Comments on
ICR Addendum for the Second List of Chemicals;
Tier 1 Screening of Certain Chemicals Under the
Endocrine Disruptor Screening Program (EDSP);
EPA ICR No. 2488.01, OMB Control No. 2070-[new]

"Tier 1 List 2 ICR"

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I. EXECUTIVE SUMMARY

From the outset, the Endocrine Disruptor Screening Program (EDSP) has been plagued with a host of conceptual, technical and implementation difficulties, and adherence to applicable Paperwork Reduction Act (PRA) standards is no exception. The present Information Collection Request (ICR) does not advance the EDSP forward in a rational manner. Based on the unambiguous standards set forth in the PRA and its implementing regulations, OMB should disapprove the ICR as improperly submitted.

A. OMB Has an Obligation to Enforce the Statutory Requirements Set Forth in the Paperwork Reduction Act

The PRA directs OMB to make certain independent determinations based on the record provided by the agency proposing to conduct or sponsor a collection of information, public comments on this agency-supplied record, and other information OMB is able to glean from its own research and analysis. First, OMB must determine whether the information to be collected has actual, not merely theoretical, practical utility for the agency. Second, OMB must determine whether the burden imposed on the public, properly estimated, is reasonable given the information's practical utility. Only after practical utility has been demonstrated, however, does the magnitude of burden matter. No burden is too small if the information that would be obtained has no practical utility.

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B. The Limits on OMB's Authority Are Much Narrower than EPA Implies Because Most of This ICR Consists of Non-Statutory, Discretionary Information Collections

EPA correctly notes that it has a statutory obligation to obtain data necessary and sufficient to determine whether pesticides may interact with the endocrine system. This authority is not a blank check authorizing EPA to collect any data on pesticides it wishes, however. Data that do not or cannot fulfill the statutory objective are not covered by the statutory mandate.

Where OMB can determine that information an agency seeks is reasonably necessary to fulfill a statutory mandate, it is obligated to defer to Congress. But OMB is not required to defer to agency representations of Congressional directives. Rather, it must conduct its own review to independently determine whether the information an agency seeks to collect actually fulfills a claimed statutory directive.

OMB's authority is even greater with respect to endpoints and substances that are not mandated by statute. While EPA was given the discretion to add androgen and thyroid endpoints, and to expand the screening regime to include chemicals other than pesticides, neither of these expansions was mandated by Congress. OMB thus has no obligation to defer to EPA claims that the Agency is required to collect these data.

The fact that EPA is statutorily required to collect certain data related to pesticides, and statutorily authorized to collect certain data related to other chemicals, such as possible Safe Drinking Water Act contaminants, does not override OMB's authorities and responsibilities under the PRA.

C. OMB Has an Obligation to Enforce Its Terms of Clearance

OMB's 2009 terms of clearance are not merely advisory, and EPA was obligated to comply with them prior to the submission of this ICR. There is nothing controversial about this; EPA agrees with it.

However, the record shows that EPA has not complied with any of the five substantive requirements in OMB's terms of clearance. EPA's Supporting Statement attempts to redefine OMB's terms of clearance in a way that would indefinitely delay the date at which compliance is required. OMB is obligated not to accept indefinite delay as equivalent to actual compliance.

D. OMB Should Disapprove this ICR as Improperly Submitted

OMB should disapprove this ICR as improperly submitted, clearly stating in its notice of action that the 2009 terms of clearance are binding and have not been fulfilled. In addition, OMB should accompany this notice of action with a reminder that compliance with the peer review task means full adherence to government-wide peer review guidelines issued by OMB in 2005. These guidelines require, among other things, that peer review panels write their own reports, without

interference or assistance from the sponsoring agency, and agencies must publicly respond to these reports. EPA should be further directed to begin a new ICR clearance process only after the 2009 terms of clearance have been fully met.

To encourage EPA toward success, OMB should strongly recommend that EPA redesign its Scientific Advisory Panel (SAP) review process to ensure that the lessons learned from these reviews are fully captured in any subsequent Tier 1 expansion. Without such process changes, it is likely that the Tier 1 battery will never be updated in accordance with scientific principles and empirical evidence.

E. A Guide to this Analysis

Section II summarizes the PRA history of the Tier 1 component of the EDSP, including the history of the Tier 1 List 1 ICR (Subsection A); OMB's terms of clearance accompanying its 2009 approval (Subsection B); and the Tier 1 List 2 ICR process up to the current submission (Subsection C). Readers familiar with this background should proceed to Section III.

Section III (beginning on page 13) summarizes recognized deficiencies in the Tier 1 List 2 ICR as submitted to OMB. These deficiencies include inadequacies in EPA's Supporting Statement and Response-to-Comments document (2013 RTC). The 2013 RTC is in many places unresponsive to the issues raised by commenters. Like preceding versions, the Supporting Statement lacks any discussion about the practical utility of Tier 1 data.

Section IV (beginning on page 15) examines EPA's peer review process using the Agency's FIFRA Scientific Advisory Panel (SAP). Because the SAP has not yet issued its reports, and EPA obviously has not yet responded to them, submission of the Tier 1 List 2 ICR is clearly premature. Problems observed in the first SAP review are noted. EPA's decision to supply the SAP with only a subset of the available Tier 1 data inhibited an effective peer review of the Tier 1 battery, and specific concerns raised by panel members cast further doubt on the practical utility of Tier 1 data. Problems are predicted with respect to the upcoming second SAP review because the first SAP review was unable to conclude that the tests in the Tier 1 battery produced scientifically interpretable results.

Section V (beginning on page 18) consists of a Paperwork Reduction Act analysis. It begins by noting that EPA's statutory duty to develop a database for endocrine effects does not overrule OMB's statutory duty to ensure that information collection requirements actually deliver practical utility to the Agency at reasonable cost to the public without duplication. OMB's terms of clearance provided a reasonable path forward, but the Agency apparently has decided not to comply in advance of expanding the scale of Tier 1 testing, as the terms of clearance require. EPA's decision to structure peer review in such a way that ensured its ineffectiveness further undermines public confidence that the statutory requirements of the PRA will ever be met.

Section VI puts together the various strands of the analysis to make the case that OMB should disapprove this ICR as improperly submitted.

II. A CONCISE HISTORY OF THIS COLLECTION OF INFORMATION

This section summarizes the multi-year history of Information Collection Requests (ICRs) submitted to OMB related to the EDSP Tier 1 screening battery. Tier 1 screening is supposed to enable EPA to identify substances that have the potential to interact with human endocrine, androgen, or thyroid systems. Tier 2 testing is supposed to enable EPA to estimate dose-response relationships for bona fide adverse effects on one or more of these systems, and be applied only to the subset of substances flagged as having endocrine effects in Tier 1.

Previous ICRs were assigned to OMB control number 2070-0176, the record for which on reginfo.gov may be incomplete.[2] The record on regulations.gov is difficult to navigate because EPA has used the same Docket ID for four separate ICRs.[3] For the current ICR, EPA seeks a new OMB control number in hopes that this will overcome this confusion.

A. Tier 1 List 1 ICR

EPA's first foray into EDSP screening consisted of an initial ICR requiring a battery of Tier 1 test orders for List 1 chemicals.

1. 60-day Notice and related documents published for public comment

EPA published a 60-Day Notice on December 13, 2007[4] along with a draft Supporting Statement.[5] EPA previously published a proposed list of chemicals to be subject to Tier 1 test orders ("List 1")[6] and a proposed policies and procedures

[2] The record for OMB control number 2060-0176 contains two entries: EPA's request for a new control number submitted April 15, 2009 (approved October 2, 2009, and expired on October 31, 2012) and an extension without change submitted October 30, 2012 (on which OMB did not act until July 3, 2013). OMB's approval includes the Terms of Clearance that are critical for evaluating the instant ICR submission, for which EPA seeks a new OMB control number. See Office of Management and Budget (2009).

