



## Chemical Producers & Distributors Association

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[VIA WWW.REGULATIONS.GOV](http://WWW.REGULATIONS.GOV)

Mr. William Wooge  
Office of Science Coordination and Policy  
U.S. Environmental Protection Agency (MC 7203M)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001

**RE: Endocrine Disruptor Screening Program; Draft Policies and Procedures for Screening Safe Drinking Water Act Chemicals; Notice; 75 Fed. Reg. 70558 (November 17, 2010); EPA-HQ-OPPT-2007-1080-9.**

Dear Mr. Wooge:

The Chemical Producers & Distributors Association (“CPDA”) appreciates this opportunity to comment on the above-referenced notice (“Draft List 2 Policies and Procedures”). CPDA is the preeminent U.S. based trade association representing the interests of generic pesticide registrants and manufacturers and suppliers of the inert ingredients used to enhance the delivery and efficacy of pesticide products. CPDA membership also includes formulators and distributors of pesticide products.

### Introduction

CPDA is pleased to offer these comments on the U.S. Environmental Protection Agency’s (“EPA” or “Agency”) new draft policies and procedures (“Draft List 2 Policies

and Procedures”) that will guide the Agency’s second phase of screening chemicals in the Endocrine Disruptor Screening Program (“EDSP”). Although these Draft List 2 Policies and Procedures apply to the chemicals selected for screening pursuant to the Safe Drinking Water Act<sup>1</sup> (“List 2”), EPA has stated that they are intended to supplement the existing EDSP policies and procedures,<sup>2</sup> which focus only on pesticide active and inert ingredients comprising the first list of chemicals.<sup>3</sup> Both policies and procedures guide EPA actions for issuing and enforcing EDSP test orders under section 408(p) of the Federal Food, Drug, and Cosmetics Act.<sup>4</sup>

Our comments address a number of issues raised by the Draft List 2 Policies and Procedures, and particularly our concerns about:

- (1) EPA’s initiating another round of screening pursuant to section 1457 of the SDWA before completing the initial screening initiative. This is inconsistent with the recommendations of EPA’s Scientific Advisory Board and the Agency’s own statements;
- (2) EPA’s failure to interpret the language of section 1457 that addresses the Agency’s authority to require testing under the SDWA. This information is crucial to the public’s ability to assess whether Agency may be acting arbitrarily in violation of the Administrative Procedure Act; and
- (3) EPA’s failure to develop meaningful guidance for weight-of-evidence determinations of Tier 1 test results and evaluating other scientifically relevant information.

We trust comments in this submission are helpful to EPA, and we look forward to the Agency’s responses and to working with the Agency to improve the EDSP.

### **EPA Must Interpret Key SDWA Language before Listing SDWA Chemicals and Issuing Phase 2 Orders**

The scope of the EDSP for screening chemicals in drinking water contaminants depends on EPA’s interpretation of the phrases “substances that may be found in sources of drinking water” and “a substantial population may be exposed.”<sup>5</sup> EPA has not interpreted this statutory language, which limits the Agency’s authority to require EDSP screening pursuant to the SDWA. Instead, EPA relies on three existing priority lists, to compile a list of substances that may occur in drinking water.<sup>6</sup> Although using these existing lists provides EPA with a convenient method for generating a list of potential

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<sup>1</sup> SDWA § 1457, 42 USC §300j-17.

<sup>2</sup> 75 Fed. Reg. 70558, 70559 (November 17, 2010).

<sup>3</sup> 74 Fed. Reg. 17579 (April 15, 2009).

<sup>4</sup> FDCA §408(p)(5); 21 U.S.C. § 346(a)(p).

<sup>5</sup> SDWA § 1457, 42 USC §300j-17.

<sup>6</sup> 75 Fed. Reg. 70248, 70250 (November 17, 2010) (“List 2”). The list is comprised of substances regulated by the Office of Water’s current National Primary Drinking Water Regulations and unregulated substances on the Contaminant Candidate List (CCL3), and the Office of Pesticide Program’s list of pesticides scheduled for registration review during fiscal 2007 and 2008.

substances for EDSP screening, those lists may not be appropriate for identifying “substances that may be found in sources of drinking water” to which a “substantial population may be exposed.” Until EPA clearly defines those key phrases, selection of substances or use of existing lists of substances for Phase 2 screening is merely arbitrary.

