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EPA Testing Protocols for Endocrine Disruptors

Docket Comments

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The Children's Environmental Health Network appreciates the opportunity to comment on the Agency's proposal for an endocrine disruptor screening and testing program, which will be critical in identifying endocrine disruptors and forming the foundation for how we will protect children from exposure to such chemicals.

The key issue in evaluating EPA's proposed Endocrine Disruptor Screening Program (EDSP) is how confident we can be that every substance that has an hormonal effect in humans will be identified. This task is especially important in protecting children from endocrine disruptors (EDs). Children are at particularly high risk from exposure to EDs due to the extreme vulnerability of the developing hormonal systems in the fetus, the infant and the child.

Endocrine disruptors (EDs) may be responsible, at least in part, for reproductive problems in both women (e.g., endometriosis, the increasingly early onset of puberty in young girls), and men (falling sperm counts, congenital birth defects of the reproductive organ) and for increases in the frequency of certain kinds of cancer (breast, prostate, and testicular). These chemicals have also been linked to developmental deficiencies and learning disabilities in children, though the mechanisms in these deficits may not be endocrine disruption. A critical part of the endocrine system is thyroid hormone, which affects many aspects of brain development. The effects of thyroid hormone compromise or receptor resistance are effects on behavior and intellectual

development.

The Network is extremely concerned about the presence of EDs in the environment and this proposal's ability to correctly identify them. Today, more than 70,000 chemicals are allowed for use in the U.S.. For the vast majority of them, little is known about their health effects on children. An appropriate screening and testing program will be the first step in identifying substances that are EDs. This knowledge will shape policies and standards relating to the release, use, and disposal of EDs and thus, how well we protect children from exposure to EDs. An inadequate testing protocol may mean that EDs are not appropriately recognized or regulated as such, leading to inadequate protection of children.

The Network commends the Agency for many aspects of its exhaustive proposal and its close adherence, in many instances, to the recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC). Unfortunately, numerous aspects of this proposal fall short of the requirements for an effective program that offers us confidence in its findings. The Network strongly urges the Agency to revisit and improve the unacceptable provisions of this proposal. Some of these insufficiencies are outlined below in greater detail. The Agency must create a program that offers the public confidence that all hormonally-active chemicals will be identified.

**Identify All Endocrine Disruptors:** One of the Network's greatest concerns in the Agency's proposal is the implication that substances will be identified as endocrine disruptors only if they are shown to have an adverse effect.

In 1996, when Congress directed the Agency to develop this program (in the Food Quality Protection Act (FQPA)), it included its definition of the chemicals to be identified. In the Federal Food, Drug, and Cosmetics Act (FFDCA) section 408(p) (21 U.S.C. 346a(p)), Congress required the program be created "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."

The statute is clear: the program is to identify substances which "may have an effect." It does not use the term "adverse effect." This is consistent with the policy change in other sections of FQPA, which required that food-use pesticide reference doses and tolerances be based on the lowest observed, or most sensitive, effect -- not on adverse effects.

An "adverse" effect can be a difficult, subjective, time-consuming and controversial label to apply. Proof of an "adverse effect" is far different -- and far more difficult to achieve -- than identifying a chemical that "may have an effect in humans." If proof of an adverse effect is required, some chemicals that are endocrine disruptors -- that "may have an effect in humans that is similar to an effect produced by a naturally occurring [hormone]" -- will not be labeled as such. Approaches based on "effects" are more health-protective than those based on "adverse effects."

The EPA must clearly identify every chemical with any hormonal effect as an endocrine disruptor. To do otherwise would be to gravely compromise the effectiveness of this testing program, to provide misleading information and, clearly, to violate the statute.

**Expeditious Action and Adequate Resources:** Instituting this program is a challenging task that will require substantial resources from the Agency and others. This challenge is compounded by the need to move as quickly as possible given the unknown level of risk posed by these substances. We cannot begin to identify these risks if we do not even know whether or not a substance is an ED. It must be a high priority of the Agency and of this Administration to secure the resources needed for this program to assure that it progresses without delays.

