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

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I. Abstract

A. This ICR was prematurely submitted.

Crucial information needed to evaluate practical utility, estimate burden, and enable respondents to respond rationally to Tier 1 Orders is not included in the ICR package. For example, the largest single burden is data generation, and this cannot be reliably estimated until EPA finalizes test guidelines and laboratory protocols. To make informed decisions concerning how to respond, firms need clear, objectively interpretable criteria for both data acceptance and the weight-of-evidence determination whether a substance "may" have the potential to interact with one or more components of the endocrine system. This information also is missing.

B. This ICR likely involves extensive duplication.

EPA permits firms receiving Tier 1 Orders to form consortia for the purpose of minimizing the burden of data generation. The Agency claims that this complies with the Paperwork Reduction Act's mandate that agencies avoid duplication. In fact, EPA merely permits firms to do what they are clearly allowed to do under § 408(p) of the Federal food, Drug, and Cosmetic Act. The Paperwork Reduction Act requires EPA not to seek information it already possesses or it can obtain from another federal agency. According to the ICR, EPA has done nothing to ascertain whether any of the test data already in government files can be used to perform the screening function that the Tier 1 battery is intended to provide.

C. If approved, this ICR would enable EPA to shift to the public the Agency's statutory duty to avoid duplication.

The Paperwork Reduction Act clearly assigns to EPA the duty of avoiding duplication. Indeed, the law assigns no duties whatsoever to the public because its purpose is to manage the government's demands for information from the public.

This ICR would shift EPA's statutory duty to avoid duplication to firms receiving Tier 1 Orders. EPA explicitly provides, as an alternative to generating data or joining a consortium for that purpose, that a firm may cite existing data that it believes satisfies the screening function intended by the Tier 1 battery. EPA reserves the authority to decide whether these data are sufficient, but does not provide the criteria that it would use to make these determinations and does not commit to make its decisions transparent and reproducible.

Both of these tasks—the identification of existing information and evaluating it to determine whether it meets EPA's needs—are the responsibility of EPA. The Paperwork Reduction Act does not permit EPA to shift this duty to firms receiving a Tier 1 Order.

D. EPA makes no showing of actual practical utility.

Taking the ICR at face value, there is no credible evidence that this information collection has any actual practical utility. EPA's practical utility claims are vague and speculative. The Agency proposes to first mandate the generation of

these data, at a cost exceeding $100 million, and only then attempt to discern whether the data have practical utility for the statutory purpose of determining whether a substance "may" or "may not" have the potential to interact with one or more components of the endocrine system. The Paperwork Reduction Act requires that EPA make its showing of "actual practical utility now, not at some future date.

E. The ICR does not justify making the information collection mandatory.

The Agency clearly has statutory authority to require respondents to provide test data, but only so long as these data satisfy explicit statutory constraints—most notably, that they come from scientifically validated test systems and are capable of scientifically distinguishing substances that "may" have the potential to interact with one or more components of the endocrine system from substances that "may not." However, the ICR makes no showing that Tier 1 data actually adhere to these statutory constraints, and it includes ample evidence suggesting that they do not.

F. EPA's burden estimates are not supportable.

EPA's burden estimates do not fairly and accurately convey the scope and scale of the information collection. EPA's aggregate monetized burden estimate—$22.4 million—is about one-fifth of the likely burden of data generation alone. EPA assumes the burden of establishing, operating, and managing 67 testing consortia will be about 10% of the cost of data generation. Anecdotal evidence from existing testing consortia indicate that 50% is a more plausible figure, thus raising non-burden hour costs to about $150 million. EPA's monetized burden-hour estimate for recipients of Tier 1 Orders is about $12 million, and this appears to understate likely burdens by at least a factor of three, and quite likely much more.

G. EPA's burden estimation methodology has several fatal flaws.

The Paperwork Reduction Act requires EPA to estimate aggregate burden and average burden per respondent, defined as a firm receiving one or more Tier 1 Orders. EPA's method does not adhere to this rule. For most burdens, the actual units are burden *per Tier 1 Order*. This understates burden per firm because many firms will receive more than one Order and the frequency distribution of Orders per firm will be skewed. Other burdens are reported *per chemical*, a unit that has little intuitive meaning unless it is linked to consortia—a link EPA does not make. These figures are then summed and aggregated, making them uninterpretable.

H. EPA's "burden statement" is not a fair and accurate portrayal of burden.

According to EPA's proposed burden statement for the information collection, this information collection entails an average of 3,008 burden-hours <u>per chemical per respondent</u>. This denominator is inconsistent with the requirements of the Paperwork Reduction Act, which requires EPA to estimate average burden <u>per firm</u>. This figure appears to be lifted from a single building-block table that, when examined carefully, is internally inconsistent, impossible to interpret, and severely biased.

II. Executive Summary

This ICR (U.S. Environmental Protection Agency 2009e) contains several serious deficiencies that make it approval inappropriate at this time. Some deficiencies are internal to the Supporting Statement, such as burden estimates that are sums of numbers that have incompatible units. These deficiencies can be partially repaired by discarding EPA's burden-estimation methodology with one that is logically consistent, then populating the model with credible, objectively supported estimates—not arbitrary but convenient assumptions that result in a gross underestimate of burden.

Other deficiencies are procedural. EPA has been spent a decade and millions of taxpayer dollars to develop the EDSP. However, EPA appears to have devoted minor sums and effort to comply with the Paperwork Reduction Act. EPA appears to have collected no new data for this ICR, despite the fact that the EDSP is a fundamentally new program different from any other the Agency has attempted. For every other testing program, the nature of the human health effects of concern has been well defined, clearly understood, and observable in human populations. That is not true for "endocrine disruption," a term that even EPA's own EPA Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), could not define scientifically.[2]

Similarly troubling is EPA's Response to Comments submitted on the draft ICR (U.S. Environmental Protection Agency 2009d). EPA mischaracterizes some comments, responds to others by non sequitur, and still other comments it simply ignores. EPA gives itself the most generous of evidentiary standards to meet for its own assumptions and assertions, but erects before the public a barrier of insuperable height and tensile strength that keep out real-world data. Most disturbing, EPA takes the position that the Agency can legally shift to the public its statutory duties under the Paperwork Reduction Act. Whereas the law clearly requires EPA to make certain showings to obtain OMB approval, EPA is in essence proposing that OMB allow it to force this duty on the public.

Still other deficiencies are more substantive because they cut to the heart of the information collection itself. In particular, EPA has not made any showing of actual practical utility. The Supporting Statement provides only vague speculations about the value of Tier 1 test data for the statutory purpose of discerning substances that "may" have the potential to interact with one or more components of the endocrine system from substances that "may not."

This literary device—distinguishing between substances that "may"have the potential to interact with one or more components of the endocrine system from substances that "may not," and sometimes abbreviated further as "may" or "may not"—is used throughout this comment as shorthand for the transparent and

[2] See Section IV.B beginning on page 18 for an explanation why EDSTAC's definition of "endocrine disruption" is based on policy rather than science. In this comment, the term "endocrine effects" incorporate only the scientific content embedded within EDSTAC's policy-driven definition.

reproducible administrative decisions for which, based on EPA's design of the EDSP, Tier 1 test data must be the scientific foundation in order for them to have actual practical utility. That is, EPA's weight-of-evidence scheme for evaluating Tier 1 test data must be able to scientifically, transparently, and reproducibly array substances so that a bright line can be drawn separating those for which Tier 2 testing would be required (they "may" have the potential to interact with one or more components of the endocrine system) from substances for which testing obligations would cease (they "may not" have such potential). If Tier 1 test data cannot be so arrayed, or EPA's weight-of-evidence scheme cannot array them in a scientific, transparent, and reproducible manner, then these data cannot have actual practical utility.

As mentioned in Section IV.B beginning on page 18, the definition of a human "endocrine effect" is scientifically obscure. Nonetheless, FFDCA 408(p) does not give a legal definition in lieu of a scientific one, and it requires EPA to make its regulatory definition scientific. The law directs EPA to establish a screening program relying on science (based on "appropriate and validated test systems") to scientifically assign substances into these two categories. EPA's administrative discretion is limited to deciding where to draw the line separating "may" from "may not." Much of today's controversy arises because EPA has not yet developed transparent and reproducible weight-of-evidence criteria that inform the public concerning where it will draw that line. Without these criteria, it is impossible for EPA to show that this information collection has actual practical utility.

Other deficiencies arise because the information collection is simply premature. EPA thus has not provided information that is crucial, not just for burden estimation, but also for deciding how to respond to a Tier 1 Order. Besides keeping them in the dark, EPA would give respondents only 90 days to comply or face extraordinary regulatory penalties, or criminal sanctions and potentially ruinous civil penalties.

A related problem is that EPA intends to make this information collection mandatory despite the fact that the several tests the Agency would require have not been scientifically validated, as required by law. In lieu of scientific validation, EPA has substituted a validation "process" that has generated insufficient evidence that certain Tier 1 tests meet the scientific standard of a validated test system. For many assays, it has turned out that actual scientific validation is technically very difficult, and in some cases infeasible. EPA has therefore instituted a check-the-box strategy in which the Agency "deems" validation to have been "achieved" if all the boxes have been checked. EPA's validation "process" glosses over critical principles of method validation—namely reliability, sensitivity and specificity.

A. The EDSP does not comply with OMB and EPA information quality guidelines.

There is no evidence in the ICR that EPA has adhered to applicable information quality standards—neither OMB's (2002a) or its own (U.S. Environmental Protection Agency 2002).EPA's guidelines commit the agency to

ensure that its ICRs comply with these guidelines,[3] and OMB has said that it expects this to happen and will not approve ICRs that do not comply.[4] Both the draft and final ICRs for Tier 1 screening are silent on the subject of information quality, however (U.S. Environmental Protection Agency 2007b, 2009e)..

A review of the EDSP archive shows that information quality also is absent from every document listed therein. Indeed, the list of EDSP documents that say nothing about information quality is extensive. It includes:

- Every document linked to the "Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC)" web page, including all EDSTAC deliberations and reports (*http://www.epa.gov/endo/pubs/edspoverview/edstac.htm*)
- Every document linked to the "Assay Development and Validation" web page (*http://www.epa.gov/endo/pubs/assayvalidation/index.htm*)
- Every document linked to the "Priority Setting Activities" web page (*http://www.epa.gov/endo/pubs/prioritysetting/index.htm*), including every document linked to the "Priority Setting Workshops" page (*http://www.epa.gov/endo/pubs/prioritysetting/workshops.htm*)
- Every document linked to the "Endocrine Disruptor Methods Validation Advisory Committee (EDMVAC) web page (*http://www.epa.gov/endo/meetings/edmvacmeetings.htm*)
- 'Every document linked to the "Endocrine Disruptor Methods Validation Subcommittee (EDMVS)" web page (*http://www.epa.gov/endo/meetings/meetings.htm*)
- Both of EPA's Reports to Congress (*http://www.epa.gov/endo/pubs/edspoverview/reports.htm*)

The record shows that EPA has not fully applied information quality principles to the EDSP. The Agency's information quality guidelines have never been part of EPA's charge to the Science Advisory Panel, and it is nowhere to be found in

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[3] See U.S. Environmental Protection Agency (2002, p. 28): "For all proposed collections of information that will be disseminated to the public, EPA intends to demonstrate in our Paperwork Reduction Act32 clearance submissions that the proposed collection of information will result in information that will be collected, maintained and used in ways consistent with the OMB guidelines and these EPA Guidelines."

[4] See Office of Management and Budget (2002b, p. 12): "[E]ach agency is already required to demonstrate the 'practical utility' of a proposed collection of information in its PRA submission, i.e., for draft information collections designed to gather information that the agency plans to disseminate. Thus, [OMB] think[s] it important that each agency should declare in its guidelines that it will demonstrate in its PRA clearance packages that each such draft information collection will result in information that will be collected, maintained, and used in a way consistent with the OMB and agency information quality standards. It is important that [OMB] make use of the PRA clearance process to help improve the quality of information that agencies collect and disseminate. Thus, OMB will approve only those information collections that are likely to obtain data that will comply with the OMB and agency information quality guidelines."

the SAP's most recent deliberations (U.S. Environmental Protection Agency FIFRA Scientific Advisory Panel 2008, Table 1).

In contrast, EPA implicitly applies relatively stringent information quality standards on public commenters who have provided alternative burden estimates. In its Response to Comments on the draft ICR (U.S. Environmental Protection Agency 2009d),. EPA rejected every one of commenters' alternative estimates—including updated burden estimates provided by Borgert (2008), whose 2003 work EPA relies on for nine of the 11 assays (U.S. Environmental Protection Agency 2009e, Attachment F).

B. EPA did not provide all of the information crucial for respondents to decide how to rationally respond to a Tier 1 Order.