[3] See http://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=2070-0176. U.S. Environmental Protection Agency (2009b), Table 10; and Regulations.Gov at http://www.regulations.gov/#!docketDetail;D=EPA-HQ-OPPT-2007-1081.

[4] U.S. Environmental Protection Agency (2007d).

[5] U.S. Environmental Protection Agency (2007b).

[6] U.S. Environmental Protection Agency (2007f). As an indicator of controversy, note that the public comment deadline was extended three times; *see* U.S. Environmental Protection Agency (2007h), U.S. Environmental Protection Agency (2007a), and U.S. Environmental Protection Agency (2007c).

guidance.[7] The draft Supporting Statement included, among other things, estimates of the number of respondents receiving Tier 1 test orders (445) who were expected to join consortia to share testing costs and data rights (367);[8] estimates of total respondent burden-hours and costs by activity[9] and burden-hours per chemical per respondent;[10] and estimates of total respondent burden-hours[11] and non-burden hour costs.[12]

The draft Supporting Statement included nothing about practical utility.[13] In lieu of what the PRA requires, the Supporting Statement discussed EPA's statutory mandate under FFDCA §408(p).[14] This appears intended to imply that any screening program the Agency might devise would *per se* fulfill its statutory responsibility and have practical utility.

2. Public comments on the 60-Day Notice

Significant public comments were submitted to EPA.[15] Commenters objected that Tier 1 assays had not actually been validated as the law requires;[16] protested that EPA had not finalized the screening battery or disclosed what test guidelines

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[7] U.S. Environmental Protection Agency (2007e). Four days after publication, EPA held a public workshop to discuss the draft policies and procedures guidance. See U.S. Environmental Protection Agency (2007g).

[8] U.S. Environmental Protection Agency (2007b), Table 1.

[9] U.S. Environmental Protection Agency (2007b), Table 6.

[10] U.S. Environmental Protection Agency (2007b), Table 7.

[11] U.S. Environmental Protection Agency (2007b), Table 8.

[12] U.S. Environmental Protection Agency (2007b), Table 9.

[13] The PRA defines *practical utility* as "the ability of an agency to use information, particularly the capability to process such information in a timely and useful fashion." 44 U.S.C. § 3502(11). OMB's Information Collection Rule defines *practical utility* as "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…" 5 C.F.R. § 1320.3(l). The draft supporting statement did not mention practical utility, much less explain how the proposed collection of information satisfied either the statutory or regulatory definitions.

[14] FFDCA § 408(p)(1) directs EPA to "develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate." EPA substituted validation processes for the statutorily-required validated test systems, discouraged the use of other scientifically relevant information, and provided no evidence that the Tier 1 Screening Battery had practical utility for determining whether substances may interact with human endocrine systems.

[15] Regulations.gov lists 12 public comments on the 60-Day Notice. EPA's Response-to-Comments document lists 11 public comments. *Cf*. U.S. Environmental Protection Agency (2011b) and U.S. Environmental Protection Agency (2009c).

[16] See, *e.g*., Center for Regulatory Effectiveness (2008), Ferenc, Siddiqui, Fratz, et al. (2009).

and protocols test order recipients would have to follow; [17] or objected to EPA's disinterest in Other Scientifically Relevant Information (OSRI) despite the law having given equal weight to it.[18] Commenters also alleged numerous burden estimation deficiencies, including that EPA had underestimated total direct testing costs by as much as threefold.[19]

3. 30-Day Notice and ICR submission

EPA published notice of its submission of this ICR to OMB on April 15, 2009,[20] including a revised Supporting Statement.[21] Despite critical public comments, EPA's burden estimates in the revised Supporting Statement did not change appreciably, as shown in Table A. Like the December 1007 draft, the April 2008 Supporting Statement was silent concerning practical utility. EPA also published a separate Response-to-Comments document (2009 RTC).[22]

The 2009 RTC provided useful information about EPA's thinking, if only unwittingly. For example, in noting the undisputed point that assays in the Tier 1 screening battery were not *validated test systems,* as FFDCA § 408(p) requires, EPA redefined the statute to require something much less demanding: adherence to its *validation process*. Whereas a validated test system is a test system that achieves a pre-defined performance standard across multiple trials within and across laboratories, EPA defined validation "as the process by which the reliability and relevance of test methods are evaluated for a specific use."[23] That is, to EPA validation is a paper exercise concerned solely with inputs, giving no weight to outputs or outcomes. An assay can pass EPA's validation process irrespective of its propensity to produce false positives or false negatives, its lack of replicability and reproducibility within or across laboratories, or even if it yields merely random data.

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[17] See, *e.g.*, Applied Pharmacology and Toxicology (2008). Agencies are required to certify, and provide a record supporting such certification, that a proposed collection of information "is written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond." 5 C.F.R. § 1320.9(d). Uncertainty about what Tier 1 test order recipients would be required to do is inconsistent with this requirement.

[18] FFDCA § 408(p)(1), the statutory authority for a portion of the original collection of information, directs EPA to "develop a screening program, using appropriate validated test systems and other scientifically relevant information." EPA's disinterest in OSRI was evident by the absence of guidelines for determining whether OSRI was sufficient and the absence of burden estimates in the Supporting Statement for the preparation and submission of OSRI.

[19] EPA's burden estimates excluded some burdens entirely (*e.g.*, costs of organizing and managing test consortia) and systematically underestimated others (*e.g.,* EPA counted only 35% of testing costs). See Ferenc, et al. (2009). For the three assays in which actual testing costs could be compared with EPA's estimates, actual costs exceeded EPA's estimates by 1.5x to 3x. See Applied Pharmacology and Toxicology (2008).

[20] U.S. Environmental Protection Agency (2009g).

[21] U.S. Environmental Protection Agency (2009b).

[22] U.S. Environmental Protection Agency (2009c).

[23] U.S. Environmental Protection Agency (2009c), p. 4.

Table A: EPA Burden Estimates Were Minimally Changed in Response to Public Comments on 60-Day Notice

	December 5, 2007 Supporting Statement	April 15, 2009 Supporting Statement
Test Order Recipients	445 [a]	390 [e]
Test Order Consortium Participants	367 [a]	323 [e]
Selected Burden Estimates		
Burden-hours	280,065 [b]	325,093 [f]
Test costs/chemical	$131,090 [c]	$141,511 [g]
Total burden ($)	$20,662,254 [d]	$22,434,349 [h]

Sources:
[a] U.S. Environmental Protection Agency (2007b, , Table 1).
[b] U.S. Environmental Protection Agency (2007b, , Table 7).
[c] U.S. Environmental Protection Agency (2007b, , Table 8).
[d] U.S. Environmental Protection Agency (2007b, , Table 9).
[e] U.S. Environmental Protection Agency (2009b, , Table 1).
[f] U.S. Environmental Protection Agency (2009b, , Table 10).
[g] U.S. Environmental Protection Agency (2009b, , Table 11).
[h] U.S. Environmental Protection Agency (2009b, , Table 12).

The 2009 RTC also asserts that completion of EPA's paper-based validation process isn't even necessary prior to the publication of a 60-day Notice and request for public comment.[24] EPA said that a "**functional** description of the information that it anticipates will be collected (e.g., indicating how, by whom, and for what purpose the information is to be used)" is sufficient to satisfy the PRA.[25] In short, in EPA's view the PRA is merely a process, much like EPA's validation process for Tier 1 assays: what matters is that the process is followed to completion at some point; it does not matter whether the performance standards for which the process was created are actually achieved. The purpose of public comment is to "help permit the agency to make the certification required by the PRA," not to help OMB ensure that the substantive standards of the PRA are actually met.[26]

[24] U.S. Environmental Protection Agency (2009c), p. 4.

