



## Chemical Producers and Distributors Association

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VIA E-MAIL

Mr. William Wooge  
Office of Science Coordination and Policy  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460-0001

**Re: Docket ID Number EPA-HQ-OPPT-2007-1081: Agency Information Collection Activities; Proposed Collection; Comment Request; Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No. 2249.02, OMB Control No. 2070-0176)**

Dear Mr. Wooge:

The Chemical Producers and Distributors Association (CPDA) is pleased to provide these comments in response to the above referenced docket entitled, “Agency Information Collection Activities; Proposed Collection; Comment Request; Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No. 2249.01, OMB Control No. 2070-0176” as announced in the *Federal Register* on November 17, 2010.

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.

CPDA has analyzed the Environmental Protection Agency’s 60-day notice<sup>1</sup> and draft Supporting Statement for this proposed Information Collection Request (ICR) revision.<sup>2</sup> With only a few exceptions, the Environmental Protection Agency has not addressed the errors and previously outlined violations of the Paperwork Reduction Act discussed in CPDA and industry comments on the original ICR.<sup>3</sup> For brevity, those errors and violations are summarized here rather than restated in full. Our review focuses on new errors and potential violations committed by EPA, and our original comments are included through citation.

### **EPA’s Burden Estimates Remain Flawed, Invalid and Unreliable**

EPA’s burden estimation methodology for the 2009 ICR was fundamentally flawed in multiple ways, many of which have been carefully documented.<sup>4</sup> A previous addendum<sup>5</sup> and the current draft addendum<sup>6</sup> to the ICR are also deficient in several aspects. As summarized below:

1. EPA did not provide objectively-supported estimates of burden by: a) ignoring significant burden components, such as the burdens of establishing, managing, and participating in testing consortia; b) incorrectly counting the burden components it acknowledged, such as by excluding 65% of the burden of generating test data; c) undercounting by about half the number of test order recipients; and d) undervaluing the test costs by 35% despite having collected more accurate information.

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<sup>1</sup> U.S. Environmental Protection Agency (2010a).

<sup>2</sup> U.S. Environmental Protection Agency (2010b).

<sup>3</sup> Ferenc, *et al* (2008).

<sup>4</sup> Ferenc, *et al* (2008, Attachment pp. 21-48).

<sup>5</sup> U.S. Environmental Protection Agency (2009a).

<sup>6</sup> U.S. Environmental Protection Agency (2010a).

2. EPA, by withholding data sources that would have allowed for independent validation and withholding essential information needed to reproduce results, demonstrates conclusively that it knowingly did not adhere to applicable information quality guidelines with respect to transparency and reproducibility.
3. EPA's dissemination of severely biased burden estimates, and its continued misrepresentation to OMB of likely burden by seeking expedient approval of the ICR revision, strongly suggests that the Agency knowingly did not adhere to applicable information quality guidelines with respect to objectivity and utility.
4. EPA relied on selective third-party information, without applying its own guidelines for the review and dissemination of such information.

### **EPA's List 1 ICR Amendment**

Recognizing the breadth and depth of deficiencies and insufficiencies in the original ICR, the Office of Management and Budget directed the Agency to, *inter alia*, collect new data about burden from respondents to the original Tier 1 test orders and utilize these new data in any subsequent ICR revisions.<sup>7</sup>

It would appear, however, that EPA attempted to address a few of the errors before OMB approved the ICR in October of 2009.<sup>8</sup> The revisions to the estimates on the number of test order recipients and test orders per respondent have dates indicating that they *could have been shared* with the public, and timely public comment *could have been obtained*<sup>9</sup> prior to OMB approval. However, EPA neither disclosed the information in a timely manner nor sought public comment on these revisions.

A comparison of the original and revised data shows just how insufficient EPA's original burden estimates were. In the original ICR, EPA estimated 207 pesticide active ingredient (PAI) test order recipients and 163 inert ingredient manufacturers/importers. In the 2009 amendment, the Agency revised the numbers and identified 219 PAI test order recipients and 530 inert ingredient test order recipients, thereby at least doubling the burden. The Agency also claimed that to ensure that burden estimates are "conservative," implying the estimates *overstate* the actual burden, it has "retained the assumption that all Order recipients will participate

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<sup>7</sup> Office of Management and Budget (2009): "[T]o 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."

