Consumer Specialty Products Association

June 9, 2009

Attention: David Rostker
Office of Information and Regulatory Affairs
Offfice of Management and Budget (OMB)
725 17th Street, NW
Washington, DC 20503

Re: EPA ICR to OMB for Review and Approval: Tier 1 Screening of Certain Chemicals Under the Endocrine Disruptor Screening Program
Docket ID # EPA-HQ-OPPT-2007-1081

Dear Mr. Rostker:

On behalf of the Consumer Specialty Products Association (CSPA) and its members, we appreciate the opportunity afforded by the June 2, 2009 stakeholder meeting with OMB and U.S. EPA to discuss the reasons this ICR for EPA's Endocrine Disruption Screening Program (EDSP) lacks actual practical utility and should not be approved by OMB in its current iteration. As the joint comments filed by the Chemical Producers and Distributors Association, the CSPA, CropLife America, and the American Chemistry Council indicate, our objections are numerous and substantive.

After the discussions on June 2nd, you asked that CSPA provide supplemental comments to underscore an aspect of the deficiencies in the ICR on which CSPA has substantial experience—the costs and burdens attendant to setting up and administering consortia to collect, generate, analyze, and submit data in support of a regulatory action. We are, therefore, supplementing our comments today with some of the information we provided at the stakeholder meeting.

EPA has failed to establish the practical utility of the EDSP ICR by failing to:

- Provide validated protocols for all Tier 1 Assays;

- Provide a clear and predictable definition of Other Scientifically Relevant Information that will be accepted in lieu of specific Tier 1 Assays;
- Provide clear criteria on how the results of each Tier 1 Assay will be interpreted regarding endocrine disruption;
- Provide clear criteria for how Tier 1 results will be used to trigger specific Tier 2 tests; and,
- Provide validated protocols for (or even a list of) Tier 2 Assays.

In addition, EPA did not properly assess the costs of the ICR by failing to:

- Assure that laboratories are available and capable of conducting all Tier 1 Assays;
- Determine what the specific costs for those laboratories to conduct all Tier 1 Assays;
- Determine how many non-ingredient-manufacturers (product formulators and marketers) have a substantial interest and may want to participate in consortia; and,
- Consider the full costs and complexities of forming consortia and determining the industry response to each of the 58 chemicals targeted for initial testing.

Because of these failures, CSPA member companies cannot make informed business decisions on how to respond to test orders. This can be illustrated by looking at the steps necessary in our member companies' decision-making process after issuance of Tier 1 Test Orders:

- All manufacturers receiving Test Orders and all users of the chemicals (including both pesticide and non-pesticide product formulators) must decide by EPA's deadline whether to join into consortia to conduct testing, or instead decide to:
    - (for manufacturers) "voluntarily" withdraw their FIFRA registration or withdraw marketing for use in FIFRA products; or ,
    - (for pesticide formulators and marketers) risk manufacturer withdrawal from FIFRA products; or,
    - (for non-pesticide product formulators and marketers) risk loss of ingredient use due to regulatory restrictions or public pressure.

- Decisions to join or not join consortia need to consider all of the following questions to adequately assess costs and business risks:

- How many Tier 1 Tests will actually need to be conducted? Which Assays can be by-passed by existing testing (Other Scientifically Relevant Information)? EPA's OSRI policy statement provides grossly inadequate information to answer these questions.
- What is the cost of the entire Tier 1 Test Battery? What laboratories are available to do the testing? EPA has provided no reliable information to answer either question.
- How many other companies have significant financial interests in the chemical that might participate in a consortium? In addition to the small number of manufacturers who supply an ingredient, there may be dozens more formulators and marketers who need to be involved in the testing consortium. How will costs be divided? EPA has provided no reliable information to answer these questions.
- How will Tier 1 Assay results be interpreted in determining whether a chemical "may" or "may not" be an endocrine disruptor? How common will "false positive" results be (suspected endocrine disruptors that elicit no adverse health effects in Tier 2 tests)? Will these false positives lead to chemical de-selection by product formulators before Tier 2 tests are complete (or even started)? Inadequate information has been provided by EPA to answer these critical questions.
- How will Tier 1 Assay results be used to trigger Tier 2 testing? What are the Tier 2 testing protocols? Will they be commonly used toxicity tests that already exist for most pesticide actives and HPV inerts or different tests and protocols that will trigger significant new expenses? Again, inadequate information has been provided for our members to answer these questions.