[25] U.S. Environmental Protection Agency (2009c), p. 6 [emphasis in the original], citing 44 U.S.C. 3506(c)(1)(A)(ii) and 5 C.F.R. 1320.8(a)(2). In EPA's view, these provisions, found within two list of *disclosure* requirements, trump the PRA's overarching *substantive* requirement that collections of information have demonstrated actual practical utility.

[26] U.S. Environmental Protection Agency (2009c), p. 5.

4. Public comments on the 30-Day Notice and related documents

Significant public comments were submitted to OMB on various parts of the ICR, including the Supporting Statement and the 2009 RTC.[27] Commenters raised the same issues they had raised in response to the 60-day Notice; indeed, no major issues were resolved. Commenters again objected to EPA's substitution of a validation process for actual validation;[28] they objected to EPA's lack of transparency concerning weight-of-evidence methods and their application;[29] they objected to EPA's material underestimate of burden generally,[30] and particularly its undercounting of the cost of conducting laboratory assays;[31] and they objected to EPA's continued failure to demonstrate that Tier 1 data would have actual practical utility for the purposes of FFDCA § 409(p).[32]

5. Last minute revisions not made available to the public

On October 1, 2009—one day before OMB approved the ICR—EPA added seven new or amended documents to the ICR docket.[33] Obviously, the public had no opportunity to review these documents and provide comments. Among these new documents was an optional survey purportedly intended to improve the quality of EPA's future burden estimates.[34] The draft survey instrument contained numerous avoidable defects that public comment could have prevented, such as the neglect of burdens associated with OSRI.

Another new document was a revised accounting of the expected numbers of Tier 1 List 1 test order recipients.[35] The size of the test order recipient list suddenly increased almost twofold, from 390 to 749 respondents. This document also revealed for the first time that some chemicals had dozens of test order recipients,

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[27] For a web page containing links to the nine public comments submitted to OMB on the 30-day Notice, *see* http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=200904-2070-001.

[28] *See, e.g.,* U.S. Environmental Protection Agency (2009c) p. 9, Janus (2009), Slaughter (2009a), Slaughter (2009b).

[29] Willett, Seidle, Stoick, et al. (2009), p. 3: "The EPA cites its extensive experience with [weight-of-evidence] approaches in other assessment areas and suggests that this experience will translate to the EDSP, yet no one, including the Agency itself, has experience interpreting the result of the Tier 1 assays as a battery."

[30] See, *e.g.*, Fratz, Law and Little (2009), Slaughter (2009a), and Willett, et al. (2009).

[31] *See*, *e.g.*, Willett, et al. (2009).

[32] See, e.g., Ferenc (2009), Center for Regulatory Effectiveness (2009), Fratz, et al. (2009), Slaughter (2009a), and Slaughter (2009b).

[33] See the seven documents dated October 1, 2009, at http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=200904-2070-001.

[34] U.S. Environmental Protection Agency (2009f).

[35] U.S. Environmental Protection Agency (2009e).

making consortia formation and management a highly complex undertaking not accounted for in EPA's burden estimates.[36]

B. OMB Approval Subject to Detailed Terms of Clearance

The record supplied by public commenters led to obvious concern about whether the ICR adhered to PRA statutory standards for practical utility, burden minimization, and the avoidance of duplication. With this in mind, OMB approved the ICR on October 2, 2009, appending the following terms of clearance:

> This information collection is approved for the 67 chemicals published by EPA at 74 Fed. Reg. 17579 (April 15, 2009). OMB appreciates the continuing dialog with respect to the practical utility of the Tier I battery of EDSP assays and the role that the results from these first 67 chemicals will play in ensuring practical utility for subsequent groups of chemicals. Nonetheless, under the principles of the PRA, 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. 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.[37]

C. Tier 1 List 2 ICR

In 2010, EPA began the public process of expanding the Tier 1 screening program to additional chemicals. The current ICR is the culmination of that process.

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[36] Under EPA's burden estimation methodology, the cost of creating, managing, and participating in a consortium was fixed irrespective of the number of members. Commenters had raised concerns, dismissed by EPA, that large consortia would be much more expensive to manage.

[37] Office of Management and Budget (2009).

1. 60-Day Notice and related documents published for public comment

EPA published a 60-Day Notice on November 17, 2010.[38] EPA simultaneously published a proposed second list of chemicals to be subjected to Tier 1 screening ("List 2")[39] and a revised policies and procedures guidance concerning the Safe Drinking Water Act (SDWA) chemicals included on this list.[40] About two weeks earlier, EPA published draft weight-of-evidence guidelines.[41] Even with extensions, interested parties thus had a highly compressed period to review and comment on the proposed ICR and its related documents.

Ten public comments were submitted, raising the same legal, technical and procedural issues that had been raised in the Tier 1 List 1 ICR review.[42] Each of these was supposed to have been resolved through EPA compliance with OMB's terms of clearance.[43]

Several new issues also were raised, including:

- EPA's noncompliance with the five requirements in OMB's terms of clearance[44]
- The absence of robust scientific weight of evidence guidelines and Standard Evaluation Procedures[45]
- Whether EPA had modified the ICR to imply that positive Tier 1 results are presumptively adverse effects[46]
- Whether EPA was authorized to impose additional testing requirements beyond the 11 assays in the Tier 1 test battery in response to OSRI submissions[47]

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[38] U.S. Environmental Protection Agency (2010e).

[39] U.S. Environmental Protection Agency (2010d). The deadline for public comment was extended to January 18, 2011. See U.S. Environmental Protection Agency (2010c).

[40] U.S. Environmental Protection Agency (2010b). The deadline for public comment—January 18, 2011—was not extended.

[41] U.S. Environmental Protection Agency (2010f) (Federal Register announcement) and U.S. Environmental Protection Agency (2010g) (text). The deadline for public comment was extended to February 3, 2011. See U.S. Environmental Protection Agency (2010h).

[42] U.S. Environmental Protection Agency (2011a) (comments uploaded January 21, 2011).

[43] Bayer CropScience (2011b), Ferenc (2011), Jones (2010), Jones (2011), Slaughter (2011), Van Volkenburg (2011), and Willett, Sullivan, Leary, et al. (2011).

[44] Bayer CropScience (2011b), Ferenc (2011), Jones (2010), Jones (2011), and Slaughter (2011).

[45] Bayer CropScience (2011b), Ferenc (2011), Jones (2011), and Slaughter (2011).

[46] Jones (2011) and Van Volkenburg (2011), subsequently recognized by Thorp (2013).

[47] Slaughter (2011), citing U.S. Environmental Protection Agency (2010a). EPA implicitly directed the test order recipient to perform an additional test not covered by OMB's ICR approval: "In the case of the Tier 1 in vivo assays, the Agency recommends the conduct of measures of RBC and

These new issues further complicate OMB's review of this ICR, making the argument for a procedural disapproval (as recommended in Section VI below) even more compelling. Further, EPA's proposed expansion of Tier 1 scope is unambiguously provocative given commenters' well-founded complaints that EPA has been systematically non-transparent and unresponsive.