Prospective respondents need certain crucial information in order to decide how to respond to a Tier 1 Order. If it is as expensive,as now appears, the burden of toxicological testing poses a threat to the market value of some substances, and a potentialthreat to the survival of some small firms. Firms have to decide within 90 days whether to "voluntarily" cancel a pesticide registration or abandon the market for a pesticide or inert ingredient.[5]

Firms receiving a Tier 1 Order need the following crucial information:

- A clear, objectively interpretable set of testing guidelines and laboratory protocols. EPA has promised to provide this information later, but neither the burden nor practical utility of this information collection can be assessed without it.
- Clear, objectively interpretable standards for data acceptance. As written, the information collection is silent concerning what constitutes adequate test data.
- Clear, objectively interpretable standards for determining when compliance with a Tier 1 Order has been satisfied. EPA intends to impose steep penalties for noncompliance, but as written, respondents cannot know if they have complied.
- Clear, objectively interpretable standards for the interpretation of Tier 1 data and the assignment of substances into the ""may" and "may not" categories. Before they decide to proceed on one of the testing routes, firms receiving Tier 1 Orders need to be able to accurately estimate the probability that the substance will be assigned to the mutually exclusive "may" and "may not" categories. Assignment to the "may not" category terminates testing obligations; assignment to the "may" category intensifies them. Assignment to the "may" category also stigmatizes the substance in the eyes of the public,

[5] Scare quotes are used around "voluntary" to remind OMB that there is nothing about EPA's threat of automatic cancellation that should imply willingness on the part of a pesticide registrant.

irrespective of how much precaution is implied by where EPA draws the line separating the two categories.[6]

- Full disclosure of the scope and scale of Tier 2 testing that would be triggered if Tier 1 testing results in assignment to the "may" category. EPA has yet to provide the suite of fully validated Tier 2 tests, and to date the only prospective Tier 2 test EPA considers "scientifically valid" is one that has been around for many years.[7]Nonetheless, a firm cannot make an informed decision how to respond without knowing the Tier 2 battery and each assay's testing guidelines and laboratory protocols. Different Tier 2 tests could result in very different decisions concerning how to respond to a Tier 1 Order.

EPA did not provide any of this information. Without it, this ICR falls short in meeting the requirement that it be "written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond" (5 C.F.R. § 1320.9(d)).

C. The ICR contains inadequate justification for making the information collection mandatory.

EPA asserts that it has authority to make this information collection mandatory, and cites as this authority § 408(p) of amendments to the Federal Food, Drug, and Cosmetic Act. (FFDCA) codified at 21 U.S.C. § 346a(p)(1). However, EPA's authority is constrained by the explicit requirement in that chemical screening must be founded on "an appropriate validated test" capable of "determin[ing] 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."

These statutory requirements are easily listed as a set of conditions. Before EPA can make the collection mandatory based on this statute, it must show (1) that the Tier 1 test battery is scientifically "appropriate," (2) that it has been scientifically validated, and (3) that it is capable of scientifically distinguishing substances that (a)

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[8] Mere inclusion on the initial list has caused some substances to be deselected in the marketplace. These are indirect burdens of the information collection.

[7] EPA has stated, "For Tier 2, EPA is in the process of validating the following four assays: 1. Avian 2-generation; 2. Amphibian Growth/Reproduction; 3. Fish 2-generation; 4. Mysid 2-generation. Also, EPA considers the existing two-generation mammalian assay valid for the identification and characterization of reproductive and developmental effects, including those due to endocrine disruption (ED), based on the long history of its use, the endorsement of the 1998 test guideline by the FIFRA Science Advisory Panel, and acceptance by member countries of the OECD." December 17, 2008 letter from F. Sanders, Director EPA OSCP to M. Wall, NRDC regarding the Settlement Agreement in NRDC et al. v. Whitman.

Section III.B beginning on page 16 discusses the fact that the Paperwork Reduction Act requires EPA to avoid duplication with existing test data, Existing two-generation mammalian assays arguably render duplicative both the proposed Tier 1 and future Tier 2 test batteries.

"may" have the potential to interact with one or more components of the endocrine system from substances that (b) "may not."

The ICR and its attachments do not include information answering any of these four conditions. In the Supporting Statement, (1) EPA assumes that the assays it has assembled into the Tier 1 battery are scientifically appropriate; (2) EPA provides no evidence that Tier 1 assays have been scientifically validated, individually or as a battery; and (3) EPA acknowledges that the Agency does not know if these assays can scientifically discriminate between substances that "may" or "may not" have the potential to interact with one or more components of the endocrine system. EPA further admits that it does not know how to scientifically interpret distinctions expected to be among test results, and plans to come up with a "weight of evidence" framework for interpreting test data sometime in the future.[8] In short, EPA says it has statutory authority to mandate the collection of § 346a(p) test data, but it merely assumes that this information collection satisfies the requirements of § 346a(p). Nothing in the ICR shows how Tier 1 data fulfill these statutory requirements.

OMB approval is not automatic in cases where an agency merely asserts without credible evidence that it has genuine statutory authority to make an information collection mandatory. The Information Collection Rule clearly states that OMB will subject such claims to close scrutiny:

> OMB will consider necessary any collection of information specifically mandated by statute or court order, but will independently assess any collection of information to the extent that the agency exercises discretion in its implementation(5 C.F.R. § 1320.5(e)(1), emphasis added).

Without a clear showing that these test data adhere to the restrictions in § 346a(p), EPA cannot assert that its statutory authority overrides the burden/practical utility balancing provisions of the Paperwork Reduction Act. This ICR would be solely founded on EPA's exercise of discretion, and OMB would evaluate it under conventional practical utility considerations.

D. The ICR provides no evidence of actual practical utility.

The Information Collection Rule, 5 C.F.R. § 1320.3(l), is clear that EPA's statutory duty is to show "the actual, not merely the theoretical or potential, usefulness" of the Tier 1 battery. In the ICR and other pertinent documents, however, EPA admits that it does not know whether Tier 1 assays are capable of discerning substances that "may" have the potential to interact with one or more components of the endocrine system from substances that "may not." This capability is essential for the Tier 1 battery to have actual practical utility.

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[8] "Weight of evidence" frameworks can be transparent and reproducible, but usually they are not. Agencies often do not disclose the weights and sometimes they do not use weights consistently. See Weed (2005).

According to the ICR, EPA intends to wait until respondents have generated and submitted the data before making any assessment of this capability. The Agency "believes" that it may be successful but it really isn't very confident:

> EPA believes that the development of tools for EPA staff, such as a Weight of the Evidence Approach (WOE) and Standard Evaluation Procedures (SEPs), will help to provide consistency in Agency decision-making, as well as provide additional transparency to order recipients and the public (U.S. Environmental Protection Agency 2009b, p. 6, emphasis added)

EPA says it will stagger the issuance of Tier 1 Orders and use the data from the first batch of Orders issued to figure out how to proceed:

> With respect to the interpretation of the results from individual assays or other data submitted or cited in response to an order, EPA is working on developing SEPs for the initial screening, and intends to consider lessons learned in any early case-by-case determinations. EPA intends to provide an opportunity for public review of the SEPs as part of a peer review process (U.S. Environmental Protection Agency 2009b, p. 6, emphasis added).

Thus, it appearsEPA intends to implement this information collection improvisationally. EPA's interpretation tools will not be available until it is ready to move forward with Tier 2, and maybe not even then because the Agency has made no actual commitment:

> Although the SEPs will not be publicly available in final form before EPA begins issuing the orders, EPA expects the SEPs to become publicly available in final form before any Tier 1 related decisions are announced to the public. EPA also expects the SEPs to be available in draft form for public comment (U.S. Environmental Protection Agency 2009b, p. 7, emphasis added).

These vague promises lead to similarly vague claims about the potential practical utility of Tier 1 test data. For example, EPA says Tier 1 test data "allow the Agency to evaluate the potential interaction of a substance with the endocrine system," and they will "help[] determine whether or not Tier 2 testing is necessary for a particular substance" (emphasis added). These practical utility claims are merely restatements of the statutory directive in § 346a(p), as if citing the law is sufficient to prove that the information collection fulfills the law's directive.

Moreover, EPA'spotential practical utility claims are merely speculative. For example, EPA writes that "Tier 1 screening data may also be used to determine what kind of Tier 2 data is [sic] appropriate, and whether or not similar substances might share common mechanisms" (U.S. Environmental Protection Agency 2009e, p. 7, emphasis added). To say that data "may" be useful for some purpose is an admission that they might not be useful at all. It is just as plausible that Tier 1 data will intensify EPA's uncertainty about how to scientifically design Tier 2.

Even more disconcerting is EPA's intention is to use Tier 1 data, for which the ICR does not identify actual practical utility, as the springboard for vastly expanding the scope and scale of EPA's pesticide registration review program:

> Subsequently, when used with the Tier 2 testing data, the Tier 1 screening data will become a part of the risk characterization of a pesticide that is intrinsic to FIFRA and FFDCA decisions (U.S. Environmental Protection Agency 2009e, pp. 7-8).

This is an extraordinarily weak foundation on which to build one, if not the largest EPA program of mandatory toxicological testing.

Complicating matters further, firms receiving Tier 1 Orders must comply with FIFRA and TSCA adverse effect reporting requirements once such data and information become known. There is no "grace period" permitted to wait for EPA to reach internal decisions. Under TSCA § 8(e) "substantial risk" reporting requirements, such information must be reported to the Agency within 30 days after becoming known to a company. Substantial civil and criminal penalties can apply for failure to report. FIFRA § 6(a)(2) requires similar adverse effect reporting. Without the SEPs and transparent, reproducible, and scientific weight-of-evidence criteria, companies will have difficulty determining what test results would trigger reporting to the Agency under TSCA § 8(e) and FIFRA § 6(a)(2). Other ICRs cover these reporting requirements, but their IC budgets do not account for the fact that this ICR would increase them significantly.[9]

In short, the ICR does not show that Tier 1 test data have actual practical utility, a showing required by the Paperwork Reduction Act. At best, EPA has put forward a potentially interesting research project that could lead to an exploratory data analysis but not hypothesis testing. OMB must evaluate whether the value of this exploratory research exceeds the approximately $100 million burden of the information collection.

E. Completion of EPA's "validation process" is not a substitute for actual scientific validation.

EPA created a "validation process" that was supposed to guide the actual scientific validation of assays proposed to be included in the Tier 1 battery (U.S. Environmental Protection Agency 2007c). Scientific validation requires clear demonstration of relevance, reliability, sensitivity and specificity. In the U.S., criteria and processes for validation and regulatory acceptance of toxicological testing methods have been published by Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) (1997).[10]The OECD also has published

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[9] For more information on the TSCA/FIFRA intersection, see Attachment 2.

[10] ICCVAM is comprised of the Consumer Product Safety Commission, the Departments of Agriculture, Defense, Energy, Interior, Transportation, several HHS components (the Centers for Disease Control and Prevention, the Agency for Toxic Substances and Disease Registry, the National Institute for Occupational Safety and Health, the Food and Drug Administration, the National Cancer Institute, the National Institute of Environmental Health Sciences, and the National Library of

guidance (Organisation for Economic Co-operation and Development 2005). The ICR provides no documentation showing that EPA's validation "process" meets the standards established by ICCVAM and OECD.

Several Tier 1 test methods and their endpoints have not been shown by EPA studies to provide the requisite degree of sensitivity and specificity. ICCVAM defines sensitivity as the proportion of active substances that are correctly identified by the new test, and specificity as the proportion of inactive substances that are correctly identified. The ICR does not document (and EPA has not shown elsewhere) that potential endocrine effects can be distinguished from unrelated phenomena, such as systemic toxicity.[11] Moreover, there is considerable uncertainty whether test results will be consistent within or across laboratories. If laboratory variation in test results is so great that it affects the assignment of substances into the "may" and "may not" categories, the test cannot be considered scientifically valid for its intended purpose.

Over time, EPA appears to have become more concerned about "checking the boxes" in this process than assuring that proposed assays are actually validated scientifically. This has led to a number of problems, including critical comments from peer reviewers and members of EPA's Science Advisory Panel, who often have been critical of the tests themselves or the quality of intra- or inter-laboratory validation.

These deficiencies were present in the draft ICR and were the subject of extensive public comment. EPA's Response to Comments largely ignores or dismisses this criticism. Consequently, the same problems persist in the final ICR. A plain reading of the Paperwork Reduction Act is that EPA cannot make this information collection mandatory unless and until it proves that the individual assay in the Tier 1 battery, and the battery as a group, have been scientifically validated—not just survivors of EPA's validation "process."

As a first-order test, OMB can review EPA's peer review process to ensure that it rigorously complied with applicable federal guidance, specifically with respect to provisions related to the charge, conflicts of interest, independence, and agency responsiveness (Office of Management and Budget 2005). Further, the results of peer review must substantively support EPA's claims unless EPA shows that the peer reviewers were scientifically wrong. Because several peer review processes were conducted under OCED auspices, they too must be examined for adherence to federal standards.

Medicine), the Occupational Safety and Health Administration, and the Environmental Protection Agency.

[11] The Tier 1 assays that are particularly lacking in specificity are the fish screening assay, the amphibian metamorphosis assay, the male pubertal assay, and the female pubertal assay. See Attachment 3.