Congress limited EPA’s authority to require EDSP screening pursuant to the SDWA by using those key phrases, and deferred to EPA to define their meaning. Before EPA can begin selecting substances for Phase 2, the Agency must interpret the Act consistent with procedures provided by the Administrative Procedure Act and subject to judicial review. The Agency is not entitled to grant itself unfettered authority and may not arbitrarily select substances for EDSP screening. Instead, it must first define the phrases “may be found in sources of drinking water” and “that a substantial population may be exposed,” and then identify chemicals under an appropriate selection scheme.

In defining those phrases, EPA should define separately the terms (1) “may be found,” (2) “sources of drinking water,” (3) “substantial population,” and (4) “may be exposed.” Moreover, when defining “may be found” and “may be exposed,” CPDA believes EPA should rely on reasonable, probable scenarios or on actual data that demonstrates a substance is found in drinking water to which people are exposed. When defining “substantial population,” EPA should be guided by realistic potential risks to human health and should assess costs as well as benefits. EPA should also review how it has defined “substantial population” under other environmental programs, such as TSCA. Finally, EPA should define “sources of drinking water” as actual, rather than theoretical, sources of drinking water. Arguably, any surface or ground water is a potential source of drinking water and any chemical might find its way into some source of drinking water. However, such a broad interpretation would render the express statutory limitations meaningless. If Congress wanted EPA to require EDSP testing for any chemical, it would have expressed that desire clearly in the statute. Therefore, EPA must assume, consistent with well established principles of statutory construction that Congress did not intend to include meaningless statutory limitations on the Agency’s authority in section 1457 of the SDWA.

CPDA believes EPA must define these terms to interpret its authority under section 1457 before it can identify List 2 chemicals for screening and before it implements the second phase of the EDSP. EPA has had 14 years to consider how it would interpret the EDSP provisions of the SDWA. Moreover, for the last decade, industry has asked EPA to define “may be found in sources of drinking water” and “a substantial population may be exposed” so that the industry could understand EPA’s interpretation of its authority under the SDWA and, therefore, the potential scope of the EDSP. This would have allowed industry to plan for EDSP compliance. Now that EPA has begun to rely on section 1457 authority, it is crucial that EPA clearly outline its interpretation of that authority. As CPDA notes in its comments on the List 2 chemicals, we are particularly concerned about EPA’s willingness to rely on a non-legislative Congressional directive as if it were a mandatory statutory requirement to unnecessarily undertake a very costly information collection before completing the current Tier 1 screening for the first list of pesticide

chemicals.<sup>7</sup> Consequently, we are concerned as well with the Agency's lack of transparency and reluctance to outline the scope of its perceived EDSP authority under the SDWA. Such information would allow the public to ensure the Agency does not act arbitrarily when listing chemicals and implementing the EDSP.

### **Final Agency Action**

CPDA is also concerned about EPA's use of a nonbinding commitment to address due process concerns related to FFDCA §408(p)(5)(d), which specifies that non-pesticide registrants who fail to comply with an EDSP testing order are subject to the stiff penalties of section 16 of the Toxic Substance Control Act ("TSCA").<sup>8</sup> Unfortunately, the FFDCA does not explicitly provide the due process protections of TSCA §4, which would require EPA to promulgate test rules under section 4 before testing is required. In lieu of express statutory due process language, EPA has attempted to avoid the legal problem of denying order recipients due process protections by interpreting TSCA in a manner that deems EDSP test orders to be judicially challengeable, final agency actions.

Although EPA's proposed approach appears to address due process concerns, order recipients are dependent solely on EPA's intention to abide by its interpretation and implementation plan. However, its interpretation and plan exists only in non-binding policies and procedures and not in an enforceable rule, which is underscored by EPA's making it very clear that the Agency is not bound by these policies and procedures. Therefore, the availability of EPA's due process plan depends on the Agency's unenforceable desire to maintain its interpretation and abide by its plan. CPDA is concerned about EPA's express determination to not bind itself to its EDSP policies and procedures, including the due process procedures. Therefore, CPDA urges EPA to promulgate a rule in the near future that establishes EPA's enforceable duties and policies and procedures and its obligation to comply with them.

