Via email: Earley.Green@mail.house.gov

June 14, 2010

The Honorable Joe Barton
House Subcommittee on Energy and Environment
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: Response to written questions related to the May 13, 2010 Subcommittee hearing on the Assistance, Quality, and Affordability Act of 2010.

Dear Congressman Barton,

Thank you for your written questions related to my May 13, 2010 testimony before the House Subcommittee on Energy and Environment related to the Assistance, Quality, and Affordability Act of 2010. Following are my written Responses.

1. Your testimony states that the timelines in the legislation should be matched up to synchronize with the existing work of the Endocrine Disruptor Screening Program. What practical as well as financial benefits do you think would accrue from such an approach?

Response

EPA has adopted a phased approach for implementing its Endocrine Disruptor Screening Program (EDSP).[1] Pursuant to the current EPA approach, the Agency has ordered Tier 1 Screening for 67 pesticide active and inert chemical ingredients. After receiving results for this first phase of screening, which is expected to take up to two years after the initial orders were issued, EPA intended to review and revise as necessary its Tier 1 battery prior to issuing new

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1 *See,* EPA's final EDSP Policies and Procedures, *Endocrine Disruptor Screening Program; Policies and Procedures for Initial Screening*, 74 Fed. Reg. 17650, Apr 15, 2009 ("EDSP Policies and Procedures"). *See, also, Final List of Initial Pesticide Active Ingredients and Inert Ingredients to be Screened Under the Federal Food, Drug, and Cosmetic Act*, 74 Fed. Reg. 17579, Apr. 15, 2009 ("EDSP Listing").

testing orders.

Although EPA has worked to validate individual Tier 1 screening assays, the Agency has not yet validated the Tier 1 battery. Information from the initial screening phase should be useful for validating the battery. Further, concerns remain as to the usefulness, accuracy and repeatability of the individual assays – the Tier 1 battery and individual assay protocols will likely need to be modified. Indeed, EPA will learn of battery, assay and compliance problems only after it assesses the results of the first phase of screening.

EPA's phased approach is consistent with its Scientific Advisory Board's (SAB's) scientific recommendation to initially screen 50 to 100 substances.[2] The SAB also recommended that, once EPA had collected the data from these 50 to 100 substances, the Agency should review all endocrine screening battery phase one screening data and test methods to revise the program "with an eye towards revising the process and eliminating those methods that don't work."[3] Likewise, the Office of Management and Budget approved EPA's Information Request (submitted pursuant to the Paperwork Reduction Act) for the initial 67 chemicals and stated in its Terms of Clearance: "This information collection is approved for the 67 chemicals published by EPA at 74 Fed. Reg. 17579 (April 15, 2009). OMB appreciates the continuing dialog with respect to the practical utility of the Tier I battery of EDSP assays and the role that the results from these first 67 chemicals will play in ensuring practical utility for subsequent groups of chemicals."[4] It is clear OMB also envisioned that EPA would not order additional

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[2] EPA, *Review of the EPA's Proposed Environmental Disruptor Screening Program; Review of the Endocrine Disruptor Screening Program by a Joint Subcommittee of the Science Advisory Board and Scientific Advisory Panel*. EPA-SAB-EC-99-013, July 1999 ("SAB EDSP Report").

[3] SAB EDSP Report at 2.

[4] Office of Information and Regulatory Affairs, Office of Management and Budget, *Approval of EPA's Information Collection Request: Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP)*, OMB Control No: 2070-0176, ICR Reference No: 200904-2070-001, Oct. 2, 2009, ("OMB Terms of Clearance").

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endocrine screening until the first phase of EDSP screening was completed, EPA assessed the performance of its screening assays and battery, and the Agency made necessary changes to the assays and battery.

For the reasons discussed above, the scientifically supportable approach is for EPA to await completion of its first phase of EDSP screening and to make necessary modifications to its Tier 1 battery and assays before ordering additional EDSP screening. This may take two years. Over the next year, EPA should develop, and has committed to develop, (1) a weight of evidence approach for assessing the results of Tier 1 screening, and (2) guidelines for assessing existing data (termed "Other Scientifically Relevant Data" or OSRI) that might obviate the need for some Tier 1 screening. These efforts should be completed before EPA orders additional EDSP screening. Indeed, EPA has stated that it intends to develop, prior to completion of the first phase of screening, a weight of evidence approach for assessing Tier 1 screening results. EPA has also indicated it will develop in the near term guidelines for assessing OSRI.[5] It is unclear what progress EPA has made in regards to those activities.

Contrary to the more scientifically supportable approach discussed above, the legislation appears to require EPA to issue additional EDSP testing orders prior to (1) completing the initial phase of EDSP screening; (2) assessing and modifying the current Tier 1 screening battery and assays; (3) developing a weight of evidence approach for assessing screening results; and (4) developing guidelines for assessing and accepting OSRI. The legislation would require EPA to issue additional EDSP testing orders within one year of enactment. Further, the legislation would not require EPA to develop approaches for assessing screening results, modifying its assays and screening battery, and assessing and accepting OSRI for two years.

The timeline mandated by the legislation could result in unnecessary

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5 EPA's stated efforts in regards to developing guidelines for assessing and accepting other scientifically relevant information is consistent with OMB's directive that "under the principles of the PRA [Paperwork Reduction Act], EPA should promote and encourage test order recipients to submit Other Scientifically Relevant Information (OSRI) in lieu of performing all or some of the Tier I assays, and EPA should accept OSRI as sufficient to satisfy the test orders to the greatest extent possible." OMB Terms of Clearance.