F. The ICR is highly ambiguous concerning the exact information respondents must provide under penalty of law.

The Paperwork Reduction Act requires the responsible EPA official to "certify (and provide a record supporting such certification, including public comments received by the agency)" that an information collection "is written using plain, coherent, and unambiguous terminology and is understandable to those who are to respond" (44 U.S.C. § 3506(c)(3)(D)). The responsible EPA official has checked a box on the submission form for this ICR "certifying" compliance with this provision.[12]

The certification should be evaluated closely by OMB because it is not accompanied by the required supporting record. Prospective respondents, who would be required to comply under penalty of law, do not know exactly what they must do to comply. EPA has not provided crucial information, including:

- <u>What are the test guidelines and laboratory protocols respondents must follow for each Tier 1 assay</u>? EPA says it intends to provide this information later, but it is an essential element of the information collection.
- <u>What are the criteria EPA will use to determine whether firms have complied with a Tier 1 Order</u>? EPA has not provided sufficient information for respondents to know what constitutes full compliance, including the conditions under which the Agency will reject test data.

Ambiguity of this magnitude is a serious deficiency in the ICR.

G. EPA's burden estimates are neither accurate nor objectively supported.

EPA's burden estimates have been controversial from the outset. EPA has not counted all obvious burdens, and it has systematically underestimated the burdens it has counted. Numerous public commenters noted these deficiencies, but in its Response to Comments, EPA did not address them fully. Problems with EPA's burden estimation are described and discussed in great detail in Section V.

H. EPA's public comment process did not comply with the Paperwork Reduction Act.

The purpose of the 60-day notice is to improve the quality of the ICR submission and make OMB review more efficient and less time-consuming.. Agencies are supposed to use 60-day notices to alert the affected public, give them a meaningful opportunity to participate, and use public comments to improve the information collection so that OMB review can be focused and its conclusion timely.

EPA's 60-day notice (U.S. Environmental Protection Agency 2007a)did not include enough information for the public to provide fully informed comments. The notice contained all of the deficiencies noted above with respect to the final ICR,

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[12] http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200904-2070-001#section0_anchor.

plus additional deficiencies because at that time even less information was publicly available. Nevertheless, the public participated in the process and provided a wealth of useful comments. EPA could have used these comments to improve the information collection.

EPA appears to have not taken public comment very seriously. In its Response to Comments (U.S. Environmental Protection Agency 2009b), EPA misrepresents many comments and responds to its misrepresentations; characterizes other comments correctly but responds by non sequitur; or just ignores comments entirely.

I. EPA has not fulfilled its statutory duty to avoid unnecessary duplication.

EPA appears to be committed to mandating the production of 67 sets of Tier 1 test data irrespective of whether it (or another federal agency) has in its possession sufficient information to determine whether a substance "may" or "may not" have the potential to interact with one or more components of the endocrine system. That determination, however, is the statutory purpose for which Tier 1 test data would be collected. It is EPA's obligation under the Paperwork Reduction Act to avoid unnecessary duplication, particularly with respect to this vast library of existing test data. EPA apparently has not examined this library, yet it acknowledges that the library may well hold information sufficient to serve the statutory purpose of Tier 1. EPA allows respondents to cite these data in lieu of performing Tier 1 tests. That is tantamount to shifting to respondents the Agency's statutory duty to avoid duplication.

This issue is addressed in greater detail in the following Section.

III. Duplication

A. Regulatory requirements

The Information Collection Rule saysthat, to obtain OMB approval, "an agency <u>shall</u> demonstrate that it has taken <u>every reasonable step</u> to ensure that the proposed collection of information … [i]s not duplicative of <u>information otherwise accessible to the agency</u>" (5 C.F.R. § 1320.5(d), emphasis added). The responsible agency official must certify this "and provide a record supporting such certification (5 C.F.R. § 1320.9)."

Duplication can take many forms, including demanding multiple sets of Tier 1 data from every pesticide registrant and inert ingredient manufacturer or importer. EPA avoids this form of duplication by permitting firms to collaborate through consortia to produce a single data set. This is nothing more than the law requires, however. Even if EPA wanted each firm to submit a separate data set, it could not legally require them to do so because this is forbidden by § 346a(p)(5)(B).

EPA incorrectly interprets this statutory prohibition as equivalent to the prohibition on duplication in the Information Collection Rule. It is not.. The Paperwork Reduction Act's prohibition is much stronger. Whereas § 346a(p)(5)(B) restricts EPA from collecting <u>new</u> duplicative information, the Paperwork Reduction

Act requires EPA to avoid duplication with existing data. OMB's Information Collection Rule does not suggest or advise agencies to avoid duplication with existing data. It's a requirement.

B. EPA has not evaluated extensive existing test data to determine whether they are sufficient for Tier 1 screening purposes.

Unnecessary duplication exists if the need for the proposed collection can be served by information "otherwise accessible to the agency." At a minimum, this includes vast quantities of test data that EPA already possesses., much of which was provided by manufacturers (under TSCA) and pesticide registrants (under FIFRA). To what extent do these data enable the Agency to determine whether a tested substance "may" have the potential to interact with one or more components of the endocrine system? EPA says it does not know, and the evidence suggests that it has not looked. According to EPA, these data are presumptively useless for this purpose and, moreover, the burden of proof rests on respondents to prove otherwise.

Unnecessary duplication also exists if sufficient test data are possessed by other federal agencies, such as the National Institutes of Health. It is useful to remember that one primary purpose of the Paperwork Reduction Act of 1980 was to stop multiple federal agencies from burdening the public with requests for the same information.

Based on the ICR, it appears that EPA has not investigated the practical utility of existing test data, whether held by the Agency or by other federal agencies. EPA appears to have substituted its own ad hoc definition for the one in the Paperwork Reduction Act:

> As used by the Agency, the term "duplicative testing" applies when more than one company conduct [sic] the exact same assay on the exact same substance(U.S. Environmental Protection Agency 2009b, p. 2, emphasis added).

The Paperwork Reduction Act does not give EPA the discretion to restrict the meaning of "duplication" this way. If allowed to stand, EPA's definition would drain the Paperwork Reduction Act of meaning.

C. EPA proposes to shift to respondents its statutory duty to avoid duplication.

What EPA proposes to do is shift to the public its statutory duty under the Paperwork Reduction Act to avoid duplication. EPA would accomplish this by

> allow[ing] the [Tier 1] order recipient to cite or provide existing data that they [sic] believe addresses the Agency's request, along with a supporting explanation (U.S. Environmental Protection Agency 2009b, p. 3).

EPA defends burden-shifting on the ground that doing so is in the Agency's interest:

> Asking the submitter to provide an explanation of how they [sic] believe the submitted or cited data fulfills the testing order will

> facilitate the Agency's review (U.S. Environmental Protection Agency 2009b, p. 3).

If it accomplishes this burden shift, EPA would review what evidence of duplication respondents might submit, in accordance with criteria it does not:

> The Agency will review **all** information that is submitted or cited by an order recipient as part of their initial response, including any responses citing "existing data"(U.S. Environmental Protection Agency 2009b, p. 3, emphases in original)

The Agency apparently intends to apply criteria that are either improvisational (e.g., case-specific) or arbitrary (e.g., all existing data will be deemed insufficient).

Finally, EPA apparently believes that it is exempt from the requirements of the Paperwork Reduction Act:

> EPA disagrees with the view … that EPA should bear the responsibility for making a determination of whether existing data are adequate for the EDSP prior to issuing an order (U.S. Environmental Protection Agency 2009b, p. 4).

EPA defends this position relying on FIFRA and FFDCA, which "clearly indicate that it is the responsibility of the manufacturer and/or registrant to demonstrate that their substance and/or product can be used safely." This is a logical non sequitur; the purpose of Tier 1 is not to "demonstrate safety." It is to screen substances to ascertain whether they "may" or "may not" have the potential to interact with one or more components of the endocrine system. Even Tier 2 is not intended to "demonstrate safety," but to estimate dose-response for the purpose of conducting a risk assessment.

Nothing in the Paperwork Reduction Act imposes duties and responsibilities on the public. Nothing in the law allows EPA to shift its duties and responsibilities to respondents. Nothing in the law allows the Agency to supplant the law's requirements with provisions it finds more convenient. EPA is not at liberty to rewrite laws and regulations that exist to prevent the agency from abusing delegated statutory authorities..

D. The ICR imposes clearly superfluous burdens on some respondents.

The stated purpose of Tier 1 testing is to distinguish between substances that "may" have the potential to interact with one or more components of the endocrine system from substances that "may not." Substances that "may" have this potential proceed to Tier 2 testing; substances that "may not" are relieved of Tier 2 testing requirements.

Some substances on the initial list may be known to have the potential to interact with the endocrine system in ways that might result in adverse human health effects. If EPA's actual purposes are consistent with its stated purposes—and with the FFDCA—these substances would be exempted from Tier 1 testing. In these cases, Tier 1 data have no informational value for making the "may"/"may not"

determination, so they cannot have actual practical utility. However, EPA appears to be unwilling to exempt substances that are known to belong to the "may" category from a screening program whose statutory purpose is to determine whether they belong to the "may" category.

Superfluous data cannot have practical utility. OMB cannot allow EPA to impose on the public the burden of generating and submitting test data that only prove what is already known.

IV. Practical Utility

A. Regulatory requirements.

The Information Collection Rule requires EPA to make certain demonstrations concerning practical utility. These demonstrations must be included in the ICR:

> As part of the agency submission to OMB of a proposed collection of information, the agency (through the head of the agency, the Senior Official, or their designee) shall certify (and provide a record supporting such certification) that the proposed collection of information—(a) Is necessary for the proper performance of the functions of the agency, including that the information to be collected will have practical utility… (5 C.F.R. § 1320.9, emphasis added).

Both the certification and the record supporting it are mandatory parts of the ICR:

> An agency shall not conduct or sponsor a collection of information unless, in advance of the adoption or revision of the collection of information, the agency has submitted to the Director … [t]he certification required under §1320.9 (5 C.F.R. § 1320.5(a)(1)(iii)).

The Information Collection Rule definespractical 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 …in a useful and timely fashion (5 C.F.R. § 1320.3(l), emphasis added)..

EPA's demonstration of practical utility thus cannot be speculative, improvisational. or imaginary. EPA must take account of the validity and reliability of the information for its intended purpose, and demonstrate its ability to actually use it in accordance with its declared intent.

B. The ICR makes no showing that Tier 1 data have actual practical utility for their intended purpose.

EPA's stated purpose of this information collection is to screen certain substances to discriminate between those that "may" have the potential to interact with components of the endocrine system from those that "may not." From the outset, the definition of an "endocrine effect" has been the subject of considerable

debate and controversy. For example, the definition that EDSTAC finally agreed upon after extensive deliberation includes scientific concepts, but at root it is a compromise policy judgment of Committee members rather than a scientific construct:

> The EDSTAC describes an endocrine disruptor as an exogenous chemical substance or mixture that alters the structure or function(s) of the endocrine system and causes adverse effects at the level of the organism, its progeny, populations, or subpopulations of organisms, based on scientific principles, data, weight-of-evidence, and the precautionary principle(U.S. EPA Endocrine Disruptor Screening and Testing Advisory Committee [EDSTAC] 1998, pp. 3-3 and 3-4).[13]

Tier 1 is not intended to estimate risk. It is solely to divide substances into one of the two bins labeled "may" and "may not." Therefore, the practical utility question OMB must address is whether EPA has demonstrated that its proposed Tier 1 test battery achieves this discrimination in a scientific, consistent, and reproducible manner.

1. EPA acknowledges that Tier 1 data do not have "actual" practical utility.

According to the ICR, EPA is hopeful that the Tier 1 test battery will be capable of making "may"/"may not" distinctions. At this time, however, the Agency does not know if the data will have this capability. It is EPA's plan to mandate the collection of Tier 1 data, examine the data, and then decide whether they have practical utility.

This strategy is not compatible with the express language of the Paperwork Reduction Act. Before obtaining OMB approval, EPA's obligation is to demonstrate "the actual, not merely the theoretical or potential, usefulness" of Tier 1 test data.

2. Tier 1 data might have practical utility as a research project to explore alternative schemes for distinguishing among substances.

A more credible justification for obtaining Tier 1 data is to explore alternative schemes for making "may"/"may not" distinctions. Alternatively, EPA might formally test the hypothesis that they can elucidate this distinction using the Tier 1 battery. Neither of these formulations of practical utility can be used to justify making the information collection mandatory, however. EPA's authority to make the collection mandatory proceeds from § 346a(p)(1), which directs EPA to:

> … develop a screening program, using appropriate validated test systems and other scientifically relevant information, to <u>determine</u> whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or

[13] In this comment, the term "endocrine effects" is used as shorthand for the three <u>scientific</u> components of the EDSTAC definition: (a) evidence of a change in structure or function that is (b) scientifically demonstrated to (c) cause injury to human health.

> such other endocrine effect as the Administrator may designate (emphasis added).

This law gives EPA the authority to mandate testing to make a determination, but it does not authorize the Agency to mandate testing for exploratory data analysis, hypothesis testing, or any other purpose. However useful an exploratory data analysis might be, it is not a statutory purpose sufficient to make the determinations § 346a(p)(1) requires.