Since toxicants released into the environment can result in harm to the health of children and others, the Network believes that those who manufacture, distribute, and use a chemical are responsible for demonstrating that the substance is safe prior to placing it in the marketplace. Thus, it is reasonable, given the resource needs of this testing program, to generate industry support and participation. It is only logical to turn to those who are responsible for generating the chemicals under question to share the burden of testing the safety of those chemicals.

Without adequate resources, key steps, such as standardizing and validating the proposed assays, will be delayed, thus essentially halting the program. Such delays will result in more exposures of more children over a longer time to endocrine-disrupting substances.

**Screen for All Hormone Effects:** In question one of its proposal, the Agency asks: "The FFDCFA, as amended, requires EPA to screen pesticides for estrogenic effects that may affect human health. EPA has decided that it is scientifically appropriate to focus on EAT (estrogen, androgen, and thyroid hormone systems) effects, not just estrogenic effects. Is this an appropriate scope for the Endocrine Disruptor Screening Program (EDSP)?"

The answer to this question is a strong yes. It is vital that the scope of the tests in the Endocrine Disruptor Screening Program include more than estrogenic effects, since endocrine disruption can occur in the androgen and thyroid hormone systems as well as the estrogen hormone system. EPA should be commended for seeking to assure that its screening and testing program look for effects on all of these hormone systems. No evidence has been presented that thyroid or androgen effects are somehow of less impact, of less interest or less likely to occur than estrogenic effects. The Agency should strongly resist any efforts to narrow the focus of this screening and testing program.

**Adequacy of Testing.** The EPA is to be commended for recognizing that new tests and assays will have to be created to assure that all potential hormonal impacts are reviewed. However, some serious gaps exist in the proposed testing protocols. Unless these shortcomings are rectified, the Agency will be unable to declare with confidence that a chemical is not an ED. If the public is to have confidence in a finding in the negative, a chemical will need to have completed assays that have yet to be identified, standardized, validated, and required by the Agency.

Even if all of these modifications were made, we would be unable to state with certainty that the proposed tests are adequate until the tests are validated and as the results of the tests are studied. Determining the adequacy of the testing battery needs to be an iterative process. The Agency will need to correct the tests on the basis of information it acquires as it is doing the testing. The Agency must evaluate the adequacy of testing as it proceeds and adjust the tests as defects are identified and as science advances.

The Network generally supports the EPA's recommendations for substantial improvements to the protocols of existing tests in recognition that these older tests were not adequate for answering questions about hormone disruption. Given the recognition of these inadequacies, tests that were conducted under old protocols should not be considered as complying with this program. Chemicals that have gone through earlier versions of a test must be required to fill the information gaps between the earlier and the improved test protocols.

Some of the Network's specific concerns follow.

**Adequacy of Testing: Developmental Effects:** The absence of an assay in Tier 1 that looks at crucial development stages, when an organism is particularly vulnerable to toxicants, is a critical gap. The Agency

must place a high priority on the creation of such an assay and its inclusion as one of the mandatory tests.

The National Academy of Sciences, in its report, "Pesticides in the Diets of Infants and Children," recognized the importance of developmental toxicity testing and recommended improved testing procedures that included testing during critical periods of development.

Given the unique susceptibility of developing organisms to EDs, and, often, the highly specific periods of vulnerability of developing organisms in different stages of development, it is crucial that all stages of development -- especially fetal, neonatal and pubertal stages -- must be studied for the effects of exposure to EDs.

The absence of this assay is perhaps the greatest single deficiency in the screening and testing battery. The Agency must place a priority on identifying such an assay and requiring that all chemicals are to be subject to it, without exemptions.

