HSIA | halogenated solvents industry alliance, inc.

October 11, 2011

Office of Pesticide Programs Regulatory Public Docket (7502P)
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: EPA-HQ-OPP-2011-0656

Dear Sirs:

The Halogenated Solvents Industry Alliance, Inc. (HSIA) offers these comments on the petition submitted on June 21, 2011 by CropLife America and two other groups requesting the Agency to develop and publish guidance explaining the criteria by which EPA will make its decisions on data received in response to the test orders issued under the Endocrine Disruptor Screening Program (EDSP) (76 Fed. Reg. 49473 (August 10, 2011)). Specifically, EPA seeks comment on the recommendations that EPA:

> (1) Publish guidance explaining the criteria by which EPA will make its decisions on data received in response to the test orders issued under the EDSP;
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> (2) Provide sufficient time for first list chemical test order recipients to prepare and submit their Tier 1 screening results in compliance with the guidance once developed; and
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> (3) Fully analyze the Tier 1 screening data received in response to the first list test orders and revise the guidance to be developed to reflect what is learned by the analysis in order to ensure scientifically sound determinations and to protect the public health and the environment.

HSIA represents manufacturers of dichloromethane (methylene chloride), trichloroethylene, tetrachloroethylene (perchloroethylene), and, for purposes of these comments, 1,1-dichloroethylene (vinylidene chloride or VDC) and carbon tetrachloride, all compounds that are included on the second list of 134 chemicals being considered for Tier 1 screening under the EDSP, announced at 75 Fed. Reg. 70248 (November 17, 2010). These comments are submitted in support of the base premise of the CropLife petition that EPA should not issue test orders for compounds on the second list until it has reviewed the data submitted in response to test orders for compounds on the first list.

The petition itself describes important supporting evidence for our position, including (i) a recent EPA Office of Inspector General report identifying serious management deficiencies and emphasizing that EPA must develop and make final the criteria by which it will evaluate the test

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data;[1] (ii) the Terms of Clearance issued on EPA's Information Collection Request by the Office of Management & Budget, which direct EPA to "ensure sufficient opportunity prior to 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";[2] and (iii) direction from the House Appropriations Committee Report for EPA's FY 2010 appropriation.[3]

There is now significant additional input on this subject to EPA, by the same Appropriations Committee that directed development of the criteria and was the prime force behind EPA's publication of the second list late last year.[4] Specifically, the Committee has directed:

> "Endocrine Disruptors (ED).— The Committee continues to have concerns with the Endocrine Disruptor Screening Program's (EDSP) slow progress and believes it needs additional guidance. The EPA Inspector General criticized the slow progress, noting several missed lawsuit-related test validation milestones. In order to spur the agency to action, the Committee directs EPA to: (1) rely on standardized laboratory performance criteria for EDSP testing; (2) include basic and clinical endocrinologists with a range of expertise and deep knowledge in endocrinology including effects of chemical stressors on the endocrine system of humans and wildlife in tier 1 assay testing results peer review; (3) take steps to ensure EDSP testing minimizes the use of animals and considers existing knowledge and targeted testing, and justifies use with appropriate statistical considerations; (4) evaluate the Tier 1 test chemicals in ToxCast assays and determine their performance in endocrine relevant estrogenic, androgenic, and thyroid assays to refine toxicological prediction models; (5) utilize high throughput in vitro screening assay results to prioritize Tier 1 chemical testing and to inform future endocrine disruptor investigations; and (6) coordinate the Agency's capabilities with those of the National Institute of Environmental Health Sciences, the National Toxicology Program, the National Chemical Genomics

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[1] EPA's Endocrine Disruptor Screening Program Should Establish Management Controls to Ensure More Timely Results, Report No. 11-P-0215 (May 3, 2011); http://www.epa.gov/oig/reports/2011/20110503-11-P-0215.pdf.

[2] ICR-OIRA Conclusion, OMB Control No. 2070-0176; ICR Ref. No. 200904-2070-001, available at http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200904-2070-001.

[3] H.R. Rep No. 111-180 (2009).

[4] The second list of 134 chemicals responds to a directive in § 1457 of the Safe Drinking Water Act (SDWA) to include in the EDSP "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 substance." It was prepared in response to language in the House Appropriations Committee FY 2010 EPA Appropriations Report, *supra,* which directed EPA "to publish within one year of enactment a second list of no less than 100 chemicals for screening that includes drinking water contaminants, such as halogenated organic chemicals . . . and issue 25 orders per year for the testing of these chemicals."