3. EPA does not now have the "ability to process the information it collects" from Tier 1 tests "in a useful and timely fashion."

EPA says it has not yet decided how it will use Tier 1 test data for the statutory purpose on which it relies to make the information collection mandatory. EPA says only that it will use these data in a yet to be defined "weight-of-evidence" process to decide whether to mandate Tier 2 Test Orders, and if so, what these Orders might contain. The Agency has not yet provided details about this process.[14] This may be the clearest possible indication that EPA has not satisfied the practical utility requirements in the Paperwork Reduction Act.

4. Some Tier 1 assays have no potential practical utility.

To have potential practical utility, an assay must not be so sensitive that everything tests "positive." If that were to happen, it is impossible to distinguish between substances that "may" have the potential to interact with one or more components of the endocrine system from substances that "may not." An assay also must be selective enough to focus on the effect of interest. An assay that lacks specificity will have too many false positives.[15]

5. Requiring Tier 1 tests for known positives cannot have practical utility.

EPA allows firms to respond to a Tier 1 Order by seeking EPA's permission to advance straight to Tier 2. The available evidence suggests that EPA will not grant these petitions. Nonetheless, it is perfectly reasonable (and concordant with § 346a(p))) to skip Tier 1 if there is no doubt that a substance "may" have the potential to interact with one or more components of the endocrine system. In these circumstances, it is not sensible to have to obtain EPA's permission to skip Tier 1. Recipients of Tier 1 Orders should have the right to proceed directly to Tier 2 as long as they accept assignment of the substance into the "may" category. Demanding Tier 1 data anyway from these recipients cannot be justified under the Paperwork Reduction Act.

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[14] For a reminder about the information quality deficiencies of most weight-of-evidence frameworks, see footnote 9.

[15] Recall that ICCVAM defines specificity as the proportion of inactive substances that are correctly identified. If all substances test positive, this proportion is zero and the test is infinitely nonspecific. The available evidence indicates that, for several Tier 1 assays, no confirmed negatives exist.

C. Balancing practical utility and burden.

It is OMB's statutory duty to balance practical utility and burden in its decision whether to approve an information collection INSERT REFERENCE. The absence of any documented practical utility should give OMB considerable concern. These concerns should be heightened because this ICR entails about $70 million in non-burden hour costs just for data generation, plus half again as much for establishing, operating, and managing up to 67 limited liability corporations that would serve as testing consortia; plus thousands of burden-hours borne by firms receiving Tier 1 Orders.

D. The ICR is arbitrary and violates fundamental principles of fairness.

Respondents cannot make fully informed choices about how to respond to a Tier 1 Order. Upon receipt of an Order, they have to decide, among other things, whether to "voluntarily" cancel the registration of a pesticide or abandon the crop protection market for an inert substance, rather than embark on a toxicological testing regimen that could cost upwards of $1 million for the first round, and likely, several millions more in the next.

1. The ICR imposes an unreasonable deadline.

Although EPA has spent a decade developing the EDSP, it intends to allow respondents only 90 days to decide how to respond. This compressed decision timeframe has no statutory basis in § 346a(p). To come up with a statutory hook, EPA proposes to graft the testing provisions of § 346a(p) into FIFRA §3(c)(2)(B)(ii), which specifies 90 days for responding to a data call-in. Had Congress intended the FIFRA deadline to apply, § 346a(p) would have included language making it so. It doesn't.[16]

2. EPA has not defined clear criteria for data acceptance.

Respondents do not know EPA's criteria for data acceptance because EPA admits it has not yet developed them. Meanwhile, respondents face potentially severe regulatory consequences (e.g., cancellation), plus criminal and large civil penalties for failing to meet its deadlines or provide the information the Agency wants.

3. EPA has provided insufficient information about how it will use Tier 1 data in fulfillment of its stated statutory purpose.

Respondents also do not know what EPA will do with Tier 1 data because EPA has not said what it will do with them. EPA has a moral obligation to reveal how it will use Tier 1 data to make the "may"/"may not" determinations for which Tier 1 test data are purported to be needed. Fortunately, this moral obligation is codified in the Paperwork Reduction Act. OMB has the authority to direct EPA to disclose this

[16] This FIFRA provision cannot be applied to firms that manufacturer or import inert ingredients because they are not regulated under FIFRA. In these cases, the 90-day deadline is purely discretionary even under EPA's proposed linkage of FFDCA and FIFRA.

information and make it part of the ICR review, or disapprove the ICR as improperly submitted.[17]

4. EPA has provided insufficientinformation about Tier 2.

EPA asserts that Tier 2 is irrelevant for evaluating the merits of Tier 1. However, at the same time EPA admits that the scope and scale of the Tier 2 battery will depend on the results of Tier 1. These statements are logically irreconcilable and incompatible with elementary decision theory. If Tier 2 is truly irrelevant to a firm's response to a Tier 1 Order, then it cannot be affected by the outcome of Tier 1. As shown below, the cost of Tier 2 must be reasonably estimable in order to make an informed decision about how to respond to a Tier 1 Order.

Firms receiving Tier 1 Orders have to make complex legal and financial decisions—as now written, under the arbitrary and unreasonable 90-day deadline discussed above. Public commenters have repeatedly noted EPA's failure to provide this crucial information. In response, EPA asserts that, as far as the Agency is concerned, firms receiving Tier 1 Orders simply do not need this information:

> EPA disagrees, however, that issuing test orders for Tier 1 screening cannot occur until after such information is available in final form, or that the availability of such information is necessary for order recipients to determine how they will respond to the order. <u>The information is not used to determine whether or not a substance is on the initial list, or to determine who should receive an order for that substance</u>. In terms of responding to an order, an order recipient can certainly determine how they want to respond to the order without considering such information.
>
> In addition, <u>Tier 2 assays are expected to be available for use before the Agency announces any Tier 1 screening results, along with the information used for making those determinations</u>"(U.S. Environmental Protection Agency 2009b, p. 7, emphasis added).

EPA's logic consists of non sequiturs; for convenience, they are underlined in the text above.[18] It also is easy to prove that EPA's conclusion is false under all circumstances, except one—the case in which EPA assigns all substances to the "may not" category, a scenario no one expects.

To see this, consider that among the options respondents have available are (1) agree to test and (2) "voluntarily" cancel a pesticide registration or, for an inert, abandon the crop protection market. The expected value of the respondent's decision depends on the cost of both Tier 1 and Tier 2 testing and the probability that EPA will assign the substance to the "may not" category, thus resulting in a no further testing obligation. The firm is well positioned to estimate the likelihood of

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[17] If EPA does not have this information, then the ICR was prematurely submitted.

[18] Each of the underlined statements is potentially true, but neither statement is relevant to the firm's decision how to respond, making it a non sequitur.

various test outcomes, but it cannot divine *p*; the firm needs to know the criteria EPA will use to convert various test outcomes into "may"/"may not" determinations.

For any specific substance subject to a Tier 1 Order:

Let Y = the expected value of the income stream.

Let T_1 and T_2 = the expected value costs of Tier 1 and Tier 2 testing, respectively.

Let *p* = the probability that EPA will assign the substance to the "may not" category after Tier 1 testing.

The firm is indifferent between the testing route and cancellation or abandonment if:

$$Y = pT_1 + (1-p)(T_1+T_2).$$

Solving for p shows that the indifference condition depends on both p and T_2:

$$p = (T_1+T_2-Y)/T_2.$$

As *p* approaches zero (meaning that no substance is ever assigned to the "may not" category), the cost of Tier 2 testing becomes the crucial unknown that the firm needs to resolve before making a decision concerning how to respond to a Tier 1 Order. Conversely, as *p* approaches unity (meaning that every substance is assigned to the "may not" category), the cost of Tier 2 testing becomes immaterial.

Contrary to EPA's assertions, it is therefore obvious that both *p* and T_2 are crucial for responding rationally to a Tier 1 Order—unless, that is, *p* equals 1, and all substances are assigned to the "may not" category. In that case, the firm's decision how to respond to a Tier 1 Order is unaffected by T_2 because Tier 2 testing would never be required.

V. Burden

The Paperwork Reduction Act requires EPA to estimate the burden of this ICR in accordance with specified statutory and regulatory standards. Burden is defined as "the time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency, including the resources expended" (44 U.S.C. § 3502(2)). OMB's Information Collection Rule contains similar language (5 C.F.R. § 1320.3(b)). The law, OMB's Information Collection Rule, and subsequent information quality guidance (Office of Management and Budget 2002a, 2002b) issued under the authority of the Paperwork Reduction Act, all impose requirements related to burden estimation. EPA must fully account for all burden elements, prepare and publish an objectively supported estimate of burden, and ensure that this estimate is itself objective—a term defined by OMB to mean accurate, clear and unbiased.

This ICR does not meet any of these requirements.

A. Statutory and Regulatory Requirements

The Paperwork Reduction Act contains clear and well-known requirements that EPA mustfulfill before OMB can issue a control number. In this section, the major statutory requirements that EPA has not fulfilled are identified, and in the following section, extensive supporting evidence is provided.

1. EPA's burden estimates must account for all significant burden elements.

The statutory and regulatory definitions of burden are designed to be exhaustive. Agencies are not permitted to pick and choose which burdens to acknowledge and which to elide.

2. EPA's burden estimates must include 100% of the burden of generating test data.

The statutory definition of burden includes the "financial resources expended by persons to generate, maintain, or provide" Tier 1 test data. The law includes this language to ensure that there is no discriminatory treatment between burden borne in-house and burden borne by outsourcing. If outsourcing is less expensive, agencies are permitted to count them as "non-burden hour costs." Nothing in the Paperwork Reduction Act permits an agency to count only an arbitrary fraction of burden-hours or non-burden hour costs.

3. EPA's burden estimates must comply with OMB's and EPA's own information quality guidelines.

OMB has publicly interpreted the Paperwork Reduction Act to require agencies to satisfy the information quality standards of utility, integrity, and objectivity(Office of Management and Budget 2002a). EPA has publicly committed to adhere to these information quality standards, and specifically, to ensure that its ICRs do so:

> For all proposed collections of information that will be disseminated to the public, EPA intends to demonstrate in our Paperwork Reduction Act clearance submissions that the proposed collection of information will result in information that will be collected, maintained and used in ways consistent with the OMB guidelines and these EPA Guidelines. These Guidelines apply to all information EPA disseminates to the public; accordingly, if EPA later identifies a new use for the information that was collected, such use would not be precluded and the Guidelines would apply to the dissemination of the information to the public(U.S. Environmental Protection Agency 2002, p. 28, internal footnotes omitted).

OMB's information quality guidelines also require, and EPA's information quality guidelines promise to achieve, burden estimates that are transparent and reproducible.(Office of Management and Budget 2002a; U.S. Environmental Protection Agency 2002). Both sets of guidelines clearly state that transparencymeans that the sources for all assumptions, data, models, and the like, are fully disclosed. Reproducibility means EPA must "show its work" so that competent third parties can obtain substantially the same results using the same inputs.

4. EPA's burden estimates must be accurate, clear, unbiased, and objectively supported.

In accordance with 44 U.S.C. § 3506(c)(1)(A)(IV), burden estimate must be specific, accurate, and objectively supported. Specificity means that burden estimates must related directly to the activities that are reasonably foreseeable responses to the information collection. Accuracy, along with clarity and unbiasedness, are established synonyms for the information quality principle of objectivity that applies to the estimation of burden (Office of Management and Budget 2002b, p. 12), a principle to which EPA is publicly committed (U.S. Environmental Protection Agency 2002, p. 28). To be objectively supported means free of subjective judgment and assumptions driven by other factors, such as an agency's policy preferences.

5. EPA's burden statement must be a true portrayal of the actual burdens imposed by the information collection

The Information Collection Rule requires EPA to publish, along with the information collection, a burden statement that "[i]nforms and provides reasonable notice to the potential persons to whom the collection of information is addressed of … [a]n estimate, to the extent practicable, of the average burden of the collection..." (5 C.F.R. § 1320.8 (b)(3)(iii)). "Average" means a central tendency estimate, but not necessarily the arithmetic mean, if the distribution of burdens is asymmetric or skewed, for the arithmetic mean is not an accurate and unbiased descriptor of the central tendency of a skewed distribution.

B. EPA's burden estimation method is invalid and unreliable.

EPA's method for estimating burden has inherent deficiencies that render it invalid and unreliable for giving a fair portrayal of the burdens in this information collection. A discussion of several of these errors follows below.

