September 20, 2007

The Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Dear Administrator Johnson:

Earlier this month, the U.S. Environmental Protection Agency (EPA) briefed staff members of the House Committee on Oversight and Government Reform on the implementation of the agency's endocrine disruptor screening program. We are writing to express our serious concerns over the agency's inability to assure the Committee that it is taking adequate and timely steps to protect the American public from dangerous endocrine-disrupting chemicals. To date, EPA's efforts in this area have been characterized by missed deadlines, prolonged delays, and inadequate incorporation of public input. EPA's actions have been a continued failure to protect the American public from these chemicals. We urge you to take immediate steps to carry out Congress' directive to test and control dangerous endocrine disrupting substances.

Endocrine disruptors interfere with important hormonal and developmental processes in a wide variety of species, including humans. These substances mimic or alter natural hormonal processes, changing the way the body functions.[1] While many endocrine disruptors have desirable primary effects, such as pest control and human fertility enhancement, they also pose a number of dangerous risks when unintentionally ingested through food and drinking water. These risks include an increased risk of cancer, birth defects, and nervous system damage.[2] Dioxin, PCBs, DDT and the drug DES are just a few of the chemicals known to disrupt human

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[1] David A. Schwartz, MD and Kenneth S. Korach, PhD, *NIEHS Director's Perspective: Emerging Research on Endocrine Disruptors*, Environmental Health Perspectives, A13 (January 2007).

[2] Agency for Toxic Substances and Disease Registry, ToxFAQs on Chlorinated Dibenzo-p-dioxins (CDDs), Polychlorinated Biphenyls (PCBs), DDT, DDE, and DDD (online at http://www.atsdr.cdc.gov/tfacts104.html; http://www.atsdr.cdc.gov/tfacts17.html; http://www.atsdr.cdc.gov/tfacts35.html) (accessed Sept. 18, 2007).

endocrine systems.[3] Many other chemicals, particularly those used in pesticides and plastics, are suspected endocrine disruptors based on limited animal studies.[4]

Congress first called on EPA to address the issue of endocrine-disrupting chemicals more than ten years ago. The 1996 Food Quality Protection Act (FQPA) required EPA to establish by August 1999 a program to screen pesticides for possible endocrine disrupting effects.[5] The results of this program should have been incorporated into all pesticide tolerance decisions by the agency since that time.[6] The Safe Drinking Water Act Amendments of 1996 included a provision authorizing EPA to screen drinking water contaminants for possible endocrine-disrupting properties as well.[7] Today, more than ten years after these laws were passed and eight years after the FQPA deadline, EPA has not tested a single chemical for endocrine-disrupting effects according to the 1996 provisions.

Last year, the Committee on Oversight and Government Reform initiated an inquiry into the reasons behind this continued delay. In October 2006, the Committee held a hearing on the status of the endocrine disruptor program and the discovery of hormonally-imbalanced intersex fish in the Potomac River watershed.[8] EPA Assistant Administrator Ben Grumbles testified at this hearing, and asserted that the agency would "work harder and faster in making more

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[3] University of Minnesota, *Environmental Estrogen Endocrine Disruptors: An Overview of Ten Notable Times When Humans or Wildlife Have Been Exposed to Endocrine Disruptors* (Fall 2003) (online at http://enhs.umn.edu/5200/estrogen/history.html).

[4] Natural Resources Defense Council, Issues: Health; Endocrine Disruptors (online at http://www.nrdc.org/health/effects/qendoc.asp) (accessed Sept. 18, 2007).

[5] The 1996 FQPA calls on EPA to "implement" a screening program "not later than 3 years after the date of enactment." Such a program shall "us[e] 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 the Administrator may designate." 21 U.S.C. § 346a(p).

[6] *See* 21 U.S.C. 346a(b)(2)(D) Federal Food, Drug, and Cosmetic Act.

[7] The 1996 SDWA amendments state that EPA may screen for endocrine disrupting properties of "any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such a substance." 42 U.S.C. § 300j–17.

[8] House Committee on Government Reform, *Hearings on Ova-Pollution in the Potomac: Egg-Bearing Male Bass and Implications for Human and Ecological Health*, 109th Cong., (Oct. 4, 2007) (H. Rept. No. 109-186) (online at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_house_hearings&docid=f:30340.wais).

progress" to implement an endocrine disruptor screening program to protect the public from these harmful chemicals.[9]

Almost a year later, EPA has made little progress towards the statutory goals of identifying these dangerous chemicals. We are trying to understand why this process is moving so slowly and what can be done to speed it up. In particular, we are focusing on a few key areas of concern: (1) the agency's prolonged delay in initiating a testing program for endocrine disrupting chemicals; (2) the agency's failure to establish a plan and timeline for completing each step of the testing program; and (3) potential flaws in the test batteries to be used to screen chemicals for endocrine disrupting properties.