Center, and the U.S. Food and Drug Administration into an integrated, comprehensive endocrine screening program.

"The Committee also directs EPA as part of the Agency's biennial budget justification to include: (a) information describing: coordination with other government research organizations that are part of the Tox21 Consortium, and in particular how the Agency works within the National Research Council's Tox 21 framework in its ED research; (b) the status of EPA's eight chemical action plans; and (c) how the ED research provides supporting science for the Agency's regulatory efforts."[5]

On the specific point of prerequisites for any future EDSP test orders, the Committee directed:

"Computational Toxicology.—Recognizing ToxCast has great promise to streamline and significantly increase the throughput of the Endocrine Disruptor Screening Program (EDSP), the Committee directs EPA to accelerate the evaluation, validation and implementation of the endocrine-relevant ToxCast assays. The Agency shall (1) in future EDSP Test Orders, use a targeted approach and adjust individual Test Orders in response to scientifically credible requests by taking existing data into account, and using information from valid in vitro assays or computer models, including ToxCast, as appropriate; and (2) use a peer consultation process to revise the EDSP weight of the evidence guidance to assure a systematic and consistent approach for evaluating other scientifically relevant information and EDSP results. These two activities shall include public comment and publication of Agency responses."[6]

Thus, in addition to the requirement that EPA review the data submitted under the existing test orders before issuing new ones, the Committee requires, at a minimum, that EPA:

- take into account Other Scientifically Relevant Information (OSRI), when presented,
- use data developed from valid *in vitro* assays or computer models, including ToxCast (the potential of which is recognized), as appropriate,
- revise its EDSP weight of the evidence guidance to assure a systematic and consistent approach for evaluating OSRI and EDSP results, and
- carry out these activities transparently, including public comment and publication of the Agency's responses thereto.

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[5] H.R. Rep. No. 112-__ (2011), at 70 (relevant excerpt enclosed).

[6] H.R. Rep. No. 112-__ (2011), at 58 (relevant excerpt enclosed).

HSIA appreciates the opportunity to submit these comments and looks forward to constructive engagement with EPA to ensure that the EDSP does not result in unnecessary and duplicative testing, wasting industry resources and causing unnecessary suffering to animals.

Respectfully submitted,

Faye Graul/WCN

Faye Graul
Executive Director

Enclosure

[FULL COMMITTEE PRINT]

112TH CONGRESS, 1st Session } HOUSE OF REPRESENTATIVES { REPORT 112–

DEPARTMENT OF THE INTERIOR, ENVIRONMENT, AND RELATED AGENCIES APPROPRIATION BILL, 2012

, 2011.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. SIMPSON, from the Committee on Appropriations, submitted the following

REPORT

[To accompany H.R.]

The Committee on Appropriations submits the following report in explanation of the accompanying bill making appropriations for the Department of the Interior, the Environmental Protection Agency, and Related Agencies for the fiscal year ending September 30, 2012. The bill provides regular annual appropriations for the Department of the Interior (except the Bureau of Reclamation and the Central Utah Project), the Environmental Protection Agency, and for other related agencies, including the Forest Service, the Indian Health Service, the Smithsonian Institution, and the National Foundation on the Arts and the Humanities.

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Agency is directed to allocate funds to grantees within 180 days of enactment of this Act.

Research: Safe and Sustainable Water Resources.—The Committee recommends $108,532,000, which is $8,765,000 below the fiscal year 2011 enacted level and $10,244,000 below the budget request. The Committee has not provided the requested $5,996,000 increase for additional green infrastructure research beyond what is already provided in the base, or the requested $4,226,000 increase for additional drinking water case studies.

Research: Sustainable and Healthy Communities.—The Committee recommends $154,324,000, which is $16,702,000 below the budget request. Resources for Endocrine Disruptor research, Computational Toxicology research, and Human Health Risk assessment have been transferred to the Research: Chemical Safety and Sustainability program area as a result of the proposed reorganization of ORD resources. The Committee has not provided funding for the Fellowships program in 2012, a $17,261,000 decrease below the budget request. The Committee has provided $2,559,000 for the laboratory study and footprint analysis, and encourages ORD to institute efficiency improvements that will result in long term savings using the amounts provided.

