



Chemical Producers and Distributors Association

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VIA E-MAIL

The Honorable Cass Sunstein
Administrator, Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
Washington, D.C. 20503

**Re: Improving Implementation of the Paperwork Reduction Act.
74 FR 55269; Docket ID Number OMB-2009-0020**

Dear Administrator Sunstein:

The Chemical Producers & Distributors Association (CPDA) appreciates this opportunity to provide comments in response to the above referenced *Federal Register* notice (FR Notice) requesting suggestions for improving implementation of the Paperwork Reduction Act of 1995 (PRA).

CPDA is the preeminent U.S. based trade association representing the interests of generic pesticide registrants, adjuvant and inert ingredient manufacturers, and product formulators and distributors. We represent over \$7.7 billion worth of pest control products used on food, feed and fiber crops and in related non-crop segments.

As noted in the FR Notice, the PRA requires Federal agencies to minimize the burden, or cost, on the public resulting from their information collection activities, and to maximize the practical utility, or benefit, of the information collected. The responsibility of the Office of Management

and Budget (OMB) is to oversee efforts by each agency's Chief Information Officer "to weigh the burdens imposed by collections of information on the public against the usefulness – or practical utility – of the information received."¹

CPDA strongly supports the statutory goal of PRA to minimize the burden on the public resulting from information collection activities of Federal agencies. We also strongly support the PRA requirement that a Federal agency maximize the practical utility of the information collected and that the agency provide "a specific, objectively supported estimate of burden" on those generating the information. Therefore, CPDA submits these comments² on reducing current paperwork burdens, especially on small entities; increasing the practical utility of information collected; ensuring accurate burden estimates; and preventing unintended consequences. We will provide supporting evidence for these comments through review of a specific approved information collection request (ICR) conducted by the Environmental Protection Agency (EPA).

Burden and Practical Utility

The PRA defines "burden" as "the time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency...",³ and OMB has clarified that such financial resources include those that are expended "for the purpose of collecting, validating, and verifying information."⁴ Moreover, EPA's Office of Pesticide Programs interprets "burden" to include resources expended to "...collect, review, validate, and verify information/data..."⁵ These definitions and interpretations clearly demonstrate that *the actual costs of generating and collecting the information sought* must be included in the burden estimate. However, historically EPA has not included data and information collection costs in burden estimates for information collections, and OMB has not required the Agency to do so.

EPA's information collections can require the generation and submission of significant amounts of newly acquired data through implementation of large-scale toxicological testing programs or "data call-ins". Despite the Agency's published interpretation of "burden," its information collection burden estimations use the test costs of the data collection only as a point of departure. For more than a decade, EPA has employed the convention of assuming that "35% of the cost of any given test reflects all burdens and costs necessary for the completion of the paperwork activities," and based on this, does not include the actual test costs in the total burden estimation. Therefore, information collections conducted by the Agency requiring the generation of new data over at least the last 10 years will have underestimated the total burden by at least 65%.

CPDA would like to reference a specific timely example of an EPA Information Collection approved by OMB wherein the *inaccuracy* and *underestimation* of the final Agency burden may

¹ Information Collection Budget of the United States Government, Fiscal Year 1999, Office of Management and Budget, Office of Information and Regulatory Affairs

² We limit our comments to Information Collection Requests as conducted by the U.S. Environmental Protection Agency (EPA), based on our historical experience and expertise with this Federal agency.

³ 44 U.S.C. § 3502(2).

⁴ 5 C.F.R. § 1320.3(b).

⁵ General Methodology Used to Estimate Paperwork Burden Hours and Costs by the Office of Pesticide Programs for Submission of Required Data/Information for Responding to a Data Call-In Notice, EPA-HQ-OPP-2007-0923

be measured in tens of millions of dollars due to the conventions and methodological estimation techniques utilized by the Agency.

In October of this year, OMB approved the first Information Collection Request under the EPA's Endocrine Disruptor Screening Program (OMB Control No. 2070-0176). This information collection consists of generating "Tier 1" screening data for 67 pesticide chemicals to determine if each chemical *may* interact with endocrine systems. If the Agency determines a chemical *may* interact with endocrine systems, it is authorized to require through a new ICR additional "Tier 2" testing to determine if and how the chemical interacts with endocrine systems and to characterize the potential risk. EPA posted the draft EDSP ICR (EPA ICR No. 2249.01) for public comment in early 2008, to which CPDA responded with comments⁶ on several aspects of the ICR, including the lack of the Agency's inclusion of the test costs in the burden estimate, significant underestimation of the test costs, and the potential impacts on small entities. In its comments, CPDA outlined how the Agency could obtain better estimates of test costs and of the costs associated with the development and implementation of consortia for cost-sharing. We also noted that the total burden proposed by the Agency, using the 35% convention referenced earlier along with inaccurate test cost estimations, was underestimated by 3 to 5-fold. In the draft ICR, EPA estimated total burden at approximately \$20 million. In contrast, currently available test cost survey results indicate that the actual total information collection burden, including test costs, could readily approach or exceed \$100 million. In its formal response to the comments submitted by CPDA, EPA did not address the comments on exclusion of test costs nor did it include test costs in the burden estimation in the final ICR. The Agency also did not respond to comments on the impacts of this information collection on small entities.