**Adequacy Of Testing: Reproduction & Development:** In Section V. B. 1. i., the Agency states: "Table 2 provides a summary of the endpoints evaluated within the framework of the experimental design of the updated 2-generation reproductive toxicity test (and some recommended additional endpoints for validation and inclusion to cover EAT concerns). These endpoints are comprehensive and cover every phase of reproduction and development."

The Network believes that the endpoints listed are not comprehensive and, as mentioned earlier in these comments, certainty of the completeness of this testing protocol can only emerge as tests are conducted and evaluated. At least one additional endpoint to be considered is bone growth and bone malformations. Additional concerns are discussed in the following section.

**Adequacy of Testing: Behavioral Effects:** The tests recommended by the Agency will not be adequate for identifying behavioral effects, especially subtle and long-term effects. The Agency's pre-FQPA toxicity testing protocols (which form a large part of the EDSP program) do not include endpoints that are sensitive enough to recognize behavioral effects. Although the Agency is proposing a number of changes to these existing protocols, which the Network supports, endpoints that would answer concerns regarding less severe behavior effects in humans are lacking. Examples of endpoints of concern are aggression and attention span. The institution of a developmental neurotoxicity testing requirement provides perhaps the greatest step forward in filling these information gaps. However, the Network remains concerned that some behavioral effects will be missed.

For example, the Agency appears to rely heavily on the two-generation reproductive toxicity test (with endpoints in addition to those required in current EPA harmonized 1998 test guidelines) for recognizing behavioral endpoints. In its description of the mammalian reproductive toxicity test, the Agency states ". . . potential hormonal effects can be detected through behavioral changes. . ."

The Network strongly supports the addition of these endpoints to this test, yet remains concerned that the endpoints are insufficient for all behavioral endpoints. The only behavioral endpoints mentioned in the existing 1998 testing guidelines are mating and sexual behavior. While important, these are not the only behavioral endpoints of interest.

The Agency should assure that the improved testing guidelines are adequate by conducting the test on a variety of known neurotoxicants, such as lead, which have effects on human behavior at even very low levels of exposure. The Network believes such validation is critical.

**Adequacy of Testing: Multigenerational Impacts:** The Agency states in Section V. B. "Tier 2 Testing": "Effects associated with endocrine disruption may be latent and not manifested until later in life or may not appear until the reproductive period is reached." The Network agrees with this statement, but believes it is far too narrow. The time frame for concern is much longer and the effects of concern are not just reproductive.

Some effects may occur only in the offspring or even in later generations. Thus, tests covering only one generation are not adequate to identify latent or multigenerational effects.

Thus, the Network is concerned about language in Section V. B.: "Unless a rationale exists to limit the test to 1 generation, tests for endocrine disruption will usually encompass 2 generations. . ."

What would be the rationale for limiting the test to one generation? If the Agency believes that such a rationale exists, it should present the rationale for public comment. The Network believes no such rationale exists and, as outlined earlier in this section, urges the Agency to require 2-generation tests.

**Low-Dose Testing and Number of Doses:** The Network is puzzled by some of the Agency's statements regarding the number of doses to be required in testing. In discussing the Tier 1 testing battery under "4. Selection of doses in screening assays," the Agency states: "EDSTAC recommended that in vivo screening assays be conducted at a single-dose level to save testing resources." This statement is curious, since EDSTAC's report did not include that recommendation. EDSTAC stated: "Subject to the results of the validation process, the EDSTAC recommends using one or more dose levels in the performance of the in vivo assays." (EDSTAC Final Report, p. 5-78)

Then the Agency states at the beginning of the notice's question nine: "EPA is planning to require that the Tier 1 screening in vivo assays be conducted at one dose, with appropriate use of range finding studies and other information (i.e., High Throughput Pre-Screen (HTPS) results) to inform dose selection. The single-dose approach was adopted to save testing resources."