<sup>8</sup> U.S. Environmental Protection Agency (2009a, 2009b).

<sup>9</sup> EPA's revision doubling the number of Tier 1 test order recipients (and thus approximately doubling aggregate burden) is dated September 10, 2009 (U.S. Environmental Protection Agency 2009a). EPA's production of an "updated estimate" of the number of test orders per respondent is dated September 3, 2009 (U.S. Environmental Protection Agency 2009b). Because it is titled an "update," EPA implicitly acknowledges having previously withheld this information from the public.

in consortium activities.” However, EPA does not do this in the actual analyses<sup>10</sup>, again contributing to an underestimate of the burden.

EPA also revised, though not transparently, the number of respondents expected to collaborate in a consortium. In the original ICR Supporting Statement, EPA claimed (without providing any documentation) that the average consortium would have “less than five” Tier 1 test order recipients, and the maximum would be 56 recipients.<sup>11</sup> The 2009 amendment to the Supporting Statement yields an average of 3.78 recipients per chemical, but a maximum of 310 recipients.<sup>12</sup>

### **EPA’s Current Draft Addendum: Supporting Statement**

In the draft Supporting Statement for the ICR revision, EPA adopts none of the recommendations CPDA and industry made in 2009 and estimates new burdens using the same methods previously discredited. EPA again describes its estimates as “conservative” implying that they probably overstate actual burdens.<sup>13</sup> On every significant margin, EPA’s estimates are “conservative” only insofar as they systematically *underestimate* likely burden.

EPA has sought and obtained new data that could be used to, at a minimum, test the validity of the Agency’s burden-estimation methodology. However, the Agency has chosen not to use them in deriving the burden estimates in this ICR revision, likely because the results indicate that EPA knowingly underestimated test costs by 35% in the original ICR.<sup>14</sup> The current draft revision continues the Agency practice of denying that the actual assay costs are a cognizable component of burden despite their recognition that they are clearly included in the regulatory definition

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<sup>10</sup> U.S. Environmental Protection Agency (2009a, Tables 1, 7, 8, 10 and 12).

<sup>11</sup> U.S. Environmental Protection Agency (2009c, p. 41).

<sup>12</sup> U.S. Environmental Protection Agency (2009b).

<sup>13</sup> U.S. Environmental Protection Agency (2009c, p. 38: "At this time, it is important to note that the estimated total burden for this ICR is based on several assumptions that are intended to be biased towards providing conservative estimates."); U.S. Environmental Protection Agency (2010b, p. 6 : "The Agency has made every effort to provide a conservative estimate..."). These claims appear to be defensive in nature, in response to pointed criticism by public commenters on the 60-day notice. EPA did not claim that its burden estimates were “conservative” in its 2007 public review draft Supporting Statement for the original ICR (U.S. Environmental Protection Agency 2007), even though there are no material differences in burden estimation methodology between the 2007 and 2009 versions.

<sup>14</sup> EPA developed a report in 2009 titled “*Laboratory testing of chemicals for endocrine disrupting potential – analysis of market factors*” which includes comprehensive test cost data collected by the Agency from 15 laboratories. The EPA data were submitted to the Organization for Economic Cooperation and Development (OECD) and the results appear in an annex of a January 2010 draft document (OECD 2010). The annex provides summary tables of the EPA data from which it can be determined that the Agency has known for at least a year that the median cost for conducting the Tier 1 battery is \$544,397—35% greater than the estimates used in the original ICR and current addendum. These data were never disclosed to the public; were not included in the original ICR Supporting Statement; and are not included in the proposed revision.

of burden.<sup>15</sup> The combination of again knowingly excluding test costs in burden estimates *and* knowingly underestimating test costs (which provide the source for the 35% paperwork burden convention employed by the Agency) leads to a significant knowing underestimate of the burden of the EDSP.