CPDA and other pesticide industry associations also provided comprehensive comments⁷ to OMB on May 22, 2009, during the public comment period of the final EDSP ICR review. Incorporated into the comments were an expert analysis of the deficiencies in the Agency's burden estimation and a discussion of EPA's failure to demonstrate the practical utility of the information collection. The expert analysis, which is appended in its entirety to these comments, provides sound rationale and substantiation in support of the following:

- EPA's burden estimates were neither accurate nor objectively supported, and the estimation methodology employed was flawed.
- EPA did not demonstrate the practical utility of the data collection or that it has "the ability to process the information it collects" from the Tier 1 tests "in a useful and timely fashion." The Tier 1 screening data may not provide EPA with unique or sufficient information needed to make crucial "may/may not" distinctions as to a chemical's potential to interact with endocrine systems.
- EPA's estimates did not conform to the Agency's information quality guidelines.

⁶ EPA-HQ-OPPT-2007-1081-0014.1

⁷ EPA-HQ-OPPT-2007-1081-0020.1

The expert analysis also offers rationale and support for:

- A refined approach for estimation of the burden imposed on individual entities.
- An approach that more accurately estimates the burden on small entities using information already in the Agency's possession.
- Approaches to more accurately monetize burden hours using industry-specific and relevant wage rates and to more accurately determine and incorporate non-burden hours for contract services as well as the burden associated with researching, citing and/or submitting existing data and establishing, operating, and managing a testing consortium.

Of particular concern to CPDA is that the Tier 1 data collection approved in the final ICR may not have actual practical utility, as the Agency acknowledged that it is only *hopeful* that the Tier 1 screening battery results will be capable of making the crucial "may/may not" distinctions. The Agency does not ensure that the information collection is non-duplicative of information it already possesses because it does not address how the collected information will be considered in a weight-of-evidence decision making process nor why existing data may be determined as insufficient for purposes of making the "may/may not" distinction. In addition, the Agency did not adequately address the range of potential impacts on small entities, which may include the inability of an entity to remain economically viable if there is no mechanism for cost-sharing of data generation. CPDA is aware of at least one instance in which only two entities received test orders for a single chemical, and one firm canceled its registration leaving a single firm to conduct the full battery of tests to maintain a pesticide registration. At the time of development of the analysis for the final ICR, the Agency had full knowledge of the size of each firm expected to receive a test order, but did not use this information to more accurately characterize potential per-entity burden.

Recommendations and Conclusions

OMB can improve implementation of the PRA by:

- Providing specific guidance to each Federal agency on developing a standardized ICR structure for repeated, significant information collections conducted by an agency. This would include directed guidance on the specific costs to be included in burden estimations, methods to acquire current and relevant cost and time resource estimations for impacted firms, and guidance on per-firm and small entity burden estimation for each Federal agency. For example, for EPA's Office of Pesticide Programs, this could begin with review of the General Methodology guidelines for burden estimation of data call-in notices.
- Consistently requiring disclosure and description of all costs of an information collection and explanation where any costs are excluded from final burden estimations.

- Making information provided to and from OMB during the course of the final ICR review process publicly available through *Federal Register* notices or a relevant docket so as to improve transparency.

On specific requests for comment by OMB, we offer the following recommendations:

- To ensure accurate burden estimates: OMB should require agencies to survey potentially affected entities to obtain the information needed to accurately develop a burden estimate and to support the practical utility of an information collection. For instance, to improve the accuracy of the cost estimates for scientific data-dependent information collected by EPA, the Agency could conduct small-scale, exploratory research on a voluntary basis with impacted entities through an on-line survey tool well in advance of drafting an ICR. Realistic time and financial burden estimates associated with test costs, consortia development and management, researching and evaluating existing data, and cost sharing – all components of the current EDSP information collection – would willingly have been provided to EPA by industry through such a tool.
- To reduce paperwork burdens on small entities and prevent unintended adverse consequences: OMB should require agencies to explicitly identify and consider the actual small entities impacted by the information collection in the draft ICR for public comment to assist the Agencies in more accurately estimating the burden and impacts for the final ICR. An assessment of the impacts on small entities should include the expected number of small firms affected and the economic worst-case scenario for small firms, and the Agencies approach to mitigate adverse consequences of the collection on these firms.
- To increase the practical utility of large information collection requests: OMB should require agencies to establish a process whereby the agency systematically provides explanation and justification where it determines that existing information is insufficient to meet the needs of the agency in performing its duties. *Only* if other relevant or functionally equivalent information is not sufficient should an information collection be approved. This would ensure that information collections are neither redundant nor duplicative, and thereby better ensure the practical utility of the collection.

In conclusion, OMB has requested comments on new or improved practices for estimating burden, such as new burden estimation methodologies and recommendations about how to use technology to seek input from those most informed about a collection's burden. With regard to new burden estimation methodologies, we have provided information on and support for an alternative mathematical approach to estimating total burden under the EDSP ICR (OMB Control No. 2070-0176) in a joint-chemical industry response to comments on the ICR in April of 2009. There are multiple robust alternative mathematical approaches that may be employed for burden estimation, but given the variety of information collection categories, a singular approach may not prove to be most efficient for all agencies or even all collections within one agency. CPDA also believes that prior to the issuance of a draft ICR, Federal agencies should solicit information from potentially affected entities through the use of a voluntary survey tool. This approach would provide comprehensive and current information that could be extrapolated industry-wide with reasonable certainty of its validity and integrity. Finally, where possible,

Federal agencies should rely on existing information in performing their regulatory duties and should be required to provide adequate justification if they determine that existing information is inadequate or insufficient to make a health or safety determination.

CPDA would like to thank OMB for the opportunity to comment on suggested methods for improving information collection procedures under the Paperwork Reduction Act. We look forward to working with the Obama Administration and providing additional comments on this initiative in the months ahead.

Sincerely,
Susan Ferenc, DVM, Ph.D.
President