2. June 2011 administrative petition

On June 21, 2011, three trade associations submitted an administrative petition seeking timely action by EPA on several matters related to the practical utility of the collection of information as approved by OMB in 2009.[48] Petitioners specifically asked EPA to:

- Provide scientifically valid, peer-reviewed critical process and procedure guidance documents for Tier I screening;
- Provide sufficient time for List 1 test order recipients to prepare and submit their Tier I screening results in compliance with that guidance; and
- Fully analyze the List 1 screening data, and revise EDSP guidance based on lessons learned prior to the issuance of List 2 test orders.

Petitioners noted that EPA's 60-day Notice for Tier 1 List 2 indicated that the Agency was "beginning the process for screening additional chemicals" before these actions had been completed, contrary to OMB's terms of clearance and the recommendations in a May 2011 EPA Inspector General report.[49]

Practical utility concerns were self-evident:

> The value of the unique data-rich history of the List 1 Chemicals to the Program will be diminished unless the production and review of the List 1 Chemical screening data can be organized and conducted under a logical, systematic process, and reviewed and characterized before testing of List 2 Chemicals begins.[50]

Petitioners broadly invoked the PRA, the Administrative Procedure Act, and the Federal Food, Drug, and Cosmetic Act, asking EPA to respond within 30 days.

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brain cholinesterase activity. These measures should be made in addition to the Tier 1 assay measurements" (emphasis added).

[48] Crop Life America, Consumer Specialty Products Association and Responsible Industry for a Sound Environment (2011).

[49] U.S. Environmental Protection Agency Office of the Inspector General (2011). EPA was obligated by law to respond to this report by August 1, 2011.

[50] Crop Life America, et al. (2011), pp. 1-2.

Petitioners' sought an early response because some respondents were obligated to provide results in response to List 1 test orders by October 2011.[51]

EPA published notice on August 12, 2013 making the petition publicly available and provided 60 days to submit comments.[52] Seven comments were submitted; all but one broadly supported the petitioners.[53] To date, EPA has not responded to this petition.

3. December 2011 administrative petition

On December 6, 2011, two trade associations and a public interest group submitted an administrative petition seeking EPA compliance with OMB's 2009 terms of clearance.[54] Petitioners asked EPA to:

- Demonstrate that the information collected during Tier 1 screening is not duplicative of already existing information; and
- Demonstrate the practical utility of the information collected in Tier 1 screening.

With respect to duplication, petitioners specifically noted that while OMB's terms of clearance require EPA to accept OSRI to the greatest extent possible, EPA had thus far rejected 78% of the OSRI submissions reviewed.[55] Petitioners wanted EPA to scientifically demonstrate that Tier 1 assays were not duplicative, as required by the PRA, noting that the duty to avoid unnecessary duplication rests with the Agency and it may not legally shift the burden of proof to the public. [56] With respect to

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[51] Crop Life America, et al. (2011), p. 3: "[W]e submit this petition now to encourage the Agency to heed the direction of Congress, OIRA and the OIG Report and address these issues in a timeframe that might provide meaningful relief and due process to all List 1 Chemical test order recipients."

[52] U.S. Environmental Protection Agency (2011c). The deadline for public comment was October 11, 2011.

[53] Bayer CropScience (2011a), Bishop, Willett and Sullivan (2011), Conlon (2011), Graul , Palmer (2011), and Watson and Ortego (2011) supported the petitioners; Janssen and Gerhart (2011), representing the litigants that compelled EPA to begin implementing FFDCA ß 408(p), opposed them.

[54] Chemical Producers & Distributors Association, Halogenated Solvents Industry Alliance and People for the Ethical Treatment of Animals (2011).

[55] Chemical Producers & Distributors Association, et al. (2011), pp. 4-5. Petitioners attributed this, in part, to the absence of weight-of-evidence guidelines: "Without having published the [weight-of-evidence] Guidance prior to its review of OSRI submitted in response to List 1 chemical test orders, the Agency cannot justify the OSRI determinations it made at that time. It is obvious from EPA's dismissive treatment of OSRI for List 1 chemicals that the body of knowledge for a particular chemical had not been fully considered in a [weight-of-evidence] approach, nor had a consistent weighting scheme been applied to assess the quality of the studies and results submitted."

[56] 44 U.S.C. § 3506(c)(3)(B): "With respect to the collection of information and the control of paperwork, each agency shall certify (and provide a record supporting such certification, including public comments received by the agency) that each collection of information submitted to the

practical utility, petitioners noted that the absence to date of a scientifically sound Weight of Evidence framework made this impossible to demonstrate.[57]

On February 29, 2012, EPA published a notice making the petition publicly available and provided six months to submit.[58] Six public comments were submitted, all broadly in agreement with the petitioners.[59] To date, EPA has not responded to this petition.

III. 30-DAY NOTICE AND REQUEST FOR PUBLIC COMMENT TO OMB ON TIER 1 LIST 2

On June 14, 2013, EPA published notice of its submission of this ICR to OMB and a request for public comment,[60] along with the Agency's final List 2[61] and a revised policies and procedures guidance applicable to the SDWA chemicals on this list.[62] EPA's submission to OMB included a Supporting Statement,[63] a second Response-to-Comments document (2013 RTC),[64] test cost calculations,[65] and numerous other attachments such as proposed test orders.[66]

A. 2013 Response-to-Comments Document (2013 RTC)

The 2013 RTC addresses some but not all public comments received on the 60-Day Notice. It does not mention either of the administrative petitions submitted in 2011.

In response to commenters who had objected to EPA's noncompliance with OMB's 2009 terms of clearance, the 2013 RTC communicates EPA's intention to postpone compliance to an unspecified future date.[67] In response to commenters

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Director for review … is not unnecessarily duplicative of information otherwise reasonably accessible to the agency" (emphasis added).

[57] Chemical Producers & Distributors Association, et al. (2011), pp. 6-8, pp. 6-8.

[58] U.S. Environmental Protection Agency (2012). The deadline for public comment was August 27, 2012.

[59] Gordon (2012), McLallen (2012), McMahon (2012), Palmer (2012), Slaughter (2012), and Sullivan (2012).

[60] U.S. Environmental Protection Agency (2013i). Contrary to the requirements of 5 C.F.R. § 1320.10(a), which requires agencies to direct public comments on 30-Day Notices to OMB, the Agency misdirected the public to submit comments to EPA.

[61] U.S. Environmental Protection Agency (2013h)

[62] U.S. Environmental Protection Agency (2013d)

[63] U.S. Environmental Protection Agency (2013c).

[64] U.S. Environmental Protection Agency (2013a).

[65] U.S. Environmental Protection Agency (2013b).

[66] See supplementary documents at http://www.reginfo.gov/public/do/PRAViewDocument?ref_nbr=201306-2070-003.

[67] U.S. Environmental Protection Agency (2013a), p. 5: "EPA fully intends to follow the terms of clearance as additional information becomes available."

alleging that Tier 1 still lacks practical utility, the 2013 RTC stated EPA's belief that explanations in the draft Supporting Statement are sufficient.[68] The Supporting Statement is silent on the subject of practical utility.[69]

In response to commenters alleging that Tier 1 assays are duplicative of OSRI, the 2013 RTC notes that test order recipients "are entitled to submit the data as OSRI along with a clear rationale why it would suffice for the required data."[70] The 2013 RTC does not address commenters complaints that EPA's decisions whether to accept OSRI have lacked transparency and are substantively incompatible with OMB's directive to maximize the acceptance of OSRI. As EPA stated in the 2009 RTC, notwithstanding the clear requirements of the PRA,[71] EPA believes that the public bears the burden of proving that a collection of information is unreasonably burdensome.[72]

In response to commenters alleging that EPA has repeatedly and systematically understated burden, the 2013 RTC states that the Agency agrees that previous burden estimates were understated, and several changes are noted.[73] These changes are minor, however. EPA now estimates the median cost of the Tier 1 battery at about $580,000, but this is approximately half of the burden estimate provided by commenters, who actually have to pay for them.[74] Further, EPA continues to assume that each assay will be performed only once despite evidence

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[68] U.S. Environmental Protection Agency (2013a), pp. 6-7: "EPA disagrees with this comment. The draft ICR Addendum Supporting Statement explained the utility of the data generated by each assay and its intended use in decision-making, as well as the estimated cost and burden for each assay."