**EPA's Optional "Level of Effort" Questionnaire**

Of significant interest in this amendment was the burden analysis conducted by the Agency for the "Optional Questionnaire"<sup>16</sup> appended to the Test Orders. Any valid information achievable from the test order-appended Optional Questionnaire that could inform EPA, in order to better estimate burden under the OMB directive, is likely not yet available (the Questionnaire includes responses to questions through the conclusion of data collection and report submission). Making matters worse, EPA structured the Questionnaire to avoid obtaining information about burdens the Agency appears determined to exclude.<sup>17</sup> Fortunately, a coalition of Tier 1 test order recipients simultaneously collected pertinent data from a revised version of the Questionnaire and has published preliminary results.<sup>18</sup> The coalition reports that the actual number of burden-hours *to date*, per chemical per respondent, has exceeded EPA's estimates by a range of 14% (for single test order recipients) to 201% (for large consortia). Actual non-burden hour costs *to date*, per chemical per respondent, have exceeded EPA's estimates by a range of 196% (for single test order recipients) to 445% (for large consortia).<sup>19</sup> The authors of the report conclude that the Agency has significantly underestimated not only the burden-hours for submitting an initial response and participating in a consortium, but also has misrepresented the labor level of participation in the initial response and consortium activities, and has further underestimated the associated labor rates for both activities. Much of the underestimation for both activities is due to the development and submission of OSRI in the initial response, the cost of which triples the EPA estimated

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<sup>15</sup> See U.S. Environmental Protection Agency (2010c, page 32), citing the definition in 5 C.F.R. § 1320.3(b)(1).

<sup>16</sup> U.S. Environmental Protection Agency (2009d).

<sup>17</sup> The questionnaire excludes significant burden components related to OSRI as well as consortium establishment, management, and participation, which EPA similarly omitted from the original ICR.

<sup>18</sup> Endocrine Policy Forum and Crop Life America (2010).

<sup>19</sup> Endocrine Policy Forum and Crop Life America (2010, p. 11). These percentages are overly precise. They should be interpreted as strong qualitative evidence supporting the inference that EPA's burden estimates, for the burden components EPA included, were at best valid only for substances in which there was a single test order recipient, and strikingly deficient for substances in which testing would be procured by a consortium, with the degree of error rising with the size of the consortium. At the time EPA developed its burden estimates, the Agency expected only 15 of 56 substances would have a single test order recipient (See U.S. Environmental Protection Agency 2009b, p. 2).

burden.<sup>20</sup> CPDA strongly recommends the Agency revise the Questionnaire in order to more accurately estimate the burden of future information collection requests.<sup>21</sup>

### **Original ICR Terms of Clearance**

Given the deficiencies in EPA's original ICR, OMB's approval on its face would appear to violate the Paperwork Reduction Act. OMB has sole authority for interpreting the PRA's provisions and applying them to the ICRs agencies submit, but it cannot defer to the judgment of EPA. OMB concurs, for in the Information Collection Rule OMB says:

*OMB [not the agency] shall determine whether the collection of information, as submitted by the agency, is necessary for the proper performance of the agency's functions...*<sup>22</sup>

and

*OMB [not the agency] will ... independently assess any collection of information to the extent that the agency exercises discretion in its implementation.*<sup>23</sup>

Similarly, it is OMB—not EPA—that has the sole authority to determine “whether the burden of the collection of information is justified by its practical utility.”<sup>24</sup>

OMB has attempted to redress this issue via Terms of Clearance.<sup>25</sup> The text implicitly and undeniably recognizes that EPA's burden estimates were flawed and insufficient and that the Agency had failed to demonstrate practical utility.<sup>26</sup> OMB thus qualified its approval of the ICR through the Terms of Clearance and in doing so, limited the approval in certain ways:

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<sup>20</sup> From our evaluation of information from the Endocrine Policy Forum report, as of December 2010 the cost *per individual* OSRI submitter for development and submission of OSRI in the initial response to a test order is approximately \$8,900. There appears to be no consideration or inclusion of this burden by EPA in the Supporting Statement. The EPA estimate of burden associated with the initial response is \$4,169.40.

<sup>21</sup> The current Questionnaire consists of 18 questions, several of which require multiple, detailed responses on the time (in hours and minutes) and costs (shared and individual) expended by the recipient. In the amendment analysis, EPA estimated the time burden of responding to the full questionnaire at 37.8 minutes, by a clerical-level employee, for a total burden estimate of \$39 per response. It is highly improbable that reliable information could be provided under this scenario.