1. EPA uses multiple and incompatible units of analysis and performs impermissible arithmetic operations on them.

In different components of the ICR, EPA states that it has estimated burden per substance (Tables 6, 11, 14, and 15), for pesticide registrants generally (Tables 7 and 9), and for manufacturers and importers of an inert ingredient generally (Tables 8 and 9). The bottom-line burden statement is described as burden "per substance/per respondent" (U.S. Environmental Protection Agency 2009e, p. 46), This unit of analysis does not comply with the Paperwork Reduction Act, which

requires average burden to be expressed per person. This ratio cannot be obtained from the subordinate tables upon which it is allegedly based, and burden per person cannot be derived from it given the information provided.[19]

The figures reported in these tables do not, in fact, correspond to EPA's stated units. Some of the activities listed in Tables 6 and 11, for example, are correctly denominated as burden per substance. Rows 5-10 are activities that a consortium manager would undertake once per substance. However, Rows 1-4 and Row 11 are activities that would be performed by every firm receiving a Tier 1 Order, and they would perform these activities separately for each Order they receive. These rows can be added if and only if EPA sends exactly one Tier 1 Order per substance.

In short, EPA estimates burden assuming that the EDSP Tier 1 program is fundamentally different than what it has said it is. The ICR says EPA expects pesticide registrants will receive an average of two and a maximum of four Tier 1 Orders, and manufacturers and importers of inert ingredients will receive an average of five and a maximum of 56 Tier 1 Orders (U.S. Environmental Protection Agency 2009e, p. 41). Therefore, Table 6 contains both internal inconsistencies and methodological flaws that render it useless as a building block for developing per-firm burden estimates.

Similarly, Table 7 is inaptly labeled. Figures in this table are closer to (but still less than) the aggregate burden on pesticide registrants associated with 207 Tier 1 Orders.[20] To obtain an unbiased estimate of burden per firm, the matrix of (corrected) values in these tables has to be multiplied by an array consisting of the frequency distribution of Tier 1 Orders per pesticide registrant, which the ICR does not provide.[21]

Similar flaws arise in Table 8, this time for manufacturers and importers of inert ingredients. To use EPA's stated methodology correctly, obtaining an unbiased estimate of burden per firm requires multiplying the matrix of (corrected) values in Table 8 by the (not provided) frequency distribution of Tier 1 Orders per inert ingredient manufacturer/importer.

EPA's bottom-line burden estimate—3,008 burden hours "per substance/per respondent"—is thus incomprehensible as the product of the previous calculation.It is identical to the total burden estimate in Table 6, which as noted above, would be methodologically valid if and only EPA sent each firm exactly one Tier 1 Order.

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[19] EPA's burden statement relies on a summary statistic from Table 6 and ignores the remainder of the Agency's burden analysis.

[20] EPA assumes that there the burden of consortium participation is zero for 58 Tier 1 Orders.

[21] Although it is essential for estimating average burden per firm, EPA does not provide this information in the ICR. For a more detailed explanation of this problem, and how to easily fix it, see Section V.C.1, beginning on page 31.

The firm is the proper unit of analysis for burden estimation. Indeed, it is the statutorily mandated unit of analysis. Burden is defined as applying to "persons" (44 U.S.C § 3502(2); 5 C.F.R. § 1320.3(b)(1)), and the term "person" is broadly defined as:

> an individual, partnership, association, corporation, business trust, or legal representative, an organized group of individuals, a State, territorial, tribal, or local government or branch thereof, or a political subdivision of a State, territory, tribal, or local government or a branch of a political subdivision (44 U.S.C. § 3502(10)).

There is no statutory basis for EPA's invention and use of other units of analysis, such as "burden per chemical" or "burden per chemical per respondent." Besides being technically indecipherable, particularly when summed, they are contrary to law and give a misleading portrayal of burden per firm.

2. EPA's estimates do not account for the full burden of establishing, operating, and managing testing consortia.

EPA expects that respondents will form consortia to share the financial burden of testing. In most cases, this assumption is justified because the burden of generating Tier 1 is so great—at least $400,000 per substance under EPA's unrealistic assumptions, and close to $1,000,000 based on recent survey data—that generally it will be cost-effective to form alliances to share the burden.

However, EPA does not actually estimate the burden of establishing, operating, and managing a testing consortium. EPA uses the counterfactual assumption that, for each of the 58 pesticides and nine inert ingredients, one firm receiving a Tier 1 Order will take the lead and perform the consortium management function on behalf of the others. Hundreds of testing consortia now exist for other purposes besides EDSP screening, and none of them appear to be managed this way.

Even if this counterfactual assumption were valid, EPA does not account for the transactions costs of determining which firm would become the consortium manager, even for the "average" consortium. And, "average" consortia are the easy cases; EPA acknowledges that at least one consortium may have "as many as 56" members (U.S. Environmental Protection Agency 2009e, p. 41). Whatever the transactions costs for the "average" consortium might be, transactions costs for this one will be staggeringly large.

The practical effect of EPA's counterfactual model is that the non-burden hour costs of consortia are grossly underestimated.

3. EPA invites respondents to "cite or submit existing data" in addition to generating the Tier 1 battery data, but neglects to count the burden.

Tier 1 Order recipients have the option of citing or submitting existing data in lieu of data from Tier 1 testing. According to the ICR, submitting existing data

entails no burden. As a first approximation, this is reasonable because EPA has assumed that every substance proceeds to Tier 1 testing.

A more likely scenario is respondents will supplement the laboratory data they generate from Tier 1 assays with citations or submission of pre-existing data that they believe are relevant to weight of evidence conclusion that the substance belongs in the "may not" category. The citation or submission of pre-existing data entails potentially significant burden. To estimate this, one must have several types of data, the most important of which are the weights EPA will assign to existing data in EPA's yet-undefined weight-of-evidence framework. The larger the weights on existing data, the greater will be the effort devoted to identifying, citing, and submitting them.

Still, if EPA is serious about considering all data (U.S. Environmental Protection Agency 2009b, p. 3) and the option to cite or submit other scientifically relevant information is genuine (U.S. Environmental Protection Agency 2009c), then EPA is obligated to account for the burdens of these activities. It cannot simply ignore them.

4. EPA's estimates do not include the full burden of generating test data.

EPA has not included all the "financial resources expended by persons to generate, maintain, or provide" Tier 1 test data. EPA counts 35% of testing costs instead of 100%, allegedly based on a convention apparently adopted about 25 years ago:

> This percent-based estimate of paperwork associated with conducting a test was initially established in consultation with OMB in the 1980's in an effort to provide a reasonable estimate of the burden associated with the paperwork component of data generation, which may vary based on the complexity of the test performed (U.S. Environmental Protection Agency 2009e, p. 36).

Substantively, EPA defends counting 35% because it

> appears to be a reasonable and fair alternative to simply setting a single estimate for data generation burden or perhaps using some set criteria like high, medium or low burden, neither of which may fairly reflect potential differences in burden.

In the 1980s, many firms that received test orders operated their own laboratories. Therefore, the time spent by their laboratory personnel was properly counted in burden-hours. Since then, however, virtually every manufacturing firm that had an animal testing laboratory has closed it. Animal laboratory work has become much more complex and specialized. For years, it has been standard practice for firms to hire contract laboratories to perform animal tests mandated by the federal government. These burdens must be counted as non-burden hour costs.

One public commenter faulted EPA's decision not to count 100% of the burden of data generation in the draft ICR. In its Response to Comments, EPA

dismissed this comment without explanation. EPA merely restated its initial position, that "[t]he ICR does include the paperwork burden for conducting the tests" (U.S. Environmental Protection Agency 2009d, p. 15).

Whatever its original merit might have been, the 1980s-vintage agreement is long since obsolete. Unless EPA can show otherwise, firms receiving Tier 1 Orders must be assumed to follow standard industry practice and hire contract laboratories to perform animal experiments required by EPA. The Agency must count 100% of the burden, and count it as a non-burden hour cost.

5. EPA's estimates are not objectively supported.

EPA relies on Borgert (2003) for estimates of the burden of generating test data for nine of the 11 assays in the Tier 1 battery. These burden estimates are transparent and reproducible because Borgert supplied extensive documentation. For the remaining two assays, EPA relies on

> the professional judgement [sic] and expertise considering the prices EPA paid to have these tests conducted [during the Agency's validation studies], and <u>adjusted to reflect the expected protocol details that impact cost</u>" (U.S. Environmental Protection Agency 2009e, Attachment F, emphasis added).

Professional judgment is highly susceptible to the influence of personal, institutional, policy, and political bias. These biases might be ruled out if EPA had fully disclosed the basis for these judgments and fully disclosed their empirical basis. It did not.

The underlined text deserves special attention. It appears that EPA has not actually paid a laboratory to perform either of these two assays in accordance with the actual testing guidelines and laboratory protocols that it would require firms receiving Tier 1 Orders to follow.

6. EPA's burden estimates do not comply with OMB's and EPA's own information quality guidelines

Information quality guidelines require this ICR to be transparent and reproducible so that the public can test whether they meet substantive information quality standards. Critical parts of EPA's burden estimate are not transparent and reproducible, and many parts that are transparent and reproducible do not comply with these substantive standards.

a) Lack of transparency and reproducibility.

As noted above, EPA did not document in the ICR the basis for the burden estimates derived from Agency employees' professional judgment. These burden estimates are neither transparent nor reproducible. Transparency and reproducibility are fundamental procedural requirements. When an agency declines to make influential information transparent and reproducible, it has an unusually high burden of proof that the information satisfies substantive information quality standards. The ICR is bereft of any information that would support the inference that these figures are objective.

Burden estimates based on professional judgment might satisfy the Paperwork Reduction Act, provided that EPA demonstrated that these judgments are unbiased and objectively supported. The ICR lacks that demonstration, too. The text quoted in subsection 5 above is the sum total of EPA's documentation. EPA has not revealed who within the Agency produced these estimates, what EPA paid for the assays, or how it adjusted actual costs to account for the "expected protocol details that impact cost." That there was a significant discrepancy in protocols between the tests EPA funded and the tests EPA proposes to require respondents to perform raises additional uncertainty about EPA's "professional judgment" estimates.

This lack of documentation contrasts starkly with the industry-funded estimates provided by Borgert (Borgert 2003; U.S. EPA Endocrine Disruptor Screening and Testing Advisory Committee [EDSTAC] 1998, Appendix S). Borgert's estimates are well documented, transparent, and with reasonable effort capable of being substantially reproduced by EPA or another independent party.[22]

b) Lack of clarity.

EPA's burden estimate methodology also lacks clarity because the Agency uses inappropriate units and combines them in arithmetically improper ways. Burdens are supposed to be estimated at the firm level. The practical consequence of conflating respondents, Tier 1 Orders, and substances is that EPA's burden estimates are invalid and unreliable irrespective of each of the other deficiencies discussed here.

c) Inaccuracy and bias.

EPA's burden estimates are unmistakably inaccurate and biased because of the Agency's exclusion of 65% of the financial resources that would be expended by respondents to generate test data, and gross undercounting of the financial resources necessary to fund consortia. These non-burden hour costs easily exceed $100 million, and they are about five times greater than the monetized sum of all

[22] Borgert (2008) is not fully documented, but the author is known and available to provide documentation on request. Neither of these facts apply to EPA's undocumented "professional judgment.

burdens EPA has counted: $22.4 million (U.S. Environmental Protection Agency 2009e, p. 42, Table 12).

EPA is obligated by law, regulation and guidance to prepare burden estimates that are accurate, objectively supported, transparent, and reproducible. Pursuant to its public recitation of its statutory duty under the Paperwork Reduction Act(Office of Management and Budget 2002b, p. 12), OMB should direct EPA to prepare burden estimates that comply with the law.

C. EPA's burden estimates have numerous and significant technical errors.

The ICR is replete with technical errors that result from its flawed burden estimation methodology. A short list of these errors is discussed below.

1. EPA did not provide a frequency distributions for the number of Tier 1 Orders per firm in each relevant category.

The "persons" who would bear the burden of this information collection are firms that are pesticide registrants and firms that manufacture or import inert ingredients used in crop protection products. To estimate burden on these "persons," one needs to know the number of Tier 1 Orders that EPA plans to send to each firm and whether the firm is "small."[23] There is reason to believe that this distribution is highly asymmetric, which has serious effects on the estimation of average burden.[24]

Constructing this data table requires information on four variables (a) the list of substances; (b) the list of Tier 1 Orders; (c) the firms to which each Tier 1 Order will be sent; and (d) the tagging of firms that are "small."

Fortunately, EPA has all of this information in hand to a reasonable degree of certainty. The Agency has finalized the list of substances to be screened in this round (U.S. Environmental Protection Agency 2009e, Attachment G). EPA knows the number of Tier 1 Orders it expects to send (U.S. Environmental Protection Agency 2009e, Table 1 and accompanying text). EPA knows the identities of every firm to which it expects to send a Tier 1 Order (U.S. Environmental Protection Agency 2009e, p. 29). For each firm, EPA knows if it is a "small business."

OMB should direct EPA to populate Figure A below. The rows in the matrix represent unique substances on the initial list (*s*); they range from 1 to 67. The

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[23] In the Supporting Statement EPA asserts that it has provided significant flexibility for small business compliance (U.S. Environmental Protection Agency 2009e, p. 33): "If there is a small business that does happen to manufacture one of the chemicals and therefore receives a Tier 1 Order, the small business may minimize potential burden by joining a consortium or task force, which may relieve the small business of direct responsibility for generating or submitting the data."

