Union effective August 15, 2004.)

3. Although the FQPA specifies estrogen effects as one endpoint for the endocrine testing program, EPA must exercise its discretion to identify other key endpoints of concern.

In addition to estrogenic effects, EPA's screening program should look at thyroid, pancreatic, and adrenal effects, since these hormonal systems have been insufficiently addressed in the past. In particular, thyroid hormones play a critical role in early brain development. Interference with thyroid hormones during development can lead to irreversible damage such as changes in behavior and intellectual impairment.

4. EPA ought to clarify how the scope and timing of the EDSP relates to other agency testing programs, most notably the HPV program.

In prioritizing pesticides and HPV inerts for screening, EPA should take into account data already developed for the HPV program, which is off to a faster start than the EDSP program. WWF recognizes that the limited health end points addressed in the HPV program cannot substitute for the more sensitive endocrine endpoints of the EDSP program. *Yet these other effects may provide a sufficient basis for voluntary or regulatory action on specific chemicals so that screening under the EDSP will prove not to be necessary.*

5. WWF is concerned that EPA's proposed prioritizing process is too complex and may lead to unnecessary delays in devising the list of chemicals for initial screening. (EPA Issues for Comment B1, B2, C1)

EPA's conceptual framework wisely recognizes the incompleteness of most government data sets on environmental exposures. Consequently, EPA proposes to rely on multiple sources of data. Many of these data sources, however, suffer from limited scope or are old. For example, the TEAM studies were path-breaking when conducted, but should not now be used for priority-setting.

By attempting to draw on too many incomplete exposure data bases with numerous limitations, EPA risks getting bogged down in an unwieldy analytical process. EPA should instead "keep it simple" by dramatically narrowing down the number of data bases on which it relies. We suggest a pragmatic focus on pesticides and household chemicals found in human blood, urine, and reproductive fluids in recent studies, and on pesticides most heavily used on foods most likely to be consumed by children and pregnant women. A clear benefit of this approach is that these two strategies, supplemented by information on occupational exposures and exposures of farm families and children, place the highest priority on actual measurements and on especially vulnerable populations. This is the right approach to address the primary health-related concerns about sensitive populations that underpin the FQPA.

Pesticides that are still heavily used in and around homes should be placed high on the priority list. In its rulemaking, EPA expressed reservations about the adequacy of its database for assessing the extent of residential uses. In WWF's view, even though these data are uncertain, they are preferable to data from some of the other data bases mentioned in EPA's notice. EPA

should consider how it might develop some expert judgment systems to identify those chemicals of greatest concern in residential settings.

To make the database on actual exposures more robust in the coming years, WWF urges EPA to nominate pesticides and HPV inerts for analysis by the Centers for Disease Prevention and Control in future expansions of CDC's annual toxic report card on human exposures. *In the interest of reducing animal testing, EPA should not test chemicals which it has already banned or strictly regulated, except as part of suspect mixtures.*

6. The need to continue taking account of effects on wildlife (EPA Issue for Comment A.3)

WWF commends EPA's proposal to examine data on contaminant concentrations in fish and sediments. It was wildlife populations that first signaled many endocrine-related effects were occurring in nature. EPA has authority under existing law to take environmental effects into account in its regulatory decisions on pesticides. In taking account of measurements of contaminants in fish and sediments, and subjecting suspect chemicals to the EDSP, EPA can help reduce the hazards to wildlife populations caused by currently-used pesticides and HPV inerts.

7. WWF believes EPA *must* consider data on effects, and not confine its assessment to data on exposure.

In an attempt to simplify its task, EPA has unwisely deviated from EDSTAC's recommendation that priorities be set on the basis of both exposures and effects. The Agency has proposed to focus exclusively on exposure data bases. WWF believes that the agency must not ignore effects completely, especially when its notice indicates that when enough is known about endocrine-mediating effects of a chemical, the substance will bypass screening and go directly to more detailed testing.

The pesticide atrazine highlights the hazard of minimizing effects information in setting priorities. In recent rule-makings, EPA has been reluctant to declare atrazine and other pesticides endocrine disruptors, pending the outcome of further analysis in the EDSP. In such rulemakings, e.g., for atrazine and endosulfan, WWF has argued that enough is known about endocrine disrupting effects that these data and data on other health end points are sufficient justification for outright bans. *For these chemicals, WWF urges that EPA act now and that no additional testing therefore is necessary.*

Waiting instead for the EDSP will have the perverse effect of keeping on the marketplace chemicals that ought to be banned, while promoting unnecessary tests on laboratory animals. If EPA insists that the existing endocrine data on atrazine and other pesticides are insufficient to allow it to act now, these chemicals should be placed at the very top of EPA's priority list for screening or else passed directly to Tier 2 for testing. They should be given the highest priority without resorting to complicated mathematical calculations based on multiple data bases.

WWF recommends that EPA review the data underlying its regulatory rulemakings for pesticides during the last three years. EPA should focus on each pesticide for which there is evidence of endocrine disruption (including thyroid effects) and for which there is sizeable exposure,

especially of children, pregnant women, the unborn, and other vulnerable populations. If the chemical is unlikely to be banned or phased out prior to implementation of the EDSP, these chemicals should be placed at the top of the EDSP priority list for screening or else immediately be placed in Tier 2 for testing.

8. EPA's short-term emphasis on assessing individual chemicals cannot justify the Agency ignoring the most common combinations of chemicals that threaten humans and wildlife. (EPA Issue for Comment A-5)

WWF strongly disagrees with EPA's decision to avoid completely addressing the threat of chemical mixtures in the initial phase of the EDSP. While testing all the theoretical combinations of chemicals is, of course, impossible, this cannot acquit the Agency of its responsibility to test some of the more common and potentially dangerous mixtures. To this end, the EDSTAC identified specific candidate mixtures for analysis which EPA could consider, among them contaminants in human breast milk, phytoestrogens in soy-based infant formulas, and pesticide/fertilizer mixtures. Since residential exposure to commonly occurring pesticide mixtures in the U.S. is likely to be high, EPA should select the most common formulations of mixtures as determined by retail sales figures, and screen several of them simultaneously in its first round.

The need for EPA to address mixtures of chemicals is underscored by a number of recent studies showing that, when in combination with one another, groups of chemicals have endocrine effects that would not be expressed by individual chemicals alone at the same concentrations. Virtually no pesticide is used singly.

9. WWF supports EPA's short-term decision not to employ a nominations process for selecting this initial round of chemicals for the EDSP, but we urge EPA to establish such a process expeditiously for subsequent priority-setting exercises.

WWF appreciates this opportunity to provide comment.

Richard A. Liroff, Ph.D
Policy Director
Wildlife and Contaminants Program
World Wildlife Fund
1250 24th St NW
Washington DC 20037
202 778-9644
Rich.Liroff@wwfus.org

Theo Colborn, Ph.D
Senior Scientist and Director
Wildlife and Contaminants Program
World Wildlife Fund
Washington DC