<sup>22</sup> 5 CFR § 1320.5(e), emphasis added.

<sup>23</sup> 5 CFR § 1320.5(e)(1), emphasis added.

<sup>24</sup> 5 CFR § 1320.5(e).

<sup>25</sup> Office of Management and Budget (2009).

<sup>26</sup> “OMB appreciates the continuing dialog with respect to the practical utility of the Tier I battery of EDSP assays.”

1. OMB stipulated that EPA's statutory authority to compel respondents to provide test data does not supersede the Paperwork Reduction Act's prohibition on the imposition of a duplicative information collection.<sup>27</sup>
2. To ensure that duplication did not occur, OMB required EPA to promote and encourage submission of Other Scientifically Relevant Information (OSRI) and describe any instance in which OSRI is rejected.<sup>28</sup>
3. OMB required EPA to publish for meaningful public comment and peer review its weight-of-evidence guidance and standard evaluation procedures, both of which test order recipients clearly need to make informed decisions about how to respond.<sup>29</sup>
4. OMB required EPA to re-estimate burden using new data derived from actual experience.<sup>30</sup>

The first of these conditions implicitly denied OMB approval of any attempt by EPA to compel respondents to conduct testing where OSRI satisfies statutory requirements; any more expansive approval would have violated the Paperwork Reduction Act because it would have compelled the generation and submission of unnecessarily duplicative information.<sup>31</sup> OMB imposed the second condition in support of the first. The third condition sought to address commenters' complaints that EPA had failed to disclose essential information needed to decide how to respond to the ICR.<sup>32</sup> The fourth condition spoke directly to the known deficiencies in EPA's burden estimate.

EPA was directed to comply with these conditions prior to submitting any request for renewal or revision of the ICR. The Agency has not done so.

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<sup>27</sup> "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."

<sup>28</sup> ... with a "description of any instances in which submission of OSRI was deemed insufficient to satisfy the testing order." Nothing in this condition diminished or compromised the statutory authorities conferred by FFDCA § 408(p).

<sup>29</sup> "In addition, 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."

<sup>30</sup> "[T]o 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..."

<sup>31</sup> The statute prohibits agencies from imposing information collections that are "unnecessarily duplicative" (44 U.S.C. § 3506(c)(3)(b)). OMB has by rule defined information to be unnecessarily duplicative if it is "otherwise accessible to the agency" (5 C.F.R. § 1320.5 (d)(1)(ii)).

<sup>32</sup> Ferenc, *et al* (2008, Attachment pp. 19-21).

**Condition #2: EPA has supplied no report documenting and explaining its rejections of OSRI.**

EPA is proposing to expand the Tier 1 testing program before providing the required report. EPA has approved a small percentage of waiver requests based on OSRI, denied others, and not yet responded to some OSRI submissions and waiver requests. Without the report required by OMB, which should disclose publicly the criteria the Agency is using, current respondents (and prospective future respondents who would be covered by the ICR revision) can only speculate whether OSRI will satisfy a test order mandate.

Unless and until EPA acts on OSRI claims in a transparent, reproducible and consistent manner, respondents cannot rationally respond to Tier 1 test orders. As noted in our comments on the original ICR, the practical utility of the Tier 1 test battery remains negligible, at best, until respondents can reasonably know the criteria EPA will use to accept or reject OSRI.

**Condition #3: EPA has published for public comment a draft weight-of-evidence guidance document, but this document has no content.**

On November 3, 2010, EPA published for public comment a draft weight-of-evidence guidance document that the Agency says complies with OMB's Terms of Clearance.<sup>33</sup> To actually comply, however, this document would have to set forth, in a transparent, reproducible, and consistent way, how EPA plans to determine whether Tier 1 test data and/or OSRI satisfy EPA's stated purpose for the information (i.e., enable it to simply scientifically discriminate between substances that "may" or "may not" have the potential to interact with the endocrine system). In other words, EPA's weight-of-evidence guidance must explain how it intends to weigh the evidence.