[69] The closest text is in the section titled "Need for and Use of the Collection." This text recites EPA's statutory mandate to "identify substances that have the potential to interact with the estrogen, androgen, or thyroid hormone systems" but does not explain how Tier 1 data have practical utility for this statutory purpose, the specific issue commenters addressed. *See* U.S. Environmental Protection Agency (2013c), p. 3. The text also attributes to statute what EPA has decided administratively—the expansion of screening and testing with respect to interactions with the androgen and thyroid hormone systems.

[70] U.S. Environmental Protection Agency (2013a), p. 7.

[71] 5 C.F.R. § 1320.5(d)(1)(ii): "To obtain OMB approval of a collection of information, an agency shall *demonstrate* that it has taken every reasonable step to ensure that the proposed collection of information … is not duplicative of information otherwise accessible to the agency" (emphasis added).

[72] U.S. Environmental Protection Agency (2013a), p. 7: "Implicit in the comment is the idea that EPA should bear the responsibility for making a determination of whether existing data are adequate for the EDSP prior to issuing an order. However, both FIFRA and FFDCA clearly indicate that it is the responsibility of the manufacturer and/or registrant to demonstrate that their chemical and/or product can be used safely." EPA's argument is a *non sequitur.* The production of Tier 1 data is not a prerequisite demonstrating safety under FIFRA or FFDCA, and no such demonstration is required under SDWA.

[73] U.S. Environmental Protection Agency (2013a), p. 8.

[74] See, *e.g.,* Thorp (2013).

from Tier 1 List 1 screening that some assays had to be performed multiple times to meet the Agency's performance criteria.[75]

B. 2013 Supporting Statement

Like both predecessors, the 2013 edition of the Supporting Statement is silent concerning practical utility. Any practical utility claim must be inferred from the section titled "Need For and Use of the Collection," which merely recycles previous text summarizing FFDCA § 408(p). The Supporting Statement plows no new ground with respect to the question of duplication, and it continues to rely on the same burden estimation methodology that commenters previously criticized as defective.[76]

IV. SAP REVIEWS ARE RELEVANT TO OMB'S DETERMINATION OF PRACTICAL UTILITY, BUT STRUCTURED TO MAKE THIS IMPOSSIBLE

FFDCA § 408(p) requires EPA to rely extensively on input from its FIFRA Scientific Advisory Panel (SAP). OMB's terms of clearance reinforce the importance of peer review:

> [I]n order to ensure that EPA has maximized the practical utility of the Tier [1] 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 [2], including the Weight of the Evidence Approach and Standard Evaluation Procedures.[77]

There are government-wide guidelines EPA must follow in designing peer review to ensure that scientific information on which it relies meets rigorous information quality standards. Among other things, these guidelines call for peer review panels to be genuinely independent of the sponsoring agency and limited to scientific matter and not policy. Agencies are required to respond in writing to reports prepared by the peer reviewers.[78] EPA's Peer Review Handbook includes similar requirements.[79]

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[75] FIFRA Scientific Advisory Panel (2013a), pp. 237-238.

[76] See, *e.g.,* Belzer (2009), pp. 23-48, and Ferenc (2011), pp. 2-4 (describing EPA's burden estimation methodology as fundamentally flawed based on this analysis).

[77] Willett, et al. (2009).

[78] Office of Management and Budget (2005).

[79] See, *e.g.*, U.S. Environmental Protection Agency (2006), p. 51, Sec. 2.5.4 ("Offices should instruct peer reviewers to prepare a report that describes the nature of their review and the nature of their findings and conclusions. The peer review report should either (a) include a verbatim copy of each reviewer's comments (either with or without specific attributions) or (b) represent the views of the group as a whole, including any disparate and dissenting views, although attribution of

EPA organized and scheduled two SAP reviews highly relevant to the Tier 1 battery. The first review was supposed to evaluate the battery by reviewing the data submitted by test order recipients and consortia on List 1 chemicals. The second review was supposed to evaluate EPA's Standard Evaluation Procedures (SEPs) and weight-of-evidence guidelines. Unfortunately, the first SAP review cannot fulfill its mission and the second is highly unlikely to do so.

A. Tier 1 Screening Assays and Battery Performance (May 21-23, 2013)

This SAP review was announced on February 22, 2013, with a May 7, 2013, deadline for public comments.[80] The lead time was relatively generous, but it came with a price: SAP panel members would have little ability to consider public comments as part of their review. Further undermining the rigor of this review, EPA provided the SAP "hand selected" data from only 21 of the 53 Tier 1 chemicals screened[81] and settled on a charge some commenters considered technically problematic.[82] Some commenters interpreted the schedule as rushed.[83]

The SAP expressed frustration with the limited data provided by EPA.[84] Panel members thought that they needed the complete data set to perform their review and that complete data were required in order to make the second SAP panel (on weight of evidence) meaningful.[85]

Why EPA disclosed only limited Tier 1 data is not clear. EPA claimed that the 21 chemicals for which it provided data were representative, but it supplied no supporting evidence of this, nor is it obvious how the Agency could have determined a representative sample. While the sample of 21 is described by EPA as representative and having been chosen for "very specific" reasons, these reasons were not clearly articulated.[86]

In its description of the data, EPA acknowledged significant technical and information quality problems had rendered them difficult to interpret.[87] Technical problems reported in performing some assays undermined confidence that the

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comments to names is not necessary"… For highly influential scientific assessments, the OMB Bulletin explicitly calls for Offices to prepare a written response to the peer review report explaining (a) the agency's agreement ort disagreement with the views expressed in the report, (b) the actions that have or will be undertaken to respond to the report, and (c) the reasons the [sponsoring] Office believes those actions satisfy any key concerns or recommendations in the report."

[80] U.S. Environmental Protection Agency (2013e).

[81] FIFRA Scientific Advisory Panel (2013a), p. 28.

[82] Thorp (2013).

[83] Glenn and Walls (2013)

[84] See, *e.g.,* FIFRA Scientific Advisory Panel (2013a), pp. 238, 331, 358, 459, 481.

[85] FIFRA Scientific Advisory Panel (2013a), p. 497.

[86] FIFRA Scientific Advisory Panel (2013a), p. 32.

[87] FIFRA Scientific Advisory Panel (2013a), p. 30.

resulting data deserved much confidence.[88] SAP members shared these concerns about the test data, and struggled to distinguish adverse from nonadverse effects and significant from nonsignificant variability.[89]

A reasonable inference from this SAP review is that Tier 1 data are interesting from an exploratory data analysis perspective, but they are not particularly useful for discerning which substances may have a biologically meaningful endocrine-related effect that warrants advancement to Tier 2, which of course is the stated purpose of Tier 1 screening. Even though the panel did not have the complete 53-chemical database, it recommended that some Tier 1 assays be reconsidered based implicitly on information quality principles.[90] This recommendation is not reflected in the Tier 1 List 2 ICR.

The limited scientific value of the Tier 1 battery was summarized memorably by SAP member Terry Schultz, who said with respect to one of the lowest-value assays in the Tier 1 battery:

> We're not asking the Agency to change the horse in the middle of the stream, but as soon as you get to shallow water on the other side, start looking at another way to get across the river.[91]

Meanwhile, it will be a matter of months before this SAP peer review is completed. The panel can prepare a formal report or rely just on the transcript. In either case, EPA is obligated to prepare a response and the SAP is entitled to review it.