If the Agency is indeed planning to follow EDSTAC's recommendations for the EDSP, it will have to reconsider those statements and provide its reasoning for its single-dose decision. The "recommendation" reported in the notice is not accurate and thus cannot be used to justify the Agency's decision to use a single dose level. In addition to the fact that single-dose testing was not endorsed by EDSTAC, the Agency's own scientific advisors are concerned that relying on a single-dose level might give false negative results, as the Agency correctly notes in the text of question nine.

Thus, ultimately, question nine: "Does the potential risk of false negatives outweigh the cost savings of running the Tier 1 screening in vivo assays with only one dose?" inappropriately concentrates on "cost savings." Given the concerns raised by its own peer reviewers and the recommendation of EDSTAC that this issue must be considered in the validation process, the Agency should clearly proceed with multiple dose testing.

EDSTAC also recommended that EPA should undertake and complete within six months a program to clarify low dose issues. Yet this notice makes no mention of an EPA timeline to initiate and complete a low dose research program. Again, this is curious given the Agency's statements that it supports the EDSTAC recommendations. The silence on this recommendation is troubling.

The Network urges EPA to recognize these concerns and to move quickly in researching and resolving them so that low-dose screening and testing becomes an integral part of its program. The Agency should propose and seek comment on a plan and schedule for initiating and completing a low-dose testing program. If low-dose levels are not adequately built into the screening tier, the program will be deeply flawed.

The Network strongly supports testing at several dose levels. Relying on a single-dose level could miss effects that emerge at very low doses, giving false negative results.

**Substantial Population:** In question 17 of this notice, the Agency asks "How should EPA define substantial population as used in FFDCa section 408(p) and SDWA section 1457?"

The Agency should consider each of the following categories of children as a "substantial population" to be considered: the fetus, the infant, the toddler, the child, and the adolescent. The exposure patterns and diets of each of these groups varies greatly within the population of "children" depending upon their stage of development, as does the impact of exposure to an endocrine disruptor. As the Agency notes, "there is little doubt that small disturbances in endocrine function, especially during certain highly sensitive stages of the life cycle. . . can lead to profound and lasting effects." Arguably, a child in one of these "highly sensitive stages" may be more profoundly affected than someone who is older and the impact may be more severe and would be more likely to be life-long. Due to the increased risk of life-long impact, each of these groups is a "substantial population" due to their differing and unique susceptibilities.

Additionally, the Agency should consider as a "substantial population" those groups of children whose exposures and/or susceptibilities to toxicants are known to be or are reasonably expected to be greater than those of children in general. Groups that would fall under this definition include children in agricultural areas, children whose parents are farmworkers and/or who are farmworkers themselves, and children living in low income and/or minority communities with high levels of toxicants present.

**Use Of Estimates:** In Section IV. C. 1. ii., the Agency states: "In the absence of monitoring data, estimates from the National Occupational Environment Survey, Permissible Exposure Limits (PELs) and similar estimates will be used to infer potential exposure levels. These estimates are much less robust than monitoring data but will be used unless actual monitoring data are submitted."

The sources of exposure estimates that the Agency is proposing to use reflects the exposure patterns of adults, which is inadequate for estimating the exposure of children, as outlined by the NAS in "Pesticides in the Diets of Infants and Children." The Agency should pursue the actual monitoring of children's exposures and use actual data reflecting children's real-world exposures.

**Mixtures:** In Section IV. G., the Agency states: "EPA also plans to evaluate some mixtures in the Tier 1 screen. If results of Tier 1 are positive for a mixture, the Agency will face a choice of testing the mixture in Tier 2 or determining what substances, or combination of substances, are responsible for the activity. The Agency likely will choose this latter course of action and test the individual active chemical or active fraction in Tier 2." Later, in question 7e, the Agency asks: "If a mixture is positive in Tier 1, should the whole mixture be tested in Tier 2 or should EPA attempt to identify the active component(s) and test it (them) in Tier 2?"