The draft guidance document provides virtually no insight on this question. It lists five data attributes, notes that statistical and biological significance matter, mentions the well-known trade-off between sensitivity and specificity, specifies no rules or procedures for processing and analyzing these data, then says EPA will make its decisions in a "case-by-case" manner that is inherently non-transparent and non-reproducible (p. 6). Indeed, the closest thing EPA provides to information in the draft guidance is a statement implying that the Agency will interpret every observed effect in a Tier 1 test as presumptively "positive," with no established criteria for rebutting this presumption.<sup>34</sup> In short, the only potentially useful informa-

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<sup>33</sup> U.S. Environmental Protection Agency (2010c, (public notice of availability); 2010d, (draft guidance)). The draft guidance explicitly makes the connection to OMB's Terms of Clearance: "This document also is expected to comply with the 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..." (p. 2).

<sup>34</sup> "In general, the results of relevant studies are assumed to be indicative of interactions with the endocrine system unless data are available that demonstrate otherwise..." (pp. 6-7). Taken at face value, this means that a substance must have only unambiguously negative Tier 1 test data to be exempted from Tier 2.

tion contained in EPA's draft weight-of-evidence guidance is the implication that every substance subjected to Tier 1 testing that yields an observable effect in any assay will be assigned to Tier 2. If that interpretation is correct, then Tier 1 testing cannot have practical utility for informing Tier 2 assignment.

EPA neither promotes nor encourages test order recipients to submit OSRI. In the draft ICR amendment, EPA recommends OSRI submitters provide a "scientifically sound rationale that explains how the submitted or cited data provides information needed to satisfy part or all of the Tier 1 order and/or inform the Agency's Tier 1 determination," yet the Agency fails to provide adequate guidance about how to meet this test, through either the draft OSRI or weight-of-evidence guidelines. The Agency admits that it does not yet have an approach to confidently and scientifically review existing data for granting an exemption from testing and does not offer a timeline for review of OSRI and waiver decisions.

**Condition #4: EPA has not re-estimated burden in a valid manner.**

As noted above, EPA has not refuted any of the arguments made against its burden-estimation methodology and practice. Rather, EPA persists in using the same approach which undercounts most burden components and purposefully ignores others.

It is especially disturbing that EPA provided data to OECD that directly contradict what it has disseminated to the U.S. public and OMB. Furthermore, EPA continues this practice; the data provided to OECD are not even mentioned in the proposed ICR revision.

**EPA Still Has Not Demonstrated Practical Utility**

In the 2009 ICR Supporting Statement, EPA provided little evidence of actual practical utility.<sup>35</sup> EPA has been unable or unwilling to describe a transparent, reproducible, and consistent method by which it will use Tier 1 test data to scientifically determine whether substances may (or may not) have an effect in humans that is similar to an effect produced by naturally occurring hormones. Without such a framework, Tier 1 test data cannot have the "actual, not merely the theoretical or potential, usefulness" necessary to make a showing of practical utility.<sup>36</sup>

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<sup>35</sup> 5 CFR § 1320.3(l). Actual (as opposed to merely theoretical) practical utility is required by OMB's Information Collection Rule: "*Practical utility* means the actual, not merely the theoretical or potential, usefulness of information to or for an agency, taking into account its accuracy, validity, adequacy, and reliability, and the agency's ability to process the information it collects (or a person's ability to receive and process that which is disclosed, in the case of a third-party or public disclosure) in a useful and timely fashion." The Supporting Statement for the original ICR contained no defense of the practical utility of the information to be obtained. See U.S. Environmental Protection Agency (2009c).

<sup>36</sup> 5 C.F.R. § 1320.3(l).

The draft Supporting Statement for the ICR revision provides no new evidence that Tier 1 test data have actual practical utility.<sup>37</sup> As for the original ICR, these data have no demonstrated value for EPA's legitimate statutory purposes under Section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA). For this reason, EPA's insistence that respondents be required to provide these data violates the Paperwork Reduction Act.

OMB's Terms of Clearance also require the Agency "to ensure that EPA has maximized the practical utility of the Tier I assays as the program moves forward." EPA appears to have ignored the directive. It can still be interpreted, as it was in 2007 when the first draft Supporting Statement was published for comment, that Tier 1 is an EPA research project to test the validity and appropriateness of the Tier 1 battery, to be funded by industry. The Paperwork Reduction Act does not permit an agency to secure the data for such a research project using a mandatory information collection *unless there is specific statutory authority overriding the PRA*. FFDCA § 408(p) does not include any such language; indeed, it is the Paperwork Reduction Act's language that supersedes FFDCA § 408(p).

