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Cass Sunstein  
Administrator  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
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Dear Mr. Sunstein,

We were heartened by the instructions given to the Environmental Protection Agency (EPA) by the Office of Management and Budget (OMB) in its October 2, 2009 letter to the EPA approving the initial Information Collection Request (ICR), wherein OMB wisely instructed the EPA to “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.” In addition, OMB has requested that, “in order to ensure that EPA has maximized the practical utility of the Tier I assays as the program moves forward, EPA should ensure sufficient opportunity prior to submission of any revision to this collection for public comment and peer review of the EPA tools to be developed to guide agency decisions on whether a chemical must proceed to Tier II, including the Weight of the Evidence Approach and Standard Evaluation Procedures.”

We agree that such a period of assessment and review is critical to allow EPA to review the cost/benefit of each assay within the Tier 1 battery and to delete assays that provide no added value, In addition, EPA should take this opportunity to incorporate new technology that has been developed since the decision, in 1992, to incorporate the current battery of assays.

While it is true that the EDSP Tier 1 tests have undergone a review process, the review was in fact cursory and the validity of these tests is by no means uncontested. The EPA itself contracted the review of most of the tests, and then ignored negative aspects of the reviews. Many of the Tier 1 tests demonstrated wide variability and have not been shown to be reliably transferable between laboratories – in essence they have failed very basic elements of validation. For detailed discussions regarding these reviews, see comments submitted to the Federal Register Docket EPA-HQ-OPPT-2007-1081. Further, none of the animal based tests in either tier address low dose effects. Some of the mechanism-based in vitro tests such as the receptor binding and transcriptional activation assays are capable of detecting activity at relatively low doses, indicating a potential for endocrine disrupting activity.

For Phase I of the EDSP, the EPA chose the 67 chemicals to be tested based solely on expected exposure. This group of chemicals is comprised of 58 pesticide active ingredients and nine High Production Volume (HPV) pesticide inert chemicals. For registration, pesticides are subject to dozens of separate animal tests, often including reproductive and chronic/lifecycle studies in rodents, fish and birds.1 These tests kill thousands of animals and include many of the same endpoints addressed in the

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1 72 FR 60934, October 26, 2007: EPA 40 CFR Parts 9 and 158: Pesticides; Data Requirements for Conventional Chemicals.
presumptive EDSP Tier 2 tests. In fact, the only Tier 2 test that the EPA has agreed on is the current two-generation reproductive toxicity test currently used for pesticides. Similarly, US EPA’s Chemical Challenge Program also provides for the collection of data that may be germane to the assessment of a chemical’s potential reproductive toxicity.2

For example, Reproduction and Fertility effects (OPPTS 870.3880) and Prenatal Developmental Toxicity (OPPTS 870.3700) tests are required for both food-use and non-food-use pesticide Technical Grade of the Active Ingredients. The simple mechanistic data produced by the Tier 1 tests will not provide additional regulatory information; indeed, chemicals tested according to OPPTS 870.3880 have, in effect, already been subject to EDSP Tier 2 mammalian testing. Thus, EDSP Tier 1 screens would appear to provide little or no added value for pesticide or HPV chemicals.

Performing the entire Tier 1 battery of tests for all 67 chemicals would cause the needless death of approximately 40,000 animals, and is not likely to provide any information that will be useful in further regulating these chemicals. In this case, OMB has acted wisely by urging the use of existing relevant information, and in requesting a review of the Tier 1 battery after the completion of Phase I, before continuing with the EDSP.

A lack of information about the possible endocrine activity of chemicals in our environment is a serious issue; EPA’s response in the current form of the EDSP is inadequate. A thorough review of the Tier 1 is essential to make this an effective program. OMB recognized this and has taken steps to ensure that the program will be improved in future incarnations.

Sincerely,

[Signature]

Dr. Catherine Willett
Science Policy Advisor

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