All of these considerations must come *before* reliable and appropriate business decisions can be made by the manufacturers and their customers regarding how to respond to a Tier 1 Test Order being received by the manufacturers. CSPA member ingredient manufacturers and product formulators and marketers are willing to conduct testing that is necessary to assure the safety of its end-use products. However, as we noted at the meeting, it is essential that this testing uses validated protocols and provide clearly interpretable results. Conducting testing that is not validated or interpretable not only wastes valuable resources, but creates uncertainty that can result in inappropriate reformulations, since CSPA member companies are concerned about public perception in addition to the actual safety of its products.

At the June 2nd meeting, CSPA also conveyed further information on the process of forming and operating consortia, and the costs involved. CSPA operates a Product Ingredient Review Program (PIR) under its auspices which carries out these data generation, analysis, and submission function for a variety of ingredients under FIFRA. As a result of administering these large, medium, and small consortia, CSPA has an abundance of information about their costs and burdens. It is important that all potential consortia costs, not just those associated with "burden" as defined by the ICR, are discussed to ensure a better understanding of what the registrants face during the process.

CSPA's PIR Program, established in 1985, is currently administering 31 joint venture task forces (TFs) addressing data needs or issues related to conventional pesticides and antimicrobials. It is important to note that 29 of the TFs are comprised of both active ingredient manufacturers and formulators. Formulators, with major product lines utilizing active and inert ingredients, offer to share data development costs when the active ingredient manufacturers determine that costs are too high to continue manufacturing the active. It is anticipated this scenario will occur many times during the EDSP process, and therefore total consortia costs for individual companies will continuously increase.

Costs for the establishment of a TF average $42,000, but can increase with the number of participants. A third-party such as PIR must be retained to assure legal compliance with antitrust guidelines and to perform numerous administrative functions. Activities include:

- Identification of consortium participants;
- Contacting all prospective participants;
- Initial meeting(s) to discuss potential formation of a consortium;
- Preparation and distribution of Letters of Intent and following up with companies;
- Official formation meeting(s), which are usually large and include all participants from companies who will work at any time during the process, including business, legal, and technical representatives;
- Agreement development, which in most cases involves three comment rounds before the agreement is finalized. Each agreement will have differences based on the scope of the project and the make-up of the TF. This activity requires legal input from both the TF management and companies. Often times share values must be considered and confidential information gathered;
- The FTC and EPA must be officially notified of the formation of the TF and members must be identified;

- Company numbers must be obtained to ensure that data submissions are appropriately identified by EPA; and,
- Bank accounts must be established for each TF and accounting information set-up.

A review of the PIR TFs costs to date show that the administrative and legal costs range from 13% to 19% dependent on each TF's activities. Additionally, scientific and technical consultant costs range from 10% to 32%, again dependent on the TF's activities and requirements. If combined, the range for these overhead costs is 23% to 59% of the total TF budgets. Once TFs are formed, ongoing administrative activities include:

- Meetings and conference calls that will vary with each TF, but for the purpose of identifying burden with at a minimum include two face to face TF meetings, four to six conference calls and likely at least one meeting with EPA;
- Developing Request for Proposals (RFPs), which are sent to prospective laboratories and consultants and the selection process;
- Development of laboratory and consultant agreements, a complicated process because each lab and consultant could have different criteria required in their agreements;
- In some cases, it is necessary to develop confidentiality agreements;
- Retaining counsel;
- Oversight of protocol review, and modification as necessary;
- Oversight of study review and comment activities;
- Submission of studies, including monitoring through the Agency process and updating registrants as necessary;
- Accounts payable and receivable activities each month;
- Development of quarterly financial statements;
- Preparation of Business Committee minutes and Technical Committee notes for each meeting and conference call;
- Continuing Agency interface activities; and,
- Addressing questions from members, EPA and others.

Individual Company contributions to the TFs are generally calculated at 15% of the total costs for FIFRA data compensation purposes. However, this amount can be much higher depending on the amount of support individual companies provide for Consortia efforts. Activities required by consortia member company representatives include:

- Participation in meetings and conference calls;
- Review of RFP responses and selection of laboratories and consultants;
- Review and comment on protocols and studies and address issues;
- Attending meetings and conference calls as required;
- Providing legal and technical expertise when required; and,
- Ensuring that all activities of the TF are appropriate.

We hope that these supplemental comments are helpful in supporting an OMB decision to disapprove this ICR and require EPA to develop an ICR that has practical utility and reliable cost estimates. CSPA is willing to work with the Agency to assist in the expeditious development of such an ICR to initiate an appropriate EDSP.

Thank you once again for this opportunity to comment further. Please do not hesitate to contact us if you have any questions or require further information.

Submitted by,

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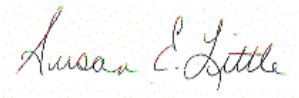

Susan E. Little, Executive Director
PIR Program