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[88] See, *e.g.,* FIFRA Scientific Advisory Panel (2013a), p. 238, where Syngenta Senior Toxicologist Su YI reported on the Steroidogenesis and Aromatase assays: "[I]n many of the cases, assays had to be repeated to get to or get close to the performance criteria, so there's quite a bit of variability. So in that respect, this decreases the usefulness of this assay. Not only does it have to be repeated many times to meet the criteria, so it's no longer rapid, nor is it actually cost-effective because it has to be repeated, but most importantly, this decreases the confidence of the data that's generated." Other laboratory personnel made similar comments; see, e.g., pp. 336-337

[89] See, *e.g.*, FIFRA Scientific Advisory Panel (2013a), pp. 398-399: SAP member Barry Delclos, commenting on the problem of distinguishing endocrine-related effects from overt toxicity: "Well I think, as already been said, in most cases the overt toxicity is going to make it impossible to clearly link observed effects to an endocrine-related mechanism. It might not always be the case. I could imagine, for example, a body weight being significantly reduced and still seeing an accelerated vaginal opening. That wouldn't interfere with the interpretation of that affect. But it is going to be problematic, particularly if it's a critical study. Affects [sic] are observed only in the dose group of overt toxicity. If only one screening assay shows a positive affect it would be difficult to weigh that in to deciding whether compounds should go on to Tier 2 without a repeat experiment of a lower dose."

[90] FIFRA Scientific Advisory Panel (2013a), p. 376: "[T]he Panel feels there is sufficient evidence with selected assays to suggest the reevaluation of the test protocols may be in order." All information quality-related comments must be inferred. Contrary to OMB and EPA peer review guidelines, the charge to the SAP did not explicitly include information quality considerations.

[91] FIFRA Scientific Advisory Panel (2013a), p. 429.

B. Weight-of-Evidence Evaluation of Results of EDSP Tier 1 Screening (July 30-August 2, 2013)

EPA announced the second SAP meeting on April 17, 2013, with a public comment deadline of July 16, 2013. Concerns that had been raised previously about the short time between the deadline and the meeting remain unabated. A draft agenda has been published[92] along with charge questions.[93]

Given that the meeting has not yet been held, it is obviously too early to evaluate whether it was a success. But the problems that afflicted the first SAP meeting will necessarily undermine the second meeting. The challenge posed to the SAP will be to evaluate the scientific rigor and utility of EPA's weight-of-evidence guidelines even though it is not clear which Tier 1 data are sufficiently valid, reliable, and scientifically meaningful to include in a weight-of-evidence analysis.

One thing is clear, however. The SAP's weight-of-evidence review cannot be used to improve the scientific merit and practical utility of this ICR. The ICR was submitted months before the transcript of the SAP review will be published. Sometime thereafter, EPA presumably will prepare a response to the SAP, which the SAP will have an opportunity to evaluate. Completion of the second SAP peer review report, EPA's written response, and public review of both is months away.

V. PAPERWORK REDUCTION ACT ANALYSIS

A. This ICR Does Not Comply with Statutory Standards in the Paperwork Reduction Act

The PRA requires agencies to demonstrate the actual practical utility of the information they seek to collect *before* they seek OMB approval to collect it. Further, EPA did not minimize the burden of this collection even if the law's practical utility requirement had been stipulated as satisfied. The only burden-minimizing actions EPA undertook were required by FFDCA § 408(p), not the PRA. Moreover, EPA placed little weight on OSRI even though § 408(p) contained a bias against new laboratory tests requiring animal sacrifice.

None of EPA's Supporting Statements have made any effort to show that Tier 1 data have practical utility. Indeed, as noted above, none of the Supporting Statements even mention practical utility. EPA simply waves FFDCA § 408(p) as if it were a talisman that confers on the Agency an exemption from the PRA's most important substantive requirement.

EPA also does not appear to be much further along toward making a practical utility demonstration today. Yet the Agency insists on expanding Tier 1 testing to new chemicals, including chemicals, such as possible SDWA contaminants, for which

[92] FIFRA Scientific Advisory Panel (2013b).

[93] U.S. Environmental Protection Agency (2013f).

its statutory authority is strictly discretionary. This is consistent with an agency charging onward to build a program for its own sake rather than for the public purpose identified by Congress.

Both the PRA and government-wide policy call for maximizing the utility of independent, external scientific peer review to inform decision making with respect to the design of Tier 1 screening. To achieve this, EPA should be utilizing the SAP effectively to ensure and maximize information quality. Instead, EPA has committed the SAP to review the performance of the Tier 1 battery without providing all of the available Tier 1 data despite the extraordinary expenditures made to acquire them. And EPA plans to force the SAP to review its weight-of-evidence guidelines before the Agency has been able to determine which Tier 1 data, if any, meet minimum information quality standards necessary for inclusion in any weight-of-evidence scheme.

B. EPA Has Not Complied with OMB's 2009 Terms of Clearance

Faced with this dilemma in its review of the Tier 1 List 1 ICR, OMB appears to have tried to execute a rough compromise. In return for acceding to EPA's insistence that it was bound by statute and consent decree to advance the EDSP program even though it was not scientifically ready, EPA would meet all applicable PRA standards before OMB approved any expansion of the program.

EPA has not lived up to its end of the bargain, however. Not only has the Agency failed to fulfill its duties under the terms of clearance, it has attempted to redefine them in ways that would render them nonbinding. This is clear from EPA's Response-to-Comments document, which characterizes the terms of clearance as hortatory goals to be met some day in the future, but certainly not now.

Terms of clearance are integral components of an OMB approval. They are intended to provide the public additional clarity and to reduce uncertainty concerning the legitimate scope, scale, and other material attributes of a collection of information, particular one that an agency intends to make mandatory. If agencies were free to ignore terms of clearance, OMB would be compelled to disapprove every collection of information in which the agency ICR, as submitted, was in any way incomplete or ambiguous. Further, the PRA's public protection provisions, without which the law is a dead letter, would be virtually impossible to invoke in any instance where an agency obtained a valid OMB control number but proceeded to implement an approved information collection in unapproved ways.

OMB's terms of clearance require EPA to accomplish five tasks:

1. Minimize duplication by maximizing its reliance on OSRI;
2. Maximize the practical utility of Tier 1 data by (a) developing scientifically sound Standard Evaluation Procedures and weight-of-evidence methods, (b) ensuring a meaningful opportunity for the

> public to comment, and (c) subjecting to rigorous, external, and independent peer review; and
>
> 3. Accurately estimate the burden of the information collection.

The terms of clearance require these tasks to be completed before OMB will approve any expansion of the Tier 1 screening program.