### **EPA Should Issue List 2 EDSP Orders Only To Current Manufacturers and Importers of Listed Chemicals**

Section 1457 of the SDWA authorizes EPA to include in the EDSP "any other substance that may be found in sources of drinking water," provided EPA determines a

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<sup>7</sup> We note in our comments that "EPA notes in the List 2 Notice that a House Appropriations Committee report directed EPA "to publish within 1 year of enactment [of the appropriations bill] a second list of no less than 100 chemicals for screening...and issue 25 orders per year for the testing of these chemicals." However, EPA ignores the fact that language in reports issued by the House or Senate is not authoritative or binding on an agency.<sup>7</sup> Moreover, the U.S. Supreme Court has expressly cautioned against treating legislative reports as binding law:

"[L]egislative materials like committee reports, which are not themselves subject to the requirements of Article I, may give unrepresentative committee members-or, worse yet, unelected staffers and lobbyists-both the power and the incentive to attempt strategic manipulations of legislative history to secure results they were unable to achieve through the statutory text."  
Exxon Mobil Corp. v. Allapattah Services, Inc., 125 S. Ct. 2166, 2626 (2005).

<sup>8</sup> TSCA §§ 2-411; 15 U.S.C. §§ 2601-2692.

“substantial population may be exposed to such substance.” EPA states that it will rely on the authority granted the Agency by FFDCA section 408(p)(5)(A) to issue test orders requiring screening of substances identified in List 2.<sup>9</sup> This section states:

“The Administrator shall issue an order to a registrant of a substance for which testing is required under this subsection, or to **a person who manufactures or imports** a substance for which testing is required under this subsection, to conduct testing in accordance with the screening program . . . .” (emphasis added)

By its terms, this section refers to current registrants, and manufacturers and importers (“manufacturers” for purposes of this comment). Congress uses the present tense when referring to potential order recipients and does not explicitly or implicitly grant EPA authority to issue testing orders to those who are no longer manufacturers of a chemical. CPDA believes this statutory use of the present tense in section 408(p)(5) precludes EPA from issuing EDSP test orders for SDWA chemicals that are no longer manufactured or imported, but which may be found in sources of drinking water. EPA has not demonstrated the practical utility of the information on these chemicals. Thus, EPA should neither list nor issue test orders for chemicals that are not currently manufactured or imported.

EPA recognized that its authority was limited to current manufacturers when it issued testing orders for the first phase of the EDSP only to current manufacturers of pesticide chemicals. Those order recipients who could demonstrate that they no longer manufactured a chemical were exempt from the orders. In addition, those who agreed to discontinue sale of the chemical into the pesticide market were also exempt from the orders.

In its List 2 Policies and Procedures, EPA generally continues to limit its order authority to current manufacturers of substances on List 2 which is consistent with its policies and procedures issued for the first phase of EDSP screening.<sup>10</sup> In its Draft List 2 Policies and Procedures, EPA acknowledges “the Agency generally intends FFDCA section 408(p) as giving the Agency authority to issue orders to **current** registrants, manufacturers, and importers of a chemical.”<sup>11</sup> (emphasis added) Specifically, EPA proposes to exempt from Phase 2 screening those manufacturers who do not currently manufacture the chemical identified for testing (Test Order response option 4).<sup>12</sup> CPDA agrees with EPA’s proposed approach for the following reasons:

- First, it is consistent with the plain meaning of the operative provisions of the FFDCA that limit the Agency’s authority to issuing test orders to current manufacturers.
- Second, it ensures that only manufacturers who continue to manufacture a chemical will receive economic benefit from the sale of the chemical with which to defray

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<sup>9</sup> Draft Phase 2 Policies and Procedures, p. 70560

<sup>10</sup> Supra, Footnote 2.

<sup>11</sup> Draft List 2 Policies and Procedures, p. 70567.

<sup>12</sup> Id. at p. 70564.

the cost of testing.