Joining a consortium might not significantly attenuate burden , however. For example, a small business may be the sole or dominant manufacturer of an active or inert ingredient.

[24] EPA uses the arithmetic mean for the "average." However, the arithmetic mean is a poor (and downwardly biased) estimate of central tendency if the distribution has a fat or long upper tail. The more asymmetric the distribution, the greater is the bias when using the arithmetic mean.

columns represent unique firms (*f*) receiving one or more Tier 1 Orders. They are numbered from 1 to *F*.[25] For each firm, EPA need only strike out the word "Not Small" (if the firm is a "small business") or strike out the word "Small" (if the firm is not).

For each firm (column), EPA would proceed row by row and strike the word "Yes" for each substance in which the Agency does not expect to send a Tier 1 Order. To avoid ambiguity, EPA should strike the word "No" for each substance in which the Agency does intend to send a Tier 1 Order. This process would be repeated for each column.[26]

[25] If there were a legitimate need to keep firms' identifies confidential, OMB can redact the names in the columns and give them unique identification numbers before making the table public. The identifies of Tier 1 Order recipients will be public knowledge once Orders are sent, so it is hard to imagine any justification for confidentiality.

[26] EPA expects to issue catch-up orders to 20 manufacturers/importers of inert ingredients that the Agency expects will "enter[] the marketplace after the issuance of the initial Orders and when they begin to sell an inert ingredient following the submission of required EDSP data on the ingredient by manufacturers or importers who were in the marketplace when the initial Orders were issued" (U.S. Environmental Protection Agency 2009e, p. 14) but says it does not know their identifies. These 20 columns can be identified generically (e.g., "Unknown Inert Mfg/Importer #1," "Unknown Inert Mfg/Importer,"…, "Unknown Inert Mfg/Importer #20").

Figure A:
Cross-Tabulation of Substances by Firm Receiving a Tier 1 Order

Instructions:
1. For each row, list a unique substance on the initial EDSP list.
2. For each column, list a unique firm receiving at least one Tier 1 Order.
3. For each cell in orange, cross out "Large" or "Small."
4. For each unshaded cell, cross out "Yes" or "No."

	Firm Receiving a Tier 1 Order (f_1 to F)				
Substance (s_1 to s_{67})	f=1 Small Large	f=2 Small Large	f=3 Small Large	…	f=F Small Large
s=1	Yes No	Yes No	Yes No	…	Yes No
s=2	Yes No	Yes No	Yes No	…	Yes No
s=3	Yes No	Yes No	Yes No	…	Yes No
…	…	…	…	…	…
s=67	Yes No	Yes No	Yes No	…	Yes No

s denotes a substance on the initial list (1 to 67).
f denotes a firm receiving a Tier 1 Order (1 to F).

2. *EPA's categorization of personnel is incomplete.*

EPA divides recipient activities into three personnel categories: managerial, technical, and clerical (U.S. Environmental Protection Agency 2009e, p. 18, Table 2). This assignment may be conventional but it is incomplete. Several respondent activities require the participation of attorneys, financial analysts, and the corporate officers who must certify responses to Tier 1 Orders and who face criminal penalties for violations.[27] Legal counsel is always required to provide proper guidance on

[27] Senior executives' burden-hours clearly are not counted within the class labeled "managerial duties," a fact that is self evident by EPA's use of a wage of $48.31 per hour (U.S. Environmental Protection Agency 2009e, p. 36, Table 5).

regulatory compliance. No senior executive of a firm receiving a Tier 1 Order would consider responding without first obtaining competent and well-informed legal counsel.[28]

Financial analysis is required to determine how to respond to a Tier 1 Order. As EPA makes clear in the ICR, respondents have several options besides generating Tier 1 data. These options include "voluntary" cancellation, product reformulation, and for manufacturers or importers of inert ingredients, the abandonment of the crop protection market. These decisions have potentially huge financial implications, especially for small firms. Significant resources could be expended before a Tier 1 Order recipient decided how to respond. Nonetheless, the burden associated with Tier 1 testing—plus the likely but not certain burden of a subsequent EPA demand for Tier 2 testing, the burden of which is expected to be much greater—has to be carefully weighed against the discounted present value of product or market abandonment. For burden estimation purposes, however, EPA assumes that done of this happens.[29]

3. EPA uses unrealistically low wage rates.

EPA's assignment of wage rates also is highly misleading and understates the true burden of the information collection. For managerial employees, EPA uses SOC 11-0000 (Management Occupations in NAICS 325300 [Pesticide, Fertilizer, and Other Agricultural Substance Manufacturing]).[30] This category is so broad that it encompasses everything from Chief Executives (SOC 11-1001, mean annual salary: $159,869] to Transportation, Storage, and Distribution Managers [SOC 11-13071, mean annual salary: $71,770). Because lower-level managers dominates SOC 11-000—only 2.6% of them are chief executives—the mean annual salary for the group is $106,090.

A similar deficiency afflicts EPA's hourly rate for "technical" employees. EPA uses SOC 19-0000 ("Life, Physical, and Social Science Occupations"), who as a group have a mean annual salary of $58,340. This category is far too broad (and insufficiently "technical") to describe the training, qualifications and expertise of the corporate scientists who will be involved. Among scientists, senior, board certified toxicologists will be disproportionately represented in the employee mix. According

[28] The fully loaded hourly rate for such legal counsel is at least $400 per hour, not the average rate that EPA might obtain from the Bureau of Labor Statistics, which is heavily weighted with attorneys who perform general legal work such as wills, contracts, divorces, real estate closings, and criminal defense for DWI violations.

[29] EPA may believe that it has overcounted burden by assuming that in all cases Tier 1 testing will occur. This might be true if the conditional outcomes from testing were irrelevant. As shown in the simple decision analysis presented in Section IV.F.3 beginning on page 22, conditional outcomes are crucial to the firm's decision. If firms believe that EPA will assign every substance to the "may" category and the expected burden of Tier 2 testing is very high, the number of cancelations, reformulations and abandonments could be very large.

[30] Many firms receiving Tier 1 Orders will not even be in NAICS 325300 because the production of pesticides is a small part of their business.

to a recent survey, EPA's assumed mean salary is less than what new hires are paid (Gad 2008, Table 7).

An apt comparison can be made between the wage rates for the corporate personnel EPA assumes will manage Tier 1 Orders and the federal employees who will write and review them. EPA assumes corporate managers are paid the same as GS-14s, corporate scientists are paid the same as GS-12s, and corporate clerical staff are paid the same as GS-6s. In short, EPA assumes that firms responding to Tier 1 Orders assign employees to respond to earn about half of the wage of the federal employees who will decide their fate.[31]This is simply implausible on its face.

For 2009, the salaries of Senior Executive Service members (such as EPA managers) range from $117,787 to $177,000.[32] This range may understate EPA salaries in the pesticide office because certain career employees can be compensated at even higher rates for the purpose of retention. When they retire from federal service (which they would do more readily without these retention bonuses), SES employees often take jobs in the private sector paying much more than they earned while federal employees. These jobs may involve serving as the senior corporate executive with responsibility for dealing with EPA.[33]

Actual corporate salaries generally are proprietary, but they are reportable for the officers of publicly traded companies under SEC rules. Many firms expected to receive a Tier 1 Order are publicly traded companies, and a corporate officer must sign a company's response to EPA. Because EPA knows with reasonable certainty the identity of every firm to which it intends to send a Tier 1 Order, and it knows the number of Tier 1 Orders it expects to send to each such firm, it is easy for EPA to use public documents to obtain salary information for those Order recipients that are publicly traded and estimate managerial burden using actual data rather than misleading economy-wide averages.

D. EPA's assumption about how consortia work is inconsistent with current practice.

For burden estimation purposes, the ICR assumes that all 67 substance-specific consortia are managed by one of the firms receiving a Tier 1 Order for the substance. EPA calls these "lead" firms "Data Generator/Submitters" (U.S. Environmental Protection Agency 2009e, p. 15).

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[31] Senior non-SES career staff may leave government for work in the private sector. Gad's survey shows that Board certified toxicologists with 20 years experience are typically paid three or more times the rate EPA uses in this ICR.

[32] There also is a separate salary scale for senior federal scientists, and the range is identical to the SES schedule.

[33] Some federal SESers are attorneys who become partners at law firms when they leave federal service. Partners routinely earn several hundred thousand dollars per year, in large part because if their specialized knowledge about the federal agency from which they retired.

The idea, apparently, is that "lead" Tier 1 Order recipients would be able and willing to perform this management function and other members would accept such an arrangement.

This assumption is counterfactual. Hundreds of multi-firm testing consortia already exist for purposes other than EDSP screening, and it appears that "lead" members manage none of them. Consortium management is a service provided by trade associations or independent consulting firms. Third-party management appears to be essential for a range of reasons including liability minimization, avoidance of conflict of interest, and protection from the risk of antitrust violations.

Several examples are instructive. The Joint Inert Task Force (JITF)is an umbrella consortium comprised of about 25 member companies that organized toxicity testing on some 57 different substances, managed separately under some 17 different chemistry classes. The JITF is managed by an independent consulting firm. The Consumer Specialties Products Association manages 31 different consortia but is not itself a pesticide registrant or inert manufacture or importer. The Spray Drift Task Force, the FIFRA Endangered Species Task Force, the Ag Handlers Exposure Task Force, and the Occupational and Residential Exposure Task Force are examples of consortia that have developed data to support pesticide product registrations, each having a few dozen corporate registrant members and each managed by an independent non-registrant firm. The granddaddy of substance testing consortia is the High Production Volume (HPV) Challenge Program. Hundreds of firms participate, but unless they are the only producer or have intellectual property concerns, they participate through consortia managed by trade associations or other independent entities.

E. EPA's estimate of burden on firms receiving Tier 1 Orders is not supportable.

In this subsection and the one that follows, EPA's estimates are reorganized to reflect the reality that firms receiving Tier 1 Orders would not be managing testing consortia. Reorganizing burden estimates this way also is necessary to produce building-block values that can be summed to produce unbiased estimates of average burden per firm. As noted earlier, burden per firm cannot be estimated from EPA's figures because the ICR does not include the number of Tier 1 Orders each firm would receive. As noted above, populating Figure A would solve this problem.

EPA's burden estimates for Tier 1 Order recipients are reported in ICR Tables 6-9. These estimates can be confusing because they do not properly distinguish between true burden-hours and the non-burden hour costs of data generation and consortium management.[34]

[34] One reason for confusion is that Table 1 (p. 14)—a crucial building block for all subsequent burden estimates—is not what it purports to be. Contrary to its title, the rows in Table 1 do not count numbers of respondents; they count numbers of Tier 1 Orders.

Beginning with Table 6, which is described as representing burden per chemical, note that it has 11 rows representing different activities. However, only the activities in Rows 6-10 are conceptually appropriate to describe as burdens that would be borne once per substance subject to Tier 1 testing. Rows 1-5 and Row 11, however, are activities that would be undertaken by each firm once per Tier 1 Order received.[35]

Burdens borne by consortia must be counted separately as non-burden hour costs. Stripping them out from Table 6 yields EPA's implied estimate of the burden-hours borne by each Tier 1 Order recipient per Tier 1 Order received.[36] To avoid getting lost in the weeds, these estimates are summarized in monetized form in Figure B below. According to EPA, the total monetized burden borne by a firm per Tier 1 Order received, exclusive of the non-burden hour costs of consortia and data generation for that substance, is $32,177.

This figure seriously underestimates the actual burden of responding to a test order.

[35] Consortium managers also would engage in the activities listed in Rows 1-4 and Row 11.

[36] EPA's burden estimates for each activity are identical for pesticide registrants and inert ingredient manufacturers and importers. Thus, there is no need to separate these categories. Moreover, separating them creates confusion because some firms will be in both categories.

Figure B:
Implied EPA Burden per Tier 1 Order Each Firm Receives

Row	Tier 1 Order Recipient Activity [1, 2]	Monetized Burden [2]
1	Read instructions	$ 2,166
2	Plan Activities	$ 8,204
3	Submit initial response	$ 4,169
4	Read/discuss protocol	$ -
5	Participate in consortium	$ 13,707
6	Generate data	$ -
7	Submit progress report	$ -
8	Compile & review data for submission	$ -
9	Assemble the submission package	$ -
10	Submit final data	$ -
11	Maintain records	$ 3,929
	TOTAL	**$ 32,177**

[1] ICR Tables 6 and 8 (excludes rows 4, 6-10 [consortium activities]).
[2] Hourly rates from ICR Table 5.

1. *EPA grossly underestimates the burden-hours for activities it counts.*

For the few activities that EPA counts, its burden-hour estimates are very low. This is obvious when burden is monetized using EPA's assumed wage rates.

a) "Read instructions"

Notice that the monetized value of EPA's estimate of burden-hours spent reading instructions is only $2,166. Many employees of the firm receiving a Tier 1 Order must perform this task, and there are literally hundreds of pages of detail they must master—not including the crucial SEP and WOE documents that EPA has thus far not developed.[37] Learning everything that needs to be known could easily require many times this level of effort.