The Network supports the testing of a mixture as a whole rather than as separate components. To test component parts separately would eliminate the possible discovery and measurement of synergistic activity.

**Exemptions From the Screening Program:** In question two of this notice, EPA asks: "Are there classes of chemicals besides the ones identified in Unit VI. L. of this notice that should be exempted (excluded) from the EDSP? What criteria and what burden of proof should be applied to claims of persons seeking to exempt

chemicals from screening? What type of process should EPA establish?"

Given that no method of predicting the hormonal effect of chemicals yet exists, the Agency has no basis for exempting any chemicals from the Endocrine Disruptor Screening Program. If, in the future, the Agency considers providing exemptions to a class of chemicals, the Agency should institute such exemptions through the rule-making process to allow for adequate public discussion and review.

The Network believes additional information should be provided as to how the Agency arrived at its decision to exempt the substances "identified in Unit VI. L." The Agency should present how it determined, before the beginning of testing, that entire classes of chemicals, such as certain "inert" chemicals, are "virtually non-toxic."

If the Agency has lessened concerns about a category of chemicals, it has the ability to give them lower priority in the testing schedule as part of the priority-setting process. The Network believes there is not adequate evidence to exempt any category of chemicals from testing.

**Exemptions From Full Tier 2 Testing:** In question 20a) of this notice, EPA asks: Should EPA permit chemicals to receive less than the full Tier 2 testing battery under certain circumstances?

The Agency expands on this question in its discussion under "B. Tier 2 Testing": "Considerations for determining whether the full battery of comprehensive tests should be implemented include an understanding of mechanisms of action, environmental fate and transport, persistence, potential for bioaccumulation, and potential exposure. EPA plans to require that all tests be performed in Tier 2 with all endpoints, unless compelling information is presented to show why testing should be limited."

It is difficult to provide a detailed answer to this question unless one knows how the Agency would define "certain circumstances" and "compelling information." Both of these terms, without better definition, are open to interpretation.

It is clear, however, that exemptions from the full Tier 2 testing battery should be extremely rare. If the basis for exemption is "an understanding of mechanisms of action, environmental fate and transport, persistence, potential for bioaccumulation, and potential exposure," virtually all chemicals would be ineligible for exemption. We do not have this information for the vast majority of chemicals, especially as related to developing organisms and the long-term impact on such organisms.

The Agency should not allow less than full Tier 2 testing for a chemical except in only the rarest cases, and then only after public notice and comment.

Similarly, it should not allow for replacement tests or "functionally equivalent information" from the battery proposed. Section V. B. 2. i. allows for replacement of an alternative mammalian reproduction test for the two-generation reproductive toxicity test as well as for replacement of the one-generation reproductive toxicity test.

The Network would be extremely concerned if tests and assays not approved as part of the testing battery are permitted to supplant tests in the battery. The theoretical basis of the EDSP battery of tests was to identify all relevant end points for all relevant exposures and the battery was carefully designed to meet this task. Tests that differ because they look at other endpoints and/or exposures by their definition do not qualify under the testing battery. If the Agency believes a different test can supplant a test in the battery, that test should be put under the same scrutiny as the tests in the EDSP battery, rather than as a brief aside in this notice.

Bypassing Tests: Just as the Agency has insufficient information to assure that classes of chemicals can be safely exempted from the testing program, it has little information to assure that chemicals can bypass screens or tests without risking the loss of relevant information. The Network is concerned about the range of exemptions to testing that the Agency is proposing.

In Section IV. B. 3., the Agency proposes that some chemicals can bypass Tier 1 testing by several routes or reasons. "Recognizing the need for flexibility, EPA has included the possibility of bypassing Tier 1 screening. For example, if sufficient, scientifically relevant information already exists regarding a specific chemical, EPA may move that chemical directly into Tier 2 testing." What is the definition of "sufficient, scientifically relevant information"? What information that normally would be acquired through Tier 1 testing does the Agency feel can be omitted for certain chemicals? And if this information is not needed for certain chemicals, why was it required in the Tier 1 battery?