- Third, it is consistent with EPA's past implementation of the EDSP, in which only current manufacturers are subject to the first phase of the EDSP and there is no legal or equitable basis for creating different duties and burdens for different phases of the EDSP.
- Fourth, it will make implementation of the EDSP easier and more equitable by not unnecessarily involving cost sharing/data compensation issues involving prior manufacturers, for which there may or may not be legal and equitable means of identifying them.

### **EPA Should Allow Order Recipients to Comply With Orders by Ceasing Manufacture of a Chemical**

Consistent with the first phase of the EDSP, EPA proposes to exempt from screening manufacturers who agree to discontinue manufacture of the chemical.<sup>13</sup> CPDA agrees with EPA's proposal to allow a List 2 order recipient to comply with a testing order by ceasing all manufacturing of the listed chemical. This option is justified primarily because an order recipient who agrees to discontinue manufacture after receiving an EDSP order, like a former manufacturer, will receive no economic benefit from the sale of the chemical with which to defray the cost of testing. However, EPA also solicits comments on "whether it is generally inappropriate to allow companies to comply with an order by agreeing to cease manufacture or import of a SDWA chemical."<sup>14</sup> CPDA believes order recipients who choose to stop manufacturing a chemical after receiving an order are similar to manufacturers who stop manufacturing at some point prior to receiving an order (i.e., non-current manufacturers), and both manufacturers should be exempt from EDSP testing by agreeing to cease manufacturing of the chemical. Whether an order recipient must conduct EDSP testing should not turn solely on when a manufacturer ceased manufacturing, it should turn on whether that manufacturer will continue manufacturing so that future sales may defray the cost of testing.

To support denying the option to cease manufacture, EPA argues that

"[t]he chemical's current presence in sources of drinking water and the corresponding potential for public exposure is not altered by the fact that a particular company may subsequently choose to no longer manufacture or import the chemical in response to the order. The potential for continued exposure to the chemical exists despite any potential decrease that might be caused by the exit of one or more test order recipients."<sup>15</sup>

CPDA does not agree that this argument justifies denying order recipients the option to cease manufacturing. Whether a chemical enters sources of drinking water likely has more

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<sup>13</sup> EPA allowed order recipients to comply with testing orders by agreeing to stop selling a listed chemical to the pesticide market (Test Order response option 5). (See Draft List 2 Policies and Procedures, p. 70564.

<sup>14</sup> Draft List 2 Policies and Procedures, p. 70567.

<sup>15</sup> Id.

to do with the use, disposal, and environmental releases of a chemical than its mere production, or when it was manufactured. Chemicals manufactured in the past may end up in drinking water in the future, and chemicals produced in the present or future may never end up in sources of drinking water. Consequently, with respect to whether chemicals are found in drinking water, there no rational basis for distinguishing manufacturers who ceased manufacture in the past and those who cease manufacture when they receive an EDSP order.<sup>16</sup>

CPDA is concerned that EPA is improperly suggesting that the EDSP be used to manage endocrine risks when it states: “[t]he chemical’s current presence in sources of drinking water and the corresponding potential for public exposure is not altered by the fact that a particular company [may choose to stop manufacturing a chemical]” and stopping manufacturing or importing “will lead to less exposure to a chemical in sources of drinking water.”<sup>17</sup> These rationales are inconsistent with the EDSP provisions of the FFDCA and the SDWA. The purpose of the EDSP is to screen chemicals for their potential effects on the human endocrine system and not to manage exposure to chemicals in drinking water. Therefore, EPA must use other statutory authority to manage endocrine risks. If EPA’s goal is to use the EDSP to manage drinking water contaminants, then the Agency is acting well outside its authority. The agency should retain the option to comply with test orders by ceasing to manufacture or import the chemical.

### **EPA Should Not Consider Persistence When Implementing the EDSP**

EPA requested comment on whether and how to factor a chemical’s persistence in the environment into EDSP policies and procedures. CPDA believes EPA should not consider persistence when listing or issuing orders for List 2 chemicals. It is not clear how EPA would incorporate persistence in determining whether a chemical may be found in sources of drinking water and whether a substantial population is exposed. Those findings should be based on actual data concerning the presence of a chemical and a determination of what constitutes a substantial population. A chemical that meets those statutory limitations will do so regardless of persistence. Trying to incorporate persistence is unnecessary and will likely confuse the listing process. As CPDA suggests above, EPA should focus on defining the terms of section 1457 of the SDWA that directly influence which chemicals should be included on List 2 before considering factors that likely will have little impact on listing.