[37] This burden differs depending on the number of Tier 1 Orders a firm receives. In theory, a firm would need to undertake this task once—for the first Tier 1 Order received, and not for any subsequent Order. Practice easily could differ from this simple theory, however. For large firms,

b) "Plan activities"

EPA describes the task titled "plan activities" as follows:

> After reading the Tier 1 Order they [sic] received, the recipient will need to plan the activities necessary to comply with the Order based on their [sic] determination regarding their intended response and whether they are interested in forming a consortia [sic] with other manufacturers of the substance or conducting the tests themselves(U.S. Environmental Protection Agency 2009e, p. 15).

It is true that a firm's "intended response" may include determining whether to join a consortium. But first the firm must determine whether to cite or submit existing data in lieu of testing (Option 2), claim not to be subject to the test Order, (Option 4), give notice of the intention to "voluntary" cancel the product registration or reformulate the product (Option 5), claim a formulators'exemption (Option 6), state that manufacturing or importation of an inert ingredient has or will be discontinued (Option 7), commit not to sell the substance for use in a pesticide product (Option 8), request an exemption under FFDCA section 408(p)(4), mount a pre-enforcement challenge to the Order (Option 10(a)), or claim that Tier 1 screening is unnecessary because the substance is an endocrine disruptor or was used as a "positive control" in a validation study (Option 10(b)).

This is an extraordinary array of options that a firm must analyze before making a decision. Just analyzing them requires sophisticated legal, financial and possibly political knowledge and skills. According to EPA, the monetized value of this burden is $8,204.

c) "Participate in consortium"

Unlike "reading instructions" and "planning activities," consortium participation burden occurs throughout the consortium's lifetime. This lifetime is not limited to the three-year period of the PRA clearance EPA seeks. It lasts until the limited liability corporation or similar entity containing the consortium is terminated. Moreover, joining a consortium does not relieve a firm of legal liability for compliance with a Tier 1 Order. Therefore, prudence requires a high level of engagement with the consortium to ensure that the firm's interests are fully protected.

Despite the magnitude of this effort, the monetized value of EPA's burden estimate for participation in a single consortium is $13,707 (U.S. Environmental Protection Agency 2009e, p. 42, Table 11). For simplicity, this burden can be spread

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different substances may reside under different divisions or groups, in which case the burden of getting up to speed with regulatory requirements will be borne redundantly. This is especially likely in the case of a firm that is both a pesticide registrant and a manufacturer or importer of an inert ingredient. Double-counting can be avoided, but only EPA completes Figure A.

evenly over 36 months, which means the monetized value of EPA's estimate is $380.75 per month.[38]

EPA's figure is significantly lower than anecdotal but reliable evidence obtained from existing consortia. Although the amount of time that individual firms devote to consortium participation is proprietary, these data suggest that the distribution of burden-hours is approximately log-normal with a long upper tail. For a small number of firms, participation is relatively intense because they have the greatest financial stakes. The geometric mean of the monetized burden is about $31,000 per consortium, or $861 per month—a factor of 2.3 greater than what EPA assumes.

EPA's figure for the aggregate burden for consortium participation is 55,233 hours spread across 323 (not 390)[39] respondents (U.S. Environmental Protection Agency 2009e, p. 41, Table 10), or total of $4,427,516 (U.S. Environmental Protection Agency 2009e, p. 42, Table 12). Using the more realistic geometric mean and applying it to every firm receiving a Tier 1 Order yields a monetized aggregate burden of ($31,000 × 390 =) $12.1 million. EPA understates the average burden of consortium participation by at least a factor of three, and quite likely, a much larger multiple.[40] Even this approach almost certainly understates actual burden by a lot because it does not account for the near certainty that every consortium will have one or more intensive participants.[41]

2. EPA does not count a wide array of respondent activities.

EPA's estimated burden also is unrealistically low because it does not count all activities that firms receiving Tier 1 Orders reasonably would undertake. Obvious examples can be found in the rows of Figure B. For example, EPA apparently assumes that employees of firms receiving Tier 1 Orders do not "read and discuss" EPA's test guidelines and laboratory protocols.[42] Similarly, EPA apparently assumes respondents devote zero staff time overseeing data generation,

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[38] EPA assumes 24 managerial hours and 145 technical hours (U.S. Environmental Protection Agency 2009e, p. 39, Table 6). Allocated over three years, that works out to 40 minutes per month of managerial time and 4 hours per month of technical time.

[39] EPA assumes that only non-"lead" firms participate in consortia; that is, for "lead" firms, participation is free.

[40] As pointed out in Section V.C below beginning on page 47, EPA easily could (and still can) survey the members of existing testing consortia to develop a more refined estimate.

[41] Whereas the aggregation procedure used here implicitly assumes that intensive consortium participation is rare—the mean is an exponential function of variance [$e^{(\mu+\sigma^2/)2}$], and thus is highly influenced by outliers—it is highly likely that every one of the 67 consortia would have intense participation by at least one firm. Instead of a handful of firms participating intensively, at least 67 would be doing so.

[42] EPA explicitly includes this only for consortium managers do this. See Tables 7 and 8, Row 4. If EPA has included it within the activity "participate in consortium," then the Agency's estimate for that activity is even more downward biased.

the progress reports prepared by the consortium, and reviewing test data. The factual basis for these assumptions cannot be found in EPA's ICR.[43]

EPA could have obtained real data, of course. Hundreds of testing consortia already exist, and EPA already knows every one of them and the identities of all their members. With sufficient protection for proprietary information, EPA still can survey them to obtain valid and reliable data on past experience in similar circumstances. While there is no guarantee that burdens would be the same for the EDSP, there also is no question that past experience is a better guide than the arbitrary assumptions EPA used in the ICR.

F. EPA's estimate of the burden of establishing, operating, and managing a testing consortium is not supportable.

In subsection E above, the activities attributed by EPA solely to "lead" Tier 1 Order recipients were stripped out because they are consortium activities, not respondent activities. In this section, the implied non-burden hour cost of consortium management is reconstructed, using EPA's burden-hours and EPA's wage rates, and characterized as a non-burden hour cost. The implied non-burden hour cost of managing a single consortium is $38,670. Details are provided in Figure C below.

1. EPA implicitly assumes that consortia can be created for free.

EPA assumes respondents bear no burden-hours or non-burden hour costs to establish testing consortia. This assumption is not credible, and it would exist even under EPA's counterfactual assumption that "lead" Order recipients manage all consotia.

Anecdotal evidence from existing consortia suggests that they entail several thousand dollars worth of burden-hours for each member, plus non-burden hour costs of about $25,000. At this rate, the aggregate non-burden hour cost just to establish 67 consortia would be $1.7 million. This figure assumes that all 67 consortium are pretty much the same size and the size is manageable. EPA acknowledges, however, that at least one testing consortium could have as many as 56 members. Chances are the cost of establishing that consortium will be significantly greater.

2. EPA assumes consortium managers would not undertake most of the activities that Tier 1 Order recipients would perform.

[43] Alternatively, the ICR can be interpreted to assume that all these respondent activities are contained within the activity labeled "consortium participation." If so, then EPA's burden-hour estimate is even less credible.

EPA assumes that consortia managers and scientists would not need to engage in any of the same activities that employees of firms receiving Tier 1 Order would undertake. For example, consortium staff would not need to "read instructions," "plan activities," or even "participate" in them.

3. EPA counts only a handful of activities that consortia would actually perform.

The activities that would be undertaken by consortium manager are assumed to be remarkably inexpensive. For example, EPA describes the activity titled "read and discuss the protocol" as follows:

> *Read and discuss the protocol* – The Order recipients will need to read the protocols for the assays identified in the Order and may have questions or may need to modify one or more of the protocols for the subject substance. An Order recipient wishing to deviate from any of the protocols identified in the Order, may do so only after

Figure C:
Implied EPA Burden Estimates for Establishing, Operating, and Managing a Consortium (With and Without Data Generation)

Row	Consortium Activity [1, 2]	Monetized Burden [2]
1	Read instructions	$ -
2	Plan Activities	$ -
3	Submit initial response	$ -
4	Read/discuss protocol	$ 14,884
5	Participate in consortium	$ -
7	Submit progress report	$ 2,292
8	Compile & review data for submission	$ 18,825
9	Assemble the submission package	$ 2,292
10	Submit final data	$ 378
11	Maintain records	$ -
	TOTAL FOR ESTABLISHMENT, OPERATION AND MANAGEMENT	**$ 38,670**
6	Generate data	$ 141,520
	TOTAL FOR ESTABLISHMENT, OPERATION, MANAGEMENT, AND DATA GENERATION	**$180,190**

[1] ICR Table 6 (excluding rows 1-3 and 5 [Tier 1 Order recipient activities]).

[2] Hourly rates from Tables 5.

> consultation with EPA. Such requests should be submitted to EPA with a clear rationale and explanation of the deviation. All protocol variations will be reviewed by EPA and a response will be sent to the specific Order recipient in a timely fashion (U.S. Environmental Protection Agency 2009e, p. 16).

If they have questions about EPA's test guidelines or laboratory protocols, consortium staff are expected to discuss these matters with EPA to ensure that they are certain about what EPA wants. EPA staff, in turn, are implicitly assumed to give clear, consistent, and timely guidance at every step. If consortium staff believe that "deviations" from an EPA protocol makes sense, they must clear them with EPA before proceeding.[44] Nonetheless, according to EPA all of this can be done by the consortium manager for less than $15,000.

EPA's model also assumes that consortia have no ongoing legal costs, accounting costs, or administrative overhead. Indeed, EPA assumes no costs for the offices in which consortia employees work.

For now, the best available information about the non-burden hour cost of consortium management is both anecdotal and proprietary; it cannot be generalized with confidence to the EDSP. Still, it is worth noting that consortium managers consulted for this review indicate that the non-burden hour cost of consortium management historically has been about one-half of the non-burden hour cost of data generation. That ratio is five times greater than the ratio implied by EPA's ICR, which is about 10%.[45]

The right approach for EPA to take is to survey existing test consortia to find out what the non-burden hour costs of consortium management have been. Well over 100 testing consortia exist today; EPA knows them all by name; and it would be simple to devise a survey sufficient to retrieve representative data sufficient for developing a generalizable burden estimate.

4. EPA understates the burden of data generation by about tenfold.

By itself, EPA's "35% assumption" understates the burden of data generation by about a factor of three.[46] In addition, the base to which EPA applies the "35% assumption" is too low by another factor of about three, resulting in about a tenfold underestimation of burden for data generation.

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[44] EPA says "a response will be sent," but it does not say that this response will be clear, consistent, or timely.

[45] From Figure C, EPA's implied non-burden hour cost of consortium management is about $40,000. Dividing by EPA's estimate of the non-burden hour cost of testing ($400,000) yields 10%.

[46] 1/.35 = 2.86.

For nine of the 11 assays in the Tier 1 battery, EPA relies on estimates provided by Borgert (2003).[47] These estimates are now outdated and were incomplete even at the time they were developed, as the author himself has noted:

> The protocols used to estimate costs in [(Borgert 2003)] were not necessarily the same as current protocols and did not include a variety of optional endpoints and additional controls that EPA is considering. As work by EPA has progressed in the development and validation of the Tier 1 protocols, additional complexity has been added, including methods/measurements to address both specific endocrine responses as well as more apical endpoints (Borgert 2008, p. 2).

In a public comment on the draft ICR, Borgert (2008) updated estimates for four assays based on "actual recent bids and costs." Borgert noted. in both his original survey (2003) and his follow-up (2008). that his estimates give only a credible starting point for burden estimation. His surveys have not attempted to capture the full burden of GLP compliance; the burden associated with having to repeat assays if initial results are ambiguous; or the burden associated with over-compliance resulting from ambiguity in EPA's test guidelines, laboratory protocols, and data acceptance criteria. Thus, from the outset EPA has needed to supplement Borgert's results with objective estimates for those burden elements he did not attempt to estimate.

EPA did not do this. In its Response to Comments, EPA asserts that Borgert's 2003 estimates are good enough and that the Agency has no obligation to do better:

> The Agency accepts that [Borgert 2003] is not perfect or complete. It does, however, provide a reasonable estimate for the burden and costs of these new tests. As indicated previously, the Agency did not believe that a survey would provide more valuable information at this time because these tests are not currently available on the market. At best, a survey might have provided different estimates, but without a clear indication that could describe the basis for those differences. (U.S. Environmental Protection Agency 2009d, p. 13).

EPA's position is contrary to the explicit language of the Paperwork Reduction Act, which makes it a nondiscretionary duty for the Agency to develop accurate and objectively based burden estimates.