### **EPA's Legislative Duty Argument**

EPA asserts that it must collect these data now pursuant to a Congressional directive.<sup>38</sup> However, the germane language the Agency cites in support of List 2 collection appears only in a House committee report, and reports issued by only the House or the Senate cannot be authoritative and are not binding on an agency.<sup>39,40</sup>

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<sup>37</sup> The draft ICR Supporting Statement for the revision contains no defense of the practical utility of the information. See U.S. Environmental Protection Agency (2010b).

<sup>38</sup> U.S. Environmental Protection Agency (2010b, pp. 1-2), citing congressional committee report language (U.S. House of Representatives 2009, p. 106).

<sup>39</sup> *Exxon Mobil Corp. v. Allapattah Servs.*, 125 S. Ct. 2166, 2626 (2005). 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."

<sup>40</sup> *Northwest Environmental Defense Center et al. v. Bonneville Power Administration*:

"The principle that committee report language has no binding legal effect is grounded in the text of the Constitution and in the structure of separated powers the Constitution created. Article I, section 7, clause 2 of the Constitution is explicit about the manner in which Congress can take legally binding action. Members of Congress cannot use committee report language to make an end run around the requirements of Article I. If Congress wishes to alter the legal duties of persons outside the legislative branch, including administrative agencies, it must use the process outlined in Article I" ...

"Treating legislative reports as binding law also undermines our constitutional structure of separated powers, because legislative reports do not come with the traditional

EPA cannot rely on committee report language to infer a statutory duty or mandate, and its authority to impose testing requirements under the Safe Drinking Water Act is qualified.<sup>41</sup> It is the Paperwork Reduction Act, duly enacted into law by Congress in 1980 and reauthorized in 1995, which governs EPA's authority to impose paperwork burden and controls OMB's ultimate determination whether to approve it. Without OMB approval, EPA is not permitted to seek this information at all, much less make it mandatory.<sup>42</sup>

### **Conclusions:**

In summary, CPDA believes the Agency has not met the letter or intent of OMB's Terms of Clearance, an integral part of OMB's approval of the original ICR. Therefore, it is premature for the Agency to revise the ICR to approve extending Tier 1 testing of additional chemicals. The Agency's claim that it has an urgent statutory duty to expand this program now is unsupported by any facts.

In addition, the Agency has significantly underestimated the burden-hours, and burden and non-burden hour costs, of responding to test orders, developing and submitting OSRI, and conducting the Tier 1 battery. The Agency still cannot demonstrate any actual practical utility for the information it proposes to mandate be collected at enormous expense. Using the data that EPA provided to OECD but withheld from the U.S. public and OMB shows that the Agency knew from the outset that the original Tier 1 testing program likely would cost over \$100 million and the expansion of the program will, at a minimum, be double that figure.

CPDA believes there is sufficient information generated by and available to the Agency to more accurately estimate the burden of the information collection and should revise the burden estimate before submitting the final estimates to the Office of Management and Budget for consideration. Moreover, before proceeding further EPA must fully comply with OMB's Terms of Clearance and, for transparency, provide the report to the public.

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and constitutionally-mandated political safeguards of legislation. As noted above, legislative reports are not acts of law satisfying the precise requirements of Article I, which were devised by the Framers to ensure separation of powers and a careful legislative process. By contrast, legislative reports may in some cases be written by an individual legislator, congressional staffers, or even lobbyists. Giving binding effect to passages in legislative reports may thus give binding legal effect to the unchecked will of a lone person, and that is not what our Constitution envisions." (965-966, internal footnotes omitted).

<sup>41</sup> Generally, EPA must first show that a substance "may be found in sources of drinking water" and "that a substantial population may be exposed to such substance." See 42 USC §300j-17. No such showings are presented in the Agency's proposed listing decision (U.S. Environmental Protection Agency 2010d).