EPA’s persistence question is more relevant to the scope of EPA’s authority to limit testing to current manufacturers and providing an order compliance option of stopping manufacture of a chemical. The Agency appears to be asking whether it should require former manufacturers to test persistent chemicals (i.e., not limiting orders to current manufacturers). EPA is also asking whether it should withdraw the option to comply with a test order by ceasing manufacturing. CPDA believes persistence should not

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<sup>16</sup> For example, what would be the basis for distinguishing an order recipient who ceased manufacturing one day before receiving an EDSP order from one who ceased manufacturing one day after receiving an EDSP order? Beyond mere semantics, why should one be exempt from EDSP testing while the other should not?

<sup>17</sup> See, Draft List 2 Policies and Procedures, p. 70567.

influence either consideration.

The issue of persistence is likely to arise only for chemicals that have not been manufactured and used by anyone for a significant period of time (i.e., “legacy chemicals”). Assuming EPA did have the authority to issue EDSP orders to former manufacturers, it would have to develop a legal and equitable process for identifying those chemicals along with all past manufacturers and importers, many of whom may not have manufactured or imported the chemical for decades. To the extent the Agency considers persistence for purposes of obtaining endocrine information, it should instead consider whether other existing authority (i.e., other environmental statutes) provide greater legal authority to generate that data. EPA would also have to determine whether other statutory authority provides a more equitable process for obtaining the screening data by focusing on use, disposal, and release of chemicals.

### **EPA Must Develop Meaningful Weight of Evidence Guidance Before Focusing on SDWA Chemicals**

Tier 1 of the EDSP will generate large amounts of data that must be assessed to determine whether a substance interacts with the endocrine system and whether those data trigger Tier 2 testing. In the Draft List 2 Policies and Procedures, EPA claims that it will use a weight-of-evidence (“WoE”) process to (1) assess whether existing data are sufficient to satisfy an EDSP order; (2) assess Tier 1 data and other information to determine if a chemical has the potential to interact with the estrogen, androgen, and thyroid (“EAT”) systems; and (3) determine which Tier 2 tests might be required. In the first policies and procedures document, EPA also committed to developing WoE guidance for evaluating Tier 1 screens and the Tier 1 battery. In addition, the Office of Management and Budget (“OMB”) in its first Terms of Clearance directed EPA to develop a WoE process for assessing Tier 1 EDSP data before it revised its ICR. OMB stated:

“[I]n 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.”<sup>18</sup>

On November 4, 2010, EPA published for comment a Draft WoE Guidance Document for evaluating EDSP Tier 1 screening and to identify chemicals for Tier 2 testing.<sup>19</sup> However, the document fails to provide any meaningful WoE guidance, and

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<sup>18</sup> 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”).

<sup>19</sup> 75 Fed. Reg. 67963 (November 3, 2010). Weight of Evidence Guidance Document; Evaluating Results of EDSP Tier 1 Screening to Identify Candidate Chemicals for Tier 2 Testing. “Draft WoE Guidance”). EPA stated this action “is in compliance with a directive from the House Appropriations Committee 2010 Report...” and on page 2 of the Draft WoE Guidance stated the document “is expected to comply with the

does not comply with the spirit of OMB's Terms of Clearance. The comment period has been extended to February 3, 2011, and CPDA hopes that the Agency will timely publish meaningful guidance to comply with those directives and fulfill its stated commitments to develop and publish peer-reviewed WoE guidance specific to the EDSP.

Without solid, functional guidance to direct Agency actions, the Agency will be unable to properly assess Tier 1 data, and actions it takes in response to Tier 1 findings may be arbitrary and may not be scientifically sound. Further, knowing how the EPA will evaluate the Tier 1 screens may influence how the assays are conducted. Industry has urged the Agency for years to develop a detailed WoE process for assessing EDSP data and has offered its assistance. EPA should leverage and apply the work of scientists who have published on the topic to develop a robust and transparent WoE guidance that will minimize arbitrary determinations as to whether substances interact with the endocrine system and trigger Tier 2 testing.