OMB's terms of clearance are founded on the statutory requirements of the PRA. These statutory requirements apply not just to agencies conducting or sponsoring collections of information, such as EPA, but to OMB as well, and the critical authorities delegated to OMB by Congress may not be re-delegated back to an agency. For example, by law it is OMB (not EPA) that "shall determine whether the collection of information … is necessary for the proper performance of the agency's functions."[94] Further, OMB's determinations under the PRA are binding on EPA:

> [T]o the extent that OMB determines that all or any portion of a collection of information is unnecessary, for any reason, the agency shall not engage in such collection or portion thereof.[95]

EPA has not adhered to OMB's terms of clearance. In particular, the available public evidence indicates that:

- EPA has *not* "promote[d] and encourage[d] test order recipients to submit Other Scientifically Relevant Information (OSRI) in lieu of performing all or some of the Tier I assays." There is no straightforward performance standard defining the minimum threshold of "promotion" and "encouragement" sufficient to satisfy the terms of clearance. EPA has made some effort to tolerate OSRI, but it has not demonstrated any effort to promote or encourage it in lieu of Tier 1 screening, and there is evidence suggesting that it may have retaliated against an OSRI submitter by imposing an unapproved, additional testing burden.
- EPA has *not* "accepted OSRI as sufficient to satisfy the test orders to the greatest extent possible." Of 51 requests, EPA has accepted no requests in full and only 29 in part, and denied 22 in full.[96] EPA has not published any explanation of its decision-making rationale that could credibly be used to predict the Agency's OSRI determinations. Nor has EPA published a transparent weight-of-evidence guidance that could credibly be used to predict how OSRI and Tier 1 test data would be interpreted.

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[94] 5 C.F.R. 1320.5(e).

[95] 5 C.F.R. 1320.5(f), emphasis added.

[96] Office of Management and Budget (2009). Requests vary with respect to which assays the respondent seeks waiver in favor of OSRI. The effort devoted by EPA to write these responses, which are generally dozens of pages long, is not captured in EPA's burden estimates.

- EPA has *not* "provide[d] a report re-estimating the burden of this information collection based on responses to the Tier I test orders" and other factors stated in the terms of clearance. EPA's burden revisions are minor and do not address commenters' most significant objections. The same errors in burden estimation that EPA committed in the 2009 ICR, and which led to OMB's terms of clearance, appear again in this ICR.
- EPA has *not* "provide[d] a report [containing a] description of any instances in which submission of OSRI was deemed insufficient to satisfy the testing order." EPA's spreadsheet of OSRI actions is not equivalent to a description, nor has EPA accompanied this spreadsheet with coherent explanations showing how it reached its decisions. The spreadsheet links to EPA response documents that in many cases are hundreds of pages long. To comply with the terms of clearance, EPA needs to produce a report that examines how it reviewed OSRI, and especially the reasons why it deemed almost all OSRI insufficient. Compliance with the spirit of the terms of clearance require EPA to seek public comments on this report and respond to these comments in good faith.
- EPA has *not* "ensure[d] 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 [2], including the Weight of the Evidence Approach and Standard Evaluation Procedures." EPA has steadfastly resisted requests by the public for transparency and meaningful opportunities to provide informed public comment and thoroughly resisted the comments it has received. EPA's decision to rush this ICR before the SAP reviews are fully complete is yet more evidence of the Agency's lack of commitment to transparency and meaningful public participation.

C. EPA Has Not Shown that the Proposed Expansion in Tier 1 Scope Has Practical Utility

The proposed inclusion of substances from the Office of Water's Contaminant Candidate List 3 ("CCL 3")[97] in List 2 marks a substantial potential expansion of the scope as well as the scale of Tier 1 screening. All of the previous arguments that favor procedural disapproval of the Tier 1 List 2 ICR grow even stronger if serious consideration is given to expanding Tier 1 beyond the confines of FFDCA § 408(p)(3)(A) and into § 408(p)(3)(B), which is wholly discretionary.[98] Whatever the case for deferring to EPA with respect to pesticides—a case that the record

[97] U.S. Environmental Protection Agency (2009d).

[98] In carrying out the screening program described in paragraph [§ 403(p)](1), the Administrator may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such substance" (emphasis added).

shows is rather weak, given the lack of practical utility for Tier 1 data—no such case exists at all for other substances.

In addition, OMB's evaluation of practical utility requires a more demanding evidentiary test. Whereas § 401(p)(3)(A) makes no distinctions among pesticides, § 408(p)(3)(B) significantly constrains EPA's discretionary authority with respect to other substances. To be eligible for the EDSP, a non-pesticidal substance must meet a pair of criteria that pesticides do not. Testing is limited to substances to which "a substantial population may be exposed," and the endpoint of interest must be "an effect that is cumulative to an effect of a pesticide chemical." In short, § 408(p)(3)(B) substances are those which are biologically similar to pesticides but are not regulated as such, and a lot of people have to be exposed to them at biologically meaningful doses.

To determine whether the proposed expansion of the scope of Tier 1 has practical utility, OMB must first address whether Tier 1 is ready to be expanded in scale to other pesticides. Then OMB must determine whether Tier 1 screening satisfies the more demanding practical utility test applicable to § 408(p)(3)(B) substances. Unfortunately, nothing in the Supporting Statement helps inform these determinations. EPA ignores how §§ 408(p)(3)(A) and (B) differ. Whereas in Tier 1 List 1, EPA strongly emphasized the statutory text in § 408(p)(3)(A), it ignores how the statutory text relevant to Tier 1 List 2 is different.

D. EPA Has Timed and Structured SAP Reviews to Make them Irrelevant to This ICR

Because they were provided a "hand selected" subset of Tier 1 data, the FIFRA Scientific Advisory Panel reviews that EPA has initiated are structured in a manner that prevents the panel from conducting a rigorous examination of the battery. EPA also has scheduled them so that their results cannot be incorporated into Tier 1 List 2 screening.

1. Structural defects in the SAP review process

To maximize the value of SAP review, EPA should have included, to assist in meeting the OMB Terms of Clearance, an iterative process consisting of at least four steps:

1. An SAP review of EPA's determinations that OSRI is insufficient;
2. An SAP review of the results from Tier 1 assays, based on information quality principles, to ascertain whether these data reveal whether a substance has the potential to interact with the endocrine, androgen, or thyroid hormone systems;
3. An SAP review of EPA's proposed Weight of Evidence analysis that includes both OSRI and data from Tier 1 assays that passed muster under the first SAP review; and

4. An SAP review of EPA's scientific inferences about the likelihood that substances may interact with the endocrine, androgen, or thyroid hormone systems.

Instead, EPA organized only two SAP reviews—one to ratify EPA's Tier 1 battery and a second to ratify EPA's proposed weight-of-evidence framework. Neither of these peer reviews is anywhere near complete.

The first review was held in May 2013, and the SAP has issued a transcript but not a final report. The second review is scheduled for the end of July; obviously, any final report authored by the SAP is months away. Meanwhile, the critical documents contained in this ICR were finalized by April 2013. It is simply impossible for these SAP reviews to play any timely role in informing EPA decision-making on Tier 1 List 2 screening. Moreover, EPA has clearly stated that it intends to rely on guidance from the same 1999 SAP report on which it relied for List 1 screening.[99] It is therefore reasonable to be concerned that EPA does not intend for these SAP reviews to play any material role, in which case it would have designed the peer review process much differently.[100]

2. The timing of this ICR is incompatible with commitments made by EPA that it intended to delay List 2 test orders until data from List 1 assays have been completely reviewed

In response to a question raised at a recent meeting of the Pesticide Policy Dialogue Committee (a chartered federal advisory committee), Mary Manibusen, Director of the Exposure Assessment Coordination & Policy Division of EPA's Office of Science Coordination and Policy, acknowledged that the Agency is obligated to comply with OMB's terms of clearance.[101] To assure the public of this understanding, she mentioned relevant text in the final policies and procedures guidance, which states:

> The Agency intends to complete review of the Tier 1 data from the EDSP test orders issued for the first list of EDSP chemicals before issuing Tier 1 test orders for the second list of EDSP chemicals.[102]

That EPA has such intentions is undoubtedly comforting to prospective List 2 test order recipients. But it raises a question: Why is EPA seeking OMB approval of a List 2 ICR now, before this review is complete? If OMB were to approve the List 2

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[99] U.S. Environmental Protection Agency (2013d), p. 35916/2.