<sup>42</sup> 44 USC § 3506(c)(1)(B)(iii)(V) ("an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number"); 5 CFR § 1320.5(a)(2) ("An agency shall not conduct or sponsor a collection of information unless ... OMB has approved the proposed collection of information").

## REFERENCES

- Endocrine Policy Forum, Crop Life America. 2010. *EDSP Tier 1 Screening: Preliminary Burden Report*. Crop Life America, 1-19.
- Exxon Mobil Corporation. v. Allapattah Services, Inc.*, 125 S. Ct. 2166, 2626 (2005)
- Ferenc S, et al. 2008. *Letter to the Office of Information and Regulatory Affairs, Office of Management and Budget Re: EPA Information Collection Submission To OMB for Review and Approval; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP). Attachment 1: An Analysis of EPA's Information Collection Request Seeking OMB Approval to Impose Mandatory Tier 1 Assay Testing in Support of the Endocrine Disruptor Screening Program;*" EPA ICR No. 2249.01, OMB Control No. 2070-New Docket ID Number EPA-HQ-OPPT-2007-1081
- Northwest Environmental Defense Center et al. v. Bonneville Power Administration*, Nos. 06-70430 and 06-71182 (9<sup>th</sup> Cir. 2007)
- Office of Management and Budget. 2009. *Notice of Office of Management and Budget Action, ICR Reference Number 200904-2070-001; New ICR 2070-0176*.
- Organization for Economic Cooperation and Development. 2010. *Guidance Document on the Assessment of Chemicals for Endocrine Disruption" Version 9*.
- U.S. Environmental Protection Agency. 2007. *Supporting Statement for an Information Request [EPA ICR No. 2249.01, OMB Control No. 2070-new]; Docket No. EPA-HQ-2007-1081-0017 [Public Review Draft, Docket ID EPA-HQ-OPPT-2007-1081-0002, December 5, 2007]*. Washington, D.C.: U.S. Environmental Protection Agency, 1-36.
- U.S. Environmental Protection Agency. 2009a. *Amendment to the Supporting Statement for the Information Collection Request (ICR): Title: Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No.: 2249.01; OMB Control No.: 2070-(tbd); Docket ID No.: EPA-HQ-OPPT-2007-1081*.
- U.S. Environmental Protection Agency. 2009b. *ICR 2070-0176 Attachment A2: Updated Estimate for Number of Potential Recipients of EDSP Tier 1 Orders/DCIs as of September 3, 2009*.
- U.S. Environmental Protection Agency. 2009c. *Supporting Statement for an Information Request [EPA ICR No. 2249.01, OMB Control No. 2070-new]; Docket No. EPA-HQ-2007-1081-0017 [Docket ID EPA-HQ-OPPT-2007-1081-0017, April 15, 2009]*.
- U.S. Environmental Protection Agency. 2009d. *ICR 2070-0176 Amendment F2: Optional Level of Effort Questionnaire*.

- U.S. Environmental Protection Agency. 2010a. Agency Information Collection Activities; Proposed Collection; Comment Request; Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No. 2249.02, OMB Control No. 2070-0176. *Federal Register* 75(221): 70568-70570.
- U.S. Environmental Protection Agency. 2010b. *Supporting Statement for an Information Collection Request (ICR) 'Addendum for the Second List of Chemicals; Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program (EDSP); EPA ICR No.: 2249.02; OMB Control No.: 2070-0176; Docket ID No.: EPA-HQ-OPPT-2007-1081 [Public Review Draft, September 23, 2010].*
- U.S. Environmental Protection Agency. 2010c. Endocrine Disruptor Screening Program (EDSP); Announcing the Availability of a Draft Weight-of- Evidence Guidance Document: Evaluating Results of EDSP Tier 1 Screening to Identify Candidate Chemicals for Tier 2 Testing. *Federal Register* 75(213): 67963-67965.
- U.S. Environmental Protection Agency. 2010d. *Weight of Evidence Guidance: Evaluating Results of EDSP Tier 1 Screening to Identify Candidate Chemicals for Tier 2 Testing [Document ID: EPA-HQ-OPPT-2010-0877-0002].*
- U.S. House of Representatives. 2009. *Committee on Appropriations Report 111-180 on Department of the Interior, Environment, and Related Agencies Appropriations Bill, 2010.*