### **EPA Should Provide a Meaningful Opportunity for Order Recipients to Rely on OSRI**

Consistent with Congress' directive in the Food Quality Protection Act to limit unnecessary testing, and with OMB's directive to promote and encourage the use of Other Scientifically Relevant Information ("OSRI"),<sup>20</sup> applying science-based policy and with consideration of the concerns of the animal protection community, EPA provided order recipients the opportunity to submit OSRI in lieu of some or all of Tier 1 screening. EPA's offer to allow order recipients to submit OSRI is especially justified given that many of the chemicals for screening on EDSP Lists 1 and 2 are data rich chemicals for which relevant data exist, including in many cases high quality reproductive and developmental toxicity data. EPA has not, however, clearly articulated its basis for evaluating the OSRI submissions and has not clearly outlined its policy goals concerning OSRI. Until it does, the Agency's OSRI determinations are vulnerable to assumptions that they are actual or possible arbitrary decisions. Moreover, without a full understanding of how the Agency makes those determinations, industry will not have the knowledge needed to assess what, and in what form, information should be submitted to the Agency. Therefore, it appears

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provision in the Office of Management and Budget Terms of Clearance for the Information Collection Request for the first list of chemicals to be screened under the EDSP and direction in the House Appropriations Committee for the Interior and Environment FY 2010 report ...."

<sup>20</sup> OMB stated in the Terms of Clearance:

"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. For this reason, and to further validate EPA's burden estimates, OMB requests that EPA provide a report re-estimating the burden of this information collection based on responses to the Tier I test orders, including the use of cost-sharing and data compensation, the submission and acceptance of existing data and OSRI, and description of any instances in which submission of OSRI was deemed insufficient to satisfy the testing order. OMB requests this report prior to or at the time of submission of revision of this information collection to cover additional chemicals."

that EPA does not intend to provide a meaningful opportunity for order recipients to rely on OSRI, and CPDA urges EPA to dispel this assumption by publishing detailed guidance stating how it will evaluate OSRI before it issues new EDSP orders.

### **EPA Should Provide for Meaningful and Enforceable Data Compensation Provisions**

Congress explicitly stated that EPA should, when collecting information pursuant to the EDSP, develop to the extent practicable procedures for fair and equitable sharing of test costs.<sup>21</sup> EPA narrowly interprets this congressional directive as “merely establish[ing] a qualified direction” that does not create new authority, and only directs the Agency to create procedures that operate within the confines of existing statutory authorities.<sup>22</sup> CPDA generally disagrees with EPA’s narrow reading of FFDCA §408(p) and believes EPA should, as Congress directed, develop new procedures to ensure fair and equitable sharing of test costs. If Congress had intended EPA to do nothing and only rely on existing data compensation procedures, it would not have explicitly directed EPA to develop data compensation procedures. Therefore, CPDA urges EPA to provide EDSP data submitters explicit, legally enforceable data compensation rights.

Despite CPDA’s disagreement concerning EPA’s authority to create new procedures for ensuring data compensation and the need for a legally enforceable program, CPDA compliments the Agency for developing a workable data compensation and cost sharing plan that utilizes EPA’s FFDCA order authority to determine compliance. CPDA also agrees with EPA’s plan to issue catch up orders to require cost sharing by manufacturers and importers who enter the market after initial orders are issued and EDSP testing has been completed. EPA suggests, however, that catch up orders be issued for 10 years rather than 5 years. While this may create an additional burden for EPA, 10 years is a reasonable period considering the significant expense of generating EDSP Tier 1 and Tier 2 data,

CPDA also notes that EPA’s proposed approach appears to provide for data compensation protection, but actual data compensation will depend on EPA’s desire to enforce the provisions. EPA offers its data compensation/cost sharing approach in non-binding policies and procedures, and EPA makes it very clear that it is not bound to these policies and procedures. Therefore, the usefulness of this approach depends on the Agency’s future desire to enforce the outlined provisions and to diligently issue catch up orders. CPDA is concerned that EPA expressly determined not to be bound by the EDSP policies and procedures and, therefore, not to its data compensation/cost sharing approach. Therefore, The Agency should promulgate a rule in the near future that establishes EPA’s duties and its policies and procedures, and legally binds the Agency to those duties and policies and procedures. At that time, EPA should consider, with input from the industry, how it might improve its cost sharing program to ensure equitable treatment of data generators.