And, in this same section: "EPA may allow a chemical to bypass Tier 1 if the chemical's producer or registrant chooses to conduct Tier 2 testing without performing Tier 1 screening." What are the conditions under which a producer or registrant can choose to bypass Tier 1 screening? Are there any conditions before Tier 1 can be bypassed, or can any chemical avoid Tier 1 screening? What will be the information that will not be available to the Agency and the public as a result of such an omission, and how will the absence of this information affect Tier 2 testing?

In Section IV. F. 1., the Agency proposes: "Chemicals that have previously been subjected to two-generation reproductive toxicity tests" can bypass Tier 1 screening. Given that the Agency and EDSTAC determined that the pre-FQPA two-generation reproductive toxicity test protocol is inadequate to include in Tier 2 testing without substantial improvements (which were proposed), how can the Agency justify bypassing tests based on studies done under the previous, admittedly inadequate, protocol?

In Section IV. F. 2., the Agency proposes: "Chemicals for which there is limited prior toxicology testing" can bypass Tier 1 screening. How many chemicals does the Agency estimate fall into this category? How does the Agency define "limited prior toxicology testing"?

In general, does the Agency see the chemicals that it allows to bypass Tier 1 screening as more likely to be high priority candidates for Tier 2 testing, or low priority for such testing? In Section II. B., the Agency states: "a negative result in all Tier 1 screening tests will be adequate to determine that a particular substance is not likely to have an effect on the estrogen, androgen, and thyroid hormone systems (EAT) and, therefore, is not a priority for testing in Tier 2. The confirmatory tests in the Tier 2 testing stage are necessary to determine whether a substance may have an effect similar to that of a naturally occurring hormone." Does this mean that chemicals that bypass Tier 1 because they have "limited prior toxicology testing" or "have previously been subjected to (a) two-generation reproductive toxicity test," and such tests are judged to show no hormonal effect, can go to the bottom of the priority list for Tier 2 testing? Does this provide an incentive to bypass Tier 1 screening? Creating such an incentive appears to be a possibility, which is a concern to the Network. The purpose of EDSP is to provide vital information about the effects of chemicals on humans and wildlife. The testing process should provide manufacturers and registrants with encouragement to test promptly and completely. Yet the array of exemptions and bypasses that the Agency is proposing for the program provides the reverse incentive -- to rely on older, inadequate testing protocols and to delay completion of the full array of tests. Such a reverse incentive is unacceptable and contrary to the intent of this program.

A similar concern emerges in the Agency's discussion of bypassing tests in terms of what it implies for chemicals that don't bypass Tier 1. "The second bypass scenario includes chemicals whose manufacturer or registrant has decided to voluntarily complete Tier 2 testing without having completed the full Tier 1 screening battery or any prior two-generation reproductive toxicity testing. Chemicals that bypass Tier 1 screening under this scenario must be evaluated using the entire Tier 2 battery (i.e., the mammalian and non-mammalian multi-generation tests with all the recommended test species and endpoints) unless scientifically sound reasons are provided to limit testing."

The implication of this last sentence is that chemicals that don't bypass Tier 1 testing are somehow rewarded

by being subject to fewer tests in Tier 2. The Agency should clarify this point and explain the rationale for creating an exhaustive testing protocol to assure that all EDs are identified, rather than creating numerous situations in which chemicals do not have to undergo the full testing battery.

This proposed series of exemptions and loopholes may be better understood if all of the necessary screens and assays had been created (which has not yet happened), standardized and validated (which has not happened for a number of these tests); a variety of chemicals had gone through the program; and the results had been reviewed and patterns regarding ED chemicals had been identified. Science is far from that point. Thus, the Agency has a long way to go before it is in a situation where it can allow test exemptions or "bypasses" with assurances that key information will not be missed.