Additional Guidance.—The Committee has included the following additional guidance with respect to funding provided under this account.

Computational Toxicology.—Recognizing ToxCast has great promise to streamline and significantly increase the throughput of the Endocrine Disruptor Screening Program (EDSP), the Committee directs EPA to accelerate the evaluation, validation and implementation of the endocrine-relevant ToxCast assays. The Agency shall (1) in future EDSP Test Orders, use a targeted approach and adjust individual Test Orders in response to scientifically credible requests by taking existing data into account, and using information from valid in vitro assays or computer models, including ToxCast, as appropriate; and (2) use a peer consultation process to revise the EDSP weight of the evidence guidance to assure a systematic and consistent approach for evaluating other scientifically relevant information and EDSP results. These two activities shall include public comment and publication of Agency responses.

Consolidation of laboratory and other research space.—From fiscal year 2007 through fiscal year 2010, EPA released approximately 250,000 square feet of space at headquarters and facilities nationwide resulting in a cumulative annual rent avoidance of over $1.1 million in this account. These achieved savings and potential savings partially offset EPA's escalating rent budget. The Committee continues to support the Agency's space strategy efforts, including those options that could lead to further efficiencies and potential reductions to the Agency's real property footprint.

Hydraulic Fracturing.—The Committee directs the Agency to submit the Final Draft of the Interim Study Results and any additional final study results of the Plan to Study the Potential Impacts of Hydraulic Fracturing on Drinking Water Resources, for Interagency Review and public comment, consistent with the processes described in Sections 2.2 and 2.5 of the Draft Hydraulic Fracturing Study Plan released February 7, 2011.

sources of energy and would lead to wide-spread economic hardship in many industries.

Brown Marmorated Stink Bug.—The Committee appreciates the work of the Office of Chemical Safety and Pollution Prevention regarding the brown marmorated stink bug. This pest is causing significant damage to agricultural products, particularly tree fruit in the mid-Atlantic States. The Committee encourages the Office to work collaboratively with the U.S. Department of Agriculture, including the Agricultural Research Service, the National Institute of Food and Agriculture, and the Animal and Plant Health Inspection Service, and state partners to expeditiously approve a control program as soon as the appropriate agents are evaluated for release.

Endocrine Disruptors (ED).— The Committee continues to have concerns with the Endocrine Disruptor Screening Program's (EDSP) slow progress and believes it needs additional guidance. The EPA Inspector General criticized the slow progress, noting several missed lawsuit-related test validation milestones. In order to spur the agency to action, the Committee directs EPA to: (1) rely on standardized laboratory performance criteria for EDSP testing; (2) include basic and clinical endocrinologists with a range of expertise and deep knowledge in endocrinology including effects of chemical stressors on the endocrine system of humans and wildlife in tier 1 assay testing results peer review; (3) take steps to ensure EDSP testing minimizes the use of animals and considers existing knowledge and targeted testing, and justifies use with appropriate statistical considerations; (4) evaluate the Tier 1 test chemicals in ToxCast assays and determine their performance in endocrine-relevant estrogenic, androgenic, and thyroid assays to refine toxicological prediction models; (5) utilize high throughput in vitro screening assay results to prioritize Tier 1 chemical testing and to inform future endocrine disruptor investigations; and (6) coordinate the Agency's capabilities with those of the National Institute of Environmental Health Sciences, the National Toxicology Program, the National Chemical Genomics Center, and the U.S. Food and Drug Administration into an integrated, comprehensive endocrine screening program.

The Committee also directs EPA as part of the Agency's biennial budget justification to include: (a) information describing: coordination with other government research organizations that are part of the Tox21 Consortium, and in particular how the Agency works within the National Research Council's Tox 21 framework in its ED research; (b) the status of EPA's eight chemical action plans; and (c) how the ED research provides supporting science for the Agency's regulatory efforts.

Personnel and Full Time Equivalents.—Many difficult decisions were required in order to identify the appropriate funding distribution for the fiscal year 2012 House budget recommendation. The Committee understands that the recommended budget will require many more difficult decisions as the Agency executes the fiscal year 2012 plan. The Committee has long been concerned about the growing disparity between EPA headquarters and regional FTE, many of whom are policy advisors to the Administrator or Assistant Administrators or who implement voluntary initiatives. The Committee recognizes that not all headquarters FTE are located in Washington DC, and a significant number of those FTE are lab and