EPA has decided to screen for endocrine disrupting chemicals through a two-step testing process in which the agency will require pesticide manufacturers to test the chemicals they manufacture and process. After EPA identifies the chemicals to be tested, manufacturers will be required to execute a battery of rapid-result "Tier 1" tests on these chemicals to determine if they have the potential to interact with the estrogen, androgen, or thyroid hormone systems. Chemicals flagged by the Tier 1 tests will then undergo more intensive "Tier 2" tests to confirm that they are endocrine disruptors, determine how they interfere with the endocrine system, and identify the dose levels that may trigger such effects.[10] If a chemical tests positive under Tier 2, EPA may choose to take regulatory action to protect against exposures to that chemical. This screening program design requires EPA to select and validate the Tier 1 and Tier 2 tests, as well as identify and prioritize chemicals to be tested. Manufacturers must then conduct the tests, and EPA must analyze the data they provide

Over the past ten years, EPA has not completed a single step of this multi-stage process. This summer, the agency finally published its first *draft* list of chemicals to be screened by pesticide manufacturers for endocrine disrupting properties.[11] This initial list of 73 chemicals is only a small fraction of the universe of 1,700 chemicals that the agency has identified for

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[9] House Committee on Government Reform, Testimony of EPA Assistant Administrator Ben Grumbles, *Hearings on Ova-Pollution in the Potomac: Egg-Bearing Male Bass and Implications for Human and Ecological Health*, 109th Cong., (Oct. 4, 2007) (H. Rept. No. 109-186) (online at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_house_hearings&docid=f:30340.wais).

[10] U.S. Environmental Protection Agency, Endocrine Disruptor Screening Program: EDSP Phases (online at http://www.epa.gov/endo/pubs/edspoverview/components.htm) (accessed Sept. 18, 2007).

[11] U.S. Environmental Protection Agency, *Draft List of Initial Pesticide Active Ingredients and Pesticide Inerts to be Considered for Screening under the Federal Food, Drug, and Cosmetic Act,* 72 Fed. Reg. 33486 (June 18, 2007).

screening under the FQPA mandate,[12] and a minute percentage of the 75,000 chemicals currently listed on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory.[13] EPA apparently has no internal deadline for identifying subsequent sets of chemicals for testing, and no plan whatsoever for ensuring that all chemicals of potential concern will be tested.

EPA also apparently has no internal deadlines for completing the testing process even for this initial set of 73 chemicals. Based on EPA staff's rough estimates for the timing of each step of the testing and assessment process, it may take seven years or more to complete tests for this group of 73.[14] Assuming that EPA identified the same number of chemicals for testing each year, testing for the pesticide chemicals alone would not be completed for roughly 30 years, and testing for other chemicals listed under the TSCA Inventory could take hundreds of years. This pace is unacceptably slow and fails to protect the American public from thousands of dangerous chemicals that may interfere with vital biological processes.

Please address these concerns and respond to the following questions:

1. How can EPA speed up this process?
   a. What is the minimum length of time manufacturers will need to test a chemical under Tier 1?
   b. What is the minimum length of time manufacturers will need to test a chemical under Tier 2?
   c. How many chemicals can be tested simultaneously?
   d. Can the time for testing be shortened?
2. When will EPA publish subsequent draft and final lists of chemicals to be tested?
3. Will the agency provide for concurrent testing of chemicals or does it intend to complete the process for the first set of chemicals prior to beginning the next set?
4. How many chemicals does EPA anticipate it will include on subsequent draft lists?
5. Will EPA commit to identifying a minimum number of chemicals to be tested each year? How many?
   a. At that rate, when will all of the pesticide chemicals be screened as the statute requires?
   b. At that rate, when will all of the other chemicals of potential concern be screened under the SDWA authority?

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[12] *See* Letter from EPA Assistant Administrator Ben Grumbles to Rep. Henry A. Waxman, 5 (Jan. 24, 2007).

[13] *See* U.S. Environmental Protection Agency, New Chemicals Program: What is the TSCA Inventory? (online at http://www.epa.gov/opptintr/newchems/pubs/invntory.htm) (accessed Sept. 19, 2007).

[14] EPA Briefing of House Committee on Oversight and Government Reform staff (Sept 11, 2007).

EPA has also failed to issue a timeline outlining the dates by which it will complete the other steps it considers necessary for implementing an endocrine disruptor screening program: finalizing the tests that will make up the Tier 1 and Tier 2 test batteries; standardizing testing procedures; issuing testing orders to pesticide manufacturers, analyzing data submitted by pesticide manufacturers, and issuing new regulations for chemicals identified as endocrine disruptors. Please submit a detailed outline of when EPA will complete each of these phases, and include in your answer responses to the following questions:

6. When will the Tier 1 testing battery be finalized?
7. When will EPA finalize the testing procedures for the Tier 1 tests?
8. When will Tier 1 testing orders be issued to PMPs for this first list of 73 chemicals?
9. How much time will PMPs be given to execute these tests?
10. When EPA receives testing results from PMPs, how long will it take the agency to determine which chemicals must be tested using Tier 2 tests?
11. When will the Tier 2 battery be finalized?
12. When will EPA finalize the testing procedures for the Tier 2 tests?
13. When will Tier 2 testing orders be issued to PMPs, for those chemicals that fail the Tier 1 screens?
14. How much time will PMPs be given to execute these tests?
15. When EPA receives testing results from pesticide manufacturers, how long will it take the agency to weigh the results, and if necessary, issue a new regulation for a chemical of concern?