### **EPA Should Not Implement EDSP Phase 2 Until It has Completed the EDSP Phase 1**

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<sup>21</sup> FFDCA §408(p)(5)(B).

<sup>22</sup> Draft Phase 2 Policies and Procedures, at 70565

EPA has wisely adopted a phased approach for implementing the EDSP and initially ordered Tier 1 Screening for 67 pesticide active and inert chemical ingredients. According to its current EDSP policies and procedures, after receiving results from the first phase of EDSP screening, EPA intended to review and revise as necessary its Tier 1 battery prior to issuing new testing orders. EPA does not indicate in its Draft List 2 Policies and Procedures when it intends to issue Phase 2 orders. CPDA strongly urges EPA to abide by its current plan to issue new orders only after it receives the results of the current pesticide chemical screening assesses those results and, if necessary, modifies the Tier 1 battery and related policies and procedures.

CPDA considers phased implementation of the EDSP scientifically justified and necessary. Although EPA has applied a validation process individual Tier 1 screening assays, the Agency has not yet validated the Tier 1 battery. Information from the initial screening phase will be needed for validating the battery. We have lingering concerns about the usefulness, accuracy and repeatability of the individual Tier 1 assays and it appears that individual assay protocols will likely need to be modified. Indeed, EPA will become aware 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") recommendation to initially screen 50 to 100 substances.<sup>23</sup> The SAB recommended that once EPA collects data from these 50 to 100 substances, the Agency should review all the resulting data and test methods to revise the program "with an eye towards revising the process and eliminating those methods that don't work."<sup>24</sup> Likewise, the OMB approved EPA's Information Collection Request 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 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."<sup>25</sup>

OMB also envisioned that EPA would not order additional endocrine screening until the first phase of EDSP screening was completed, until EPA had assessed the performance of its screening assays and battery, and until EPA made necessary changes to the assays and battery.

EPA bases its authority to list potential drinking water contaminants for EDSP screening on the FFDCA, the SDWA, and the House Appropriations Committee report for

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<sup>23</sup> *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").

<sup>24</sup> *Id.* at 2.

<sup>25</sup> *Supra* at 17.

EPA's FY 2010 appropriations. While the House Appropriations Committee report directs EPA to list potential drinking water contaminants and to issue orders for those substances, neither the FFDCFA, the SDWA, nor the report requires EPA to implement EDSP activities by a deadline or within a specific period of time. Moreover, EPA incorrectly interprets language in the Appropriations Committee report as a constitutionally valid legislative mandate to initiate EDSP screening. EPA's rush to screen additional chemicals without having to meet a statutory deadline is premature and will undermine the valuable opportunity the current phase of Tier 1 screening can provide for experience and science-based improvement of this highly complex program.

Therefore, the scientifically supportable approach EPA should follow is to await completion of the first phase of EDSP screening and then make necessary modifications to the Tier 1 battery before ordering additional EDSP screening. Premature issuance of List 2 EDSP testing orders could result in unnecessary screening, unnecessary use of inaccurate and non-repeatable assays, unnecessary testing costs, and the unnecessary use of laboratory animals. Once the first phase of EDSP screening has been completed, EPA should have sufficient reliable information to make proper adjustments to the screening phase of the EDSP.

### Conclusions

CPDA has endeavored to provide EPA with comments that are of concern to us and will improve the EDSP. First, there is no legally mandated timeframe or deadline for undertaking additional screening at this time, and doing so will undermine efforts to improve the program based on experience gained from the first round of screening. CPDA urges EPA to suspend this screening initiative until the first round of screening has been completed. Second, the public needs to know EPA's perception of its authority under section 1457 of the SDWA. We recommend that the Agency define the key language in that section so that it can select chemicals rationally based on that authority and not based on the convenience of using existing lists. Third, it is imperative that EPA develop meaningful guidance for weight-of-evidence determinations and evaluations of data and information submitted in lieu of conducting Tier 1 assays. The EDSP is a very costly program and such guidance is needed to ensure an efficient and cost-effective implementation of the EDSP.