[100] It is likely that SAP members, who presumably agreed to participate with the expectation that their work would be relevant to EPA decision-making, are unaware that their work is functionally irrelevant. For example, a review of the transcript of the first SAP review indicates that nothing was said about this ICR, even though its contents were essentially complete in April 2013 and ready to be transmitted to OMB, which occurred on June 14, 2013, shortly after the SAP review meeting had concluded. *See* U.S. Environmental Protection Agency (2011b).

[101] U.S. Environmental Protection Agency (2013g).

[102] U.S. Environmental Protection Agency (2013d), p. 35916/1.

ICR now, EPA would be prohibited from making any material changes in response to these reviews without beginning a new ICR process. That means the SAP are simply unrelated to EPA schedule for expanding the scope of Tier 1 screening.

3. The structure and timing of the SAP reviews are incompatible with OMB's terms of clearance

OMB's terms of clearance require that relevant scientific peer reviews will occur *before* EPA submits any ICR that would expand Tier 1 screening. They also require that any such ICR be informed by the results of these reviews. It makes no sense to conduct reviews after the decisions they are intended to inform have already been made.

Contrary to the terms of clearance, however, EPA designed (and has so far implemented) the SAP review process in a way that renders them irrelevant to Tier 1 screening. The first SAP review was conducted after the ICR was completed (but before it was submitted to OMB). The second SAP review would not even occur until more than six weeks after the ICR was submitted, and perhaps after EPA hopes that it would be approved. Peer reviews conducted after submission of an ICR obviously cannot have any constructive effect. Moreover, if OMB were to approve this ICR, it would be impossible for these SAP reviews to have any timely influence on the Tier 1 screening program. Indeed, OMB approval now could make it impossible for the SAP to ever constructively influence Tier 1 screening.

VI. OMB SHOULD DISAPPROVE THIS ICR AS PREMATURELY AND IMPROPERLY SUBMITTED

The record shows convincingly that this ICR was prematurely and improperly submitted. Submission was premature because it preceded the SAP review process that is supposed to inform any Tier 1 expansion. Submission was improper because EPA has declined to follow the compromise that OMB generously established through terms of clearance in 2009 to ensure that future expansions of Tier 1 screening fulfill FFDCA directives while adhering to PRA statutory requirements.

A. OMB Has an Obligation to Enforce the Statutory Requirements Set Forth in the Paperwork Reduction Act

The Paperwork Reduction Act directs OMB to make certain independent determinations based on the record provided by the agency proposing to conduct or sponsor a collection of information, public comments on this agency-supplied record, and other information OMB is able to glean from its own research and analysis. In particular, OMB must determine that the proposed information collection is consistent with the law's overarching goals, which are minimizing the

paperwork burdens imposed on the public and ensuring that those burdens which are imposed secure the greatest possible public benefit.[103]

One minimum requirement toward achieving these goals is that the information to be collected has actual, not merely theoretical, practical utility for the agency. Information that lacks practical utility cannot meet the statutory standard irrespective of its burden. A second minimum requirement, which arises only after practical utility has been demonstrated, is that the burden imposed on the public, when accurately estimated, is commensurate with the practical utility of the information.

To address the first of these minimum requirements, OMB normally begins by carefully examining the record supplied by the agency, not just accepting its claims, assertions, and pro forma certifications. If this record fails to make a prima facie case for actual practical utility, OMB's inquiry should cease and the ICR should be disapproved.

If a *prima facie* case is established, then OMB's inquiry proceeds to an examination of public comments to determine if the agency's case is wholly or substantially rebutted. If in OMB's sole judgment the agency's practical utility case is rebutted, then OMB's inquiry should end with disapproval. OMB is directed by law to balance practical utility and burden, and a lack of practical utility should commensurately reduce the amount of burden that OMB considers reasonable. Where practical utility is negligible, only negligible burdens are permissible. EPA's serial underestimation of burden, which may have the effect of inducing OMB to be satisfied with weak practical utility claims, should instead intensify OMB's insistence that there be actual practical utility in this collection of information commensurate with its extraordinary burden.

B. The Limits on OMB's Authority Are Much Narrower than EPA Implies Because Most of This ICR Consists of Non-Statutory, Discretionary Information Collections

It is not unusual for agencies to assert, as EPA does in this ICR, that Congress has required the agency to impose a collection of information and that the agency has little or no administrative discretion. Where OMB can validate these assertions, it is obligated to defer to Congress. But OMB is not required to defer to agency representations of Congressional directives. Indeed, by rule OMB has reserved to itself the authority to make its own independent judgment of the merits of such agency claims:

> OMB will consider necessary any collection of information specifically mandated by statute or court order, but will independently assess any

[103] 44 U.S.C. 3501(1)-(2).

> collection of information to the extent that the agency exercises discretion in its implementation.[104]

In this case, EPA's claim that Congress has commanded it to impose this particular collection of information is highly controversial. Through FFDCA § 408(p), Congress directed EPA to "develop a screening program" for "all pesticide chemicals" "that may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen."[105] But Congress also required EPA to base this program on "appropriate validated test systems and other scientifically relevant information."[106] The assays comprising the Tier 1 screening battery have not been actually validated, something that the first SAP review makes quite clear. If an assay has not been scientifically validated, or it is not scientifically appropriate for the statute's purpose, then EPA may not legitimately claim that it is merely implementing a nondiscretionary legislative directive.

C. OMB Has an Obligation to Enforce Its Terms of Clearance

OMB's 2009 terms of clearance are not merely advisory. They clearly direct EPA to complete certain tasks prior to the submission of any ICR that would extend the Tier 1 screening program to additional chemicals. This interpretation of the law is not controversial; EPA agrees with it, as the 2013 RTC makes clear. But EPA has not complied with any of the five substantive requirements in the terms of clearance. Further, EPA has expedited submission of this ICR in a way that forecloses the opportunity for SAP review to improve the Tier 1 screening program.

D. OMB Should Disapprove this ICR as Improperly Submitted

OMB should disapprove this ICR and accompany its notice of action with a reminder that the 2009 terms of clearance are binding and have not been fulfilled. In addition, OMB should specifically direct EPA to begin a new ICR clearance process, one that includes the statutorily-required 60-day Notice, after draft reports authored by the SAP panels themselves have been published, EPA has responded in writing, and the SAP and the public have had a meaningful opportunity to review them. It is essential that EPA staff not interpose itself as the SAP's mediator or rapporteur, or interfere in any way with the SAP's drafting of its own reports.[107]

Finally, OMB should strongly recommend that EPA redesign its SAP review process to ensure that it does more than conduct a post-mortem of the EDSP

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[104] 5 C.F.R. 1320.5(e)(1), emphasis added.

[105] 21 U.S.C. § 346a(p)(1) [requiring a screening program] and § 346(p)(3)(A) [requiring all pesticide chemicals to be covered by the program].

[106] 21 U.S.C. § 346a(p)(1).

[107] Any such interposition is inconsistent with government-wide scientific integrity guidelines. *See* Holdren (2010), III-5: "Except when explicitly stated in a prior agreement between an agency and a [Federal Advisory Committee], all reports, recommendations, and products produced by [Federal Advisory Committees] should be treated as solely the findings of such committees rather than of the U.S. Government, and thus are not subject to intra- or inter-agency revision."

program. As currently structured, SAP review has no practical utility for informing Tier 1 screening until some future, uncertain date, if ever. Indeed, it is likely that if List 2 is approved prior to the completion of the SAP review process and revision of the Tier 1 battery in accordance with scientific principles and empirical evidence, soon Tier 1 screening will be set in stone and impervious to reform.

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