In addition, we are concerned about the content of the tests to be included in the Tier 1 and Tier 2 batteries. The Tier 1 tests should flag all chemicals that have the potential to disrupt endocrine systems at any stage of development – prenatal, child and adult. Please explain how EPA is ensuring that no chemicals "fall through the cracks," and that the endocrine disruptor screening program will indeed protect the public from all chemicals of concern. Please include in your response answers to the following questions:

16. What tests will be included in the Tier 1 battery? What effects will these tests screen for?
17. Staff mentioned that a test for prenatal effects will not be included in either the Tier 1 or Tier 2 batteries.[15] Why is this the case, when endocrine disrupting chemicals can have such profound effects on developing fetuses?
18. We understand that there has been some concern over the rat strain that EPA will require manufacturers to use in the Tier 1 tests — specifically, that EPA may require a strain that is less sensitive to some endocrine disrupting effects.[16] Is EPA aware of this concern? Has EPA made a decision on what strain to use? If so, what is it? If not, what strains is

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[15] EPA Briefing of House Committee on Oversight and Government Reform staff (Sept 11, 2007).

[16] *Scientists Question EPA's Chemical Screenings*, The Dallas Morning News (May 29, 2007).

the agency considering? Will EPA commit to not selecting a rat strain that may not be sufficiently sensitive to endocrine disrupting effects?

19. What tests will be included in the Tier 2 battery? What effects will these tests screen for?
20. How does the agency plan to weigh conflicting evidence put forward by PMPs? What if the same pesticide passes a Tier 1 test undertaken by one PMP, but fails that same test undertaken by another PMP?
21. How does the agency plan to weigh conflicting evidence put forward by PMPs in Tier 2 tests?
22. How does the agency plan to weigh conflicting evidence gathered in the two rounds of testing?

We also have a number of concerns about the draft listing process. We request more information about the chemicals included on the first draft list, why they were selected, and how EPA plans to select chemicals for future lists. Please respond to the following questions:

23. We understand that EPA selected the chemicals included on the first draft list based on potential for exposure.[17] Will EPA use a similar methodology to select chemicals to be included on subsequent lists?
24. How will EPA consider substances other than pesticides for inclusion on future draft lists? In particular, what are the agency's plans for including chemical mixtures and persistent and bioaccumulative chemicals present in drinking water, waste water and commonly used consumer products? Will EPA commit to including a minimum number of such chemicals in each list?
25. EPA has included on its initial draft list for Tier 1 testing a number of chemicals — such as atrazine — that are known endocrine disruptors. Why is EPA wasting valuable agency resources by subjecting such chemicals to Tier 1 tests, when they could be immediately moved to the more intensive Tier 2 testing program?

Lastly, we are troubled by the lack of opportunity for public participation in the endocrine disruptor screening program. In particular, there are no mechanisms by which the public may participate in the draft listing process. Please outline EPA's plans for increasing opportunities for public participation, and include in your response answers to the following questions:

26. Why has EPA failed to set up a nomination process by which members of the public may submit suggestions for chemicals to be considered for draft listing? Does the agency plan to initiate such a program?
27. We understand that the public is unable to notify EPA when it can demonstrate that a chemical is a known endocrine disruptor and should be moved immediately to the second round of testing. This process would save valuable agency resources and grant the public

[17] Letter from EPA Assistant Administrator Ben Grumbles to Rep. Henry A. Waxman, 5 (Jan. 24, 2007).

a right already extended to pesticide manufacturers. Does EPA plan to initiate such a process?

Please submit responses to these questions by no later than October 18, 2007. We urge EPA to carry out its commitment to work "harder and faster in making more progress" in implementing a comprehensive, timely and scientifically sound endocrine disruptor screening program. It has been over ten years since Congress called on EPA to protect the public from dangerous endocrine-disrupting chemicals.

The Committee on Oversight and Government Reform is the principal oversight committee in the House of Representatives and has broad oversight jurisdiction as set forth in House Rule X. If you have any questions concerning this request, please have your staff contact Alexandra Teitz of the Committee staff at (202) 225-4407.

Sincerely,

Henry A. Waxman
Chairman
Committee on Oversight and Government Reform

Tom Davis
Ranking Member
Committee on Oversight and Government Reform

Elijah E. Cummings
Chairman
Subcommittee on Coast Guard and Maritime Transportation, Committee on Transportation and Infrastructure

Chris Van Hollen
Member of Congress

Eleanor Holmes Norton
Member of Congress

Wayne T. Gilchrest
Member of Congress

Jim Moran
Member of Congress

Enclosure