Figure D below illustrates the magnitude of bias in EPA's burden estimates using a modified box-and-whisker plot for the three assays Borgert (2008) updated with real cost data that are included in EPA's final Tier 1 battery. The pink boxes show the increase in burden between EPA's draft and final ICRs. The vertical green lines show the range of estimates obtained by Borgert for 2007-08. EPA's burden

Deleted: Figure D

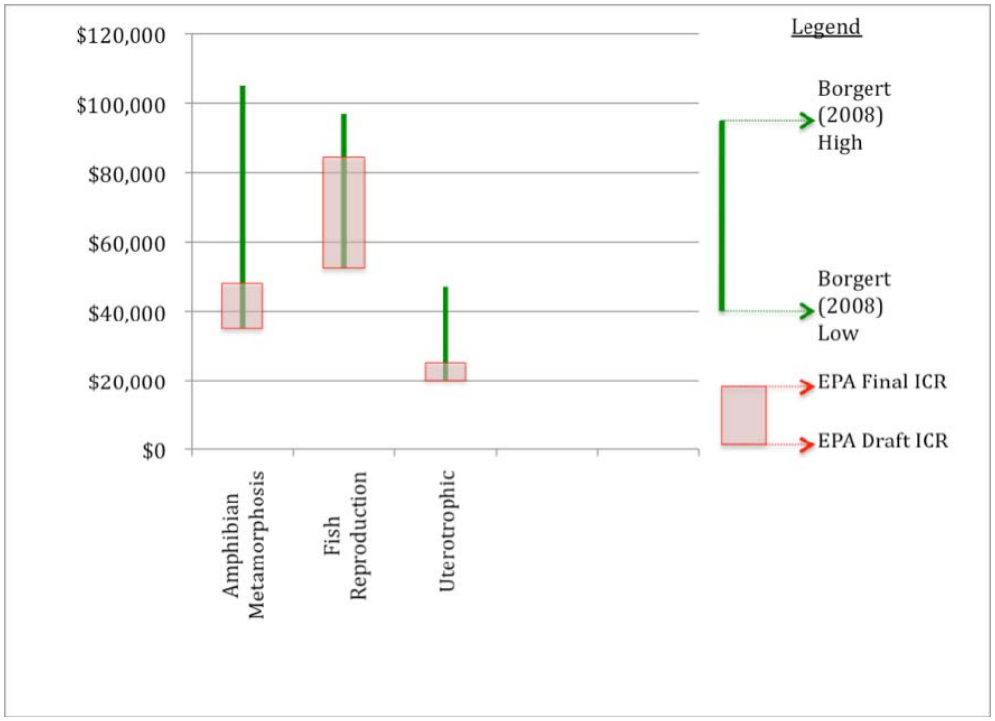
[47] EPA increases them by 14% to account for economy-wide inflation. This adjustment is technically wrong on its face. An economy-wide adjustment such as the GDP deflator does not capture inflation specific to toxicological laboratories. Inflation rates are irrelevant here. Period.

estimates increased 38%, 62%, and 26% for the three assays. Borgert's estimates increased by multiples ranging from 1.5 to 3. Because Borgert's revised estimates do not account for factors he could not estimate, the actual magnitude of downward bias in EPA's estimates is even greater.

As Borgert (2003) noted, his estimates exclude the addition burden associated with having to repeat assays that, through no fault of respondents or the laboratories, yield ambiguous results. It is highly likely that ambiguity will vary by assay. Borgert hypothesizes, based on a very small sample, that this ambiguity would affect 10-25% of all assays performed. Respondents reasonably may expect that EPA will require them to repeat ambiguous assays—or what is in effect the same thing: decline to accept ambiguous results—and EPA's final Policies and Procedures guidance does not say anything suggesting otherwise. Even if the Policies and Procedures guidance promised never to require repeated tests, respondents could not rely on it because it is only guidance, and hence not binding on EPA.

The problem of ambiguous results is a subset of a much larger problem: EPA has not yet developed objectively interpretable criteria for regulatory acceptance of Tier 1 data. Borgert (2003) did not—indeed, could not—estimate the additional burdens associated with regulatory uncertainty generally. It is well known that when respondents face regulatory uncertainty, they tend to over-comply—in this case, by generating more data and analytic results than EPA might later was necessary or by generating data that EPA did not weight very highly.

Figure D: EPA Consistently Understates Testing Burden



5. EPA undercounts the non-burden hour cost of analytical chemistry.

In the draft ICR, EPA included within its estimates of the burden for data generation nothing for analytical chemistry(U.S. Environmental Protection Agency 2007b, Attachment F). Several commenters noted this error. Borgert (2008), whose 2003 estimates "made no attempt to consider costs associated with chemical analysis of the test substance to satisfy GLP requirements" (p. 6), reminded EPA that analytical chemistry is a significant GLP requirements and that this error "should be corrected." He predicted that analytical chemistry will raise the cost of testing by 10-25% (p. 7). He recommended a path forward EPA could use to develop credible estimates:

> In order to accurately evaluate these expenses, however, the Agency should undertake a formal evaluation of the probable cost range for analytical chemistry that includes an evaluation of the number of analyses that will be required for the various individual Tier 1 assays, since these will vary according to the length and complexity of the study. Only by conducting a formal assessment can the Agency's ICR adequately estimate the significant costs associated with analytical chemistry.

EPA did not do this. Instead, EPA assumed that analytical chemistry adds 2.3% to the cost of data generation. EPA defends this figure on the ground that the Agency has used it before:

> The cost for analytical chemistry is based on that used in other EPA ICRs that contain this test. It is important to note that the chemicals on the initial list are all already well established existing pesticides, which means there will not be a need to create any new analytical methods to identify the substance for testing purposes. As such, the analytical costs included here represent the application of the existing methods to identify the substance being tested. In addition, the draft estimates were adjustedbased on public comment (U.S. Environmental Protection Agency 2009e, Attachment F, footnote (a)).

The reference to "other ICRs that contain the test" is hard to follow. None of the assays in Tier 1 are contained in any other ICR. Possibly, EPA means "other ICRs that have routine analytical chemistry costs because they require GLP compliance." That historic experience is not necessarily useful here, however, because analytical chemistry may not be routine. The Tier 1 assays are all new, and new analytical chemistry procedures may need to be developed, proved and applied. Thus, Borgert's advice remains on target: EPA needs to undertake a formal evaluation to determine the burden of analytical chemistry. The aggregate difference between EPA's assumption ($9,120× 67 = $0.6 million) and the alternative estimate derived from limited empirical evidence (10-25% × $1 million × 67 = $7 million to $17 million) is not trivial.

6. EPA's "35% assumption" must be subjected to rigorous OMB scrutiny because the Agency intends to use it in all future ICRs as a proxy estimate for all respondent burden.

During the search for an objectively supported basis for the "35% assumption," EPA provided a recent document that is attached to a different ICR, which also is under review at OMB.[48] This document is described by EPA as a "general methodology" for estimating paperwork burdens associated with data call-in notices.[49] Although it was not the basis for the EDSP ICR, it uses the same "35% assumption" found in the EDSP ICR and appears to attribute the assumption to the same origin:

> For more than a decade, EPA has been estimating all the paperwork burden hours and costs of responding to a DCI notice as approximately 35% of the cost of the study… This formula allows the Agency to derive a reasonable estimate of for PRA activities (Phases 1, 2, and 3) by using the average estimated cost of specific tests. This

[48] OMB ICR Reference Number 200809-2070-002. See http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=200809-2070-002#section0_anchor.

[49] The "general methodology" document is Attachment G.

> approach was adopted because it allows the Agency to consider the potential for there to be more burdens related to a more complex study. The premise is that a more expensive test may cause the respondent to incur more burden hours and costs than a less expensive test would. This estimate is only applicable to DCI-related data generation. This percentage was developed from numerous sources of information including agency expertise, industry consultation, and repeated review by the public, industry, key stakeholders, and OMB on the Agency's information collection activities (U.S. Environmental Protection Agency 2008, p. 10).

EPA identifies three (actually four) "phases" of the response process:

- "Phase 1: Initial Response"
- "Phase 2(a): Data Generation Using Contract Laboratory
- "Phase 2(b): PRA Data Generation Activities Conducted at the Contract Laboratory"
- "Phase 3: Data Submission to EPA"

EPA's "general methodology" assumes the "35% assumption" is a "reasonable estimate" for <u>all four</u> phases combined—that is, it covers every respondent activity related to a test rule. In the EDSP ICR, however, EPA applied the "35% assumption" only to the burden of data generation (U.S. Environmental Protection Agency 2009e, p. 39, Table 6, Row 6, transferred from Attachment F). Had EPA applied the "general methodology" to the EDSP ICR, the Agency's aggregate burden estimate for Tier 1 Orders would not have been $22.4 million. It would have been $9.4 million.[50]

The "35% assumption" is obviously wrong as a proxy for the non-burden hour cost of data generation; by definition, the burden for data generation must be 100%. It is even less justified as a proxy for the <u>sum</u> of all respondent activities.[51]

Because both ICRs are under review now, OMB should use this opportunity to insist that EPA revise its "general methodology" to make it logically correct, accurate, and objectively supported. Then it can be applied to the EDSP. Otherwise, there will be a formal precedent for using an obviously substandard technique, and errors in the "general methodology" will be propagated to all future information collections involving test orders.

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[50] EPA's estimate of burden for the entire Tier 1 battery is $0.4 million. Applying 35% to that yields $0.14 million. Multiplying by 67 Tier 1 batteries yields $9.4 million.

[51] Figure 1 in the "general methodology" (p.11, middle "ball") clearly shows that the "35% assumption" is intended to cover everything. This is arithmetically impossible because a sum of a set of positive values (Phases 1, 2(a), 2(b), and 3) cannot be less than any single value in the set.

G. EPA could have easily avoided (and can easily correct) many technical errors in the ICR.

Thus far, EPA appears to have elected not to expend the time or effort needed to accurately estimate of the burden it plans to impose.However, many of the technical deficiencies in the ICR could have been (and still can be) avoided if EPA used real data instead of arbitrary assumptions. Here are some suggestions.

1. EPA still can properly estimate the burden of generating test data by replicating Borgert (2003).

The burdens associated with Tier 1 testing have been a known concern among prospective respondents for many years. Disagreement about their magnitude has been well known for just as long. The EDSP has been under development for a decade, at a cost of millions of taxpayer dollars. Industry funded the conduct of two surveys by Borgert (1998, 2003), both of which EPA has used, and a public comment on EPA's draft ICR that included a partial update (Borgert 2008), which EPA did not.

In its Response to Comments on the draft ICR, EPA says burden cannot be estimated because Tier 1 assays are not commercially available:

> Until the tests are readily available on the market, conducting a survey about the tests would not be productive. Laboratories did not yet have any experience with these tests upon which to they could have provided information (U.S. Environmental Protection Agency 2009d, p. 12).

EPA wants to postpone burden estimation until an unspecified some future date:

> Although not possible for this ICR, the Agency does intend to consult with the recipients of these first Tier 1 Tier 1 Orders about their experiences, costs and burdens. This consultation will be used to revise the estimates presented in this ICR for the ICR renewal or future ICRs related to the EDSP (U.S. Environmental Protection Agency 2009d, p. 12).

EPA misreads the requirements of the Paperwork Reduction Act. The law requires accurate, objectively supported burden as a precondition for OMB approval. The law does not permit EPA to postpone this duty until respondents have expended millions of dollars to comply.

Several public commenters asked EPA to replicate Borgert (2003)— most notably, Borgert himself:

> Rather than use the results of [(Borgert 2003)] to estimate costs, the Agency should have used the design of that survey to guide development of its own cost assessment based on current assay protocols, taking into consideration the practical needs of potential respondents given the Agency's implementation plans (Borgert 2008, p. 3).

In its Response to Comments, EPA rejected this and others' suggestion that it develop accurate, objectively supported burden estimates. The basis for rejection was that the Agency "did not believe" that replication would yield better data (U.S. Environmental Protection Agency 2009d, p. 13). EPA's "beliefs" do not trump the law, however, and the law says accurate and objectively supported burden estimation is mandatory. It is up to OMB to enforce the law.

2. EPA still can survey respondents to obtain credible burden estimates.

Instead of surveying laboratories, EPA could survey consortium managers firms to find out what they have been paying for similar toxicological tests. Hundreds of testing consortia already exist, and EPA knows them all by name. Thus, such a survey would be easy to design and implement. At the same time, EPA could obtain data on the other non-burden hour costs of consortium management. These data can account for such important variables as the size of the consortium, the nature of the substances being tested, and the novelty of the tests being performed. A carefully designed survey using a representative sample would yield information that is far superior to the anecdotal data now available.[52]

EPA has not done this, but there is still time to do so.

3. EPA still can obtain firm bids estimates from qualified laboratories.

At any time, EPA could have obtained estimates from laboratories. EPA has unique knowledge of the test guidelines and laboratory protocols that it intends to require. Moreover, this information could have obtained at trivial cost to the Agency. EPA has not done this, either. Worse, EPA also will not identify which laboratories it considers qualified.

A consistent pattern is clear. EPA has not fulfilled its statutory duty to prepare accurate and objectively supported burden estimates for test generation. Labs routinely provide cost estimates for such studies. At the same time, the Agency appears to have treated the public dismissively. When presented with alternative burden estimates that are higher than its own, EPA has simply dismissed these estimates, saying that "there is no support" for them (U.S. Environmental Protection Agency 2009d, p. 13).

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