If the Agency cannot answer its question 13 -- "Will the Tier 2 tests be adequate to detect all known EAT endpoints in chemicals that bypass Tier 1 screening?" -- with a confident "yes" it cannot allow chemicals to bypass Tier 1 screening. Clearly science and the Agency do not yet have an answer to this question.

High Throughput Pre-Screen (HTPS): The Network strongly agrees with the proposal in Section VI. C. that EPA will subject chemicals to HTPS that will bypass Tier 1 screening as well as those that "need" screening, if the Agency should, unwisely, allow chemicals to be exempted from Tier 1 screening.

If chemicals are allowed to bypass Tier 1 screening, it is imperative that such chemicals are, at the least, subject to HTPS, assuming HTPS is proven to be accurate in identifying EDs. Since HTPS is far from being proven and implemented, it is all the more imperative that chemicals are not exempted from any part of the testing battery.

Regarding question six: "EPA is soliciting industry's cooperation in supplying chemicals for the HTPS. Is this an appropriate role for industry and is industry willing to do so?"

It is not only appropriate for industry to supply the chemicals to be tested under HTPS, it is appropriate for industry to pay for the testing. Those who wish to bring a chemical into the world of commerce, and thus, into the environment, leading to potential exposures by humans, domesticated animals and wildlife, have the responsibility of assuring that any such exposures are safe.

Public Information: The Agency did not address in this notice the important issue of disclosure to the public. The Network strongly supports the Agency's recent focus on "right to know" and its policies committing to greater public access to information, as illustrated in the 1996 report, "Environmental Health Threats to Children." In that report, the Agency outlined the principles of its "Family Right to Know Initiative:"

"assist parents in assessing and avoiding unique environmental health risks to children. . . , provide information on the whole range of environmental health risk from toxics, including cancer, developmental, endocrine and reproductive risks; and allow for informed consumer choices by providing improved information."

The report then goes on to "call on American parents, teachers and community leaders to take personal responsibility for learning about the hazards that environmental problems pose to our children" and commits that the Agency will "provide them with the information they need to help protect children from those risks at home, at school and at play."

Given both the Agency's repeated commitments to broad public disclosure of environmental health information and its challenge to the public to become informed about environmental hazards, it is incumbent upon the Agency to commit that all information developed under the EDSP is available to the public.

The Agency should clearly state that all results of the EDSP, at all tiers, will be available to the public.

Regulatory Impact: In Section IV. F. 2., the Agency states: "EPA does not intend to delay tolerance reassessments, re-registration or registration renewal actions to await implementation the EDSP."

Since the Agency will be moving forward with the regulatory decisions mentioned above without information on a chemical's endocrine disrupting status, under FQPA the Agency clearly must retain the ten-fold safety factor required by FQPA when making these decisions. The statute is clear: this margin of safety can be changed only if, on the basis of reliable data, such margin will be safe for infants and children. The Agency admits it will not have reliable data on this aspect of a pesticide's potential impact on children. To remove or lessen this margin of safety would be to violate the statute.

## Conclusion

The Agency is to be commended for a valuable first step in the process of identifying substances that are endocrine disruptors and should oppose any suggestions to weaken or shortcut its proposal. Rather, the Agency should seek to fortify the testing protocols and eliminate the exemptions and bypasses to testing to assure the inadequacies in its current proposal are properly addressed.

The main concepts guiding the Agency's decisions should be:

he definition of "endocrine disruptor" should include any substance that has any effect on hormonal systems.

Once an adequate testing protocol has been identified, the Agency should move forward expeditiously and with all possible resources to validate this protocol.

Since little evidence exists that indicates that any chemicals should be exempted from testing or allowed to bypass certain tests, exemptions and "by-pass conditions" are rarely if ever justified.

The Endocrine Disruptor Screening Program must provide confidence that it is identifying endocrine disruptors with a minimum of false negatives.

We appreciate the opportunity to submit these comments.

Sincerely,

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