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screening, unnecessary use of inaccurate and non-repeatable assays, and unnecessary use of assays and protocols that may be unable to determine whether a substance interacts with the endocrine system. Again, after completion of the first phase of EDSP screening EPA could learn of significant assay, battery and compliance problems. Requiring new EDSP testing before EPA has an opportunity to learn of and correct problems with its existing assays and battery would likely result in unnecessary testing costs and the unnecessary use of laboratory animals. Indeed, assays may need to be repeated and new assays may need to be included in the screening battery. Conceivably, tens of millions of dollars could be wasted on unnecessary or useless screening if EPA departs from its originally planed screening timeline.

Given the potential problems that are likely to arise in conducting and interpreting the Tier 1 screening assays and battery, a phased implementation of the EDSP that will allow for modifications of the Tier 1 assays and battery should serve to improve the EDSP while conserving limited testing resources. The legislation should not impose a timeline that is not scientifically supportable, contrary to good science-based policy, and contrary to scientific and policy advice provided by the Agency's SAB and by OMB.

2. You mention the scope issue in your testimony. Though the language used in Section 16 is the same as that already in law, you remain concerned. Why should this be a concern?

Section 16 of the legislation,[6] like current law, fails to clearly define the scope of the endocrine screening and testing program under the Safe Drinking Water Act. The scope of the legislation refers to the chemical substances that would be included under the Act. The scope turns on the interpretation of the terms "may be found in sources of drinking water" and "substantial population." EPA has not yet interpreted those terms as they apply to the endocrine testing provisions of the SDWA. A broad Agency interpretation of those terms will

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6 Please note that the Endocrine Disruptor Screening Program is now Section 17 of the legislation. My responses refer to the Endocrine Disruptor Screening Program provisions of the legislation.

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result in almost any substance falling within the endocrine testing provisions of the Act.

I believe the legislation provides an opportunity for Congress to clarify its intent concerning the scope of endocrine testing under the SDWA. It appears that the purpose of the legislation is to prioritize for endocrine testing those substances that may pose a real threat to human health through a drinking water route of exposure. To the extent substances that are unlikely to be found in drinking water are included within the scope of the legislation, substances of less concern (i.e., those that pose less chance of exposure) may receive greater priority over substances that are known to exist in actual sources of drinking water to which large numbers of people are exposed. Endocrine testing under the SDWA and prioritization should be driven by actual threats of exposure. By clearly defining the scope of the legislation and Act, testing can be better prioritized and limited testing resources can be maximized. It should be noted that limiting the scope of the endocrine provisions of the SWDA will not preclude endocrine testing of chemical substance. EPA has ample authority under FFDCA (Section 408p), FIFRA and TSCA to require endocrine testing.

3. **While Section 16 of the legislation suggests in one place a weight of the evidence approach to scientific review, your testimony is much more skeptical that valid, relevant, repeatable, and reliable science will be what EPA uses in this program. Why do you think it is important to have sound science provision included in the legislation?**

Section 16 suggests in only one place a weight of evidence approach for scientific review. That provision does not appear applicable to other parts of Section 16. Further, even in that single instance, the legislation fails to state that scientific evidence should be repeatable. The requirement for sound science should be a universal requirement applicable to all provisions of health and environmental legislation. This is especially true for legislation concerning endocrine disruption, an issue that has been driven as much by ideology and hypothesis as by sound science.

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Surely, some view the requirement for sound science a burden that might require additional work or inhibit non-scientific, policy-based actions. Some appear satisfied to generate rudimentary endocrine data (such as biochemical or mechanistic data) followed by hypotheses that argue for the relevance of that data to potential effects in humans and wildlife. There is certainly value in biochemical and mechanistic studies, and hypotheses are useful in directing further research. Hypotheses, however, must be tested. In the area of endocrine disruption, hypotheses are rarely tested while new hypotheses are continually created and promoted. Further, biochemical and mechanistic studies should be relied on as a basis for taking action (including prioritization of substances for screening) only when they comport with basic scientific principles: (1) measurement: scientific studies must measure what they claim to have measured within a known margin of error; (2) confounding: measurements and observations must not be confounded by extraneous factors and influences known to corrupt their accuracy and precision; and (3) replication: measurements and observations must be replicable in independent hands. I would add to this list other important scientific concepts such as the need to weigh and consider all data when forming broader scientific conclusions. I also believe it is important to understand to what extent certain data and observations are relevant to answering broader scientific questions (such as whether a substance is a potential "endocrine disruptor" or whether a substance may pose a risk to human health or the environment) and to managing related potential risks. As I stated in my testimony, I have been concerned that many involved in the endocrine disruptor issue often fail to adhere to the above-mentioned scientific principles, fail to consider all the data, and often misstate the relevance of data upon which they rely.

I believe requiring the use of sound scientific criteria will lead to the protection of health and the environment by allowing EPA to distinguish real scientific information from theory, hypothesis, bias, policy, and unsubstantiated belief. Application of sound scientific criteria will also allow the Agency to better weigh available scientific evidence to arrive at supportable and reasoned scientific conclusions. Better assessments of data quality will lead to better assessments of potential risks to health and the environment. That, in turn, will enable EPA, other agencies and Congress to better focus limited resources in areas where those resources can have a more meaningful effect. Better risk assessments also will help avoid the unintentional selection of riskier products and adoption of poor risk management choices.

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EPA is a science agency that should adhere to strict principles of sound science. My experience, however, is that the Agency's adherence to principles of sound science can vary depending on the EPA office, the views of the current Administration and broader policy objectives. Adherence to principles of sound science also varies greatly among different government agencies. For these reasons, I believe EPA and all government agencies should adopt and utilize sound scientific principles when assessing scientific studies and information. Some notice may be taken of Federal and some State courts, which have adopted rules for determining the reliability of scientific information. Congress can play a pivotal role in ensuring Agency adherence to principles of sound science by including sound science provisions in its health and environmental legislation.

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