Attachment H

EDSP ICR Renewal Consultation

In addition to the notice and comment requirement, agencies are also required under 5 CFR 1320.8(d)(1) to consult with potential respondents and data users about specific aspects of an ICR before submitting it to OMB for review and approval, regardless of whether changes have or have not been made to the collection activity.

■ Consultation Participants

EPA consulted with a variety of respondents regarding the information collection activities for this ICR during the renewal and consolidation process. A list of the respondents contacted is below:

1. **American Chemistry Council (Stakeholder)**
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3. **Natural Resources Defense Council (NRDC) (Stakeholder)**
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5. **2,4-D Consortium (Pesticide Active Ingredient)**
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6. **Atrazine EDSP Consortium (Pesticidal Inert)**
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■ Survey Questions

A. Publicly Available Data

1. Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?
2. If yes, where can you find the data?

B. Frequency of Collection

1. Can the Agency collect the information less frequently and still produce the same outcome?

C. Clarity of Instructions

1. Based on the instructions, is it clear to the respondents what they may be required to do and how to submit such data? If not, what suggestions do they have to clarify the instructions?
2. Did you understand what was required, where applicable, to submit or maintain in your records?
3. Is the format of any reporting forms is clear, logical, and easy to complete?

D. Electronic Reporting and Record Keeping

1. Would electronic alternatives to paper-based records and data submissions be preferred?

E. Burden and Costs

1. Are the labor rates EPA used to estimate burdens and costs accurate?

2. Are there other costs that should be accounted for that may have been missed, such as capital/start-up/Management & Overhead expenditures/etc.?

Appendix 1
Written Response From Bayer CropScience, LP

(A) Publicly Available Data

Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

Yes

If yes, where can you find the data?

EPA will have data in its own files that should be re-evaluated, just as is done for problem formulation at the beginning of registration review, before deciding which Tier 1 studies should be requested in a test-order. EPA holds the data that companies have submitted to the Agency to support the safety of their products (e.g., data required for pesticide registration) which contains many studies which include evaluations of estrogen, androgen and thyroid activity. In addition, screening programs and relevant research studies are performed or funded by EPA (e.g., HPV screens, ToxCast, positive control work for EDSP studies, ORD research, etc.). EPA could also search the peer reviewed literature for additional OSRI; although not all of the data may be relevant and reliable for Tier 1 data purposes, EPA could critically evaluate publications as to whether they have value in the Tier 1 process. The Agency should at a minimum re-evaluate and issue a transparent "OSRI opinion" of the studies it already has in house rather than placing the burden on industry to explain data that EPA is already familiar with.

In the List 1, Tier 1 process, test order recipients provided OSRI (other scientifically relevant information) which included a review of the existing pesticide safety data submitted to EPA. We feel this information was underutilized by EPA in the process, which is a concern for the upcoming List 2 pesticides. Our opinion is that EPA's OSRI evaluation for List 1 was too strict; EPA appeared focused on receiving the exact assays prescribed in the guidelines rather than acknowledging other types of data might provide equivalent or even superior data. While it is understandable that EPA wanted to receive a significant body of data for every List 1 Tier 1 screening study to help it determine the strengths and weaknesses of each assay, moving forward EPA should place higher weight on 40CFR part 158 studies, also drawing from the lessons that will have been learned from the List 1 Tier 1 results. EPA should also be better able to determine the utility of ToxCast assays once all List 1 Tier 1 data has been evaluated and results measured against those obtained from ToxCast screening.

(B) Frequency of Collection

Can the Agency collect the information less frequently and still produce the same outcome?

As indicated above, EPA may already have sufficient information to evaluate endocrine activity and would eliminate the need to collect additional information. A thorough review of existing data should be initiated by EPA before test orders are issued.

If studies are determined to be necessary, the Agency could eliminate the 1 year interim report requirement; this requirement was a paperwork burden on test order recipients and EPA without bringing any information value. Also, based upon our List 1 Tier 1 experience, EPA should

extend the duration of the Tier 1 program to allow test-order recipients at least 2.5 years (preferably 3) to fulfill the requirements; this would ensure that all test order recipients that file an OSRI report at 90 or 150 days and request waivers from some or all data requirements have enough time after receiving OSRI feedback from the Agency to provide both their studies and weight of evidence (WoE) summaries in a single submission package (assuming EPA continues to provide its OSRI feedback within 3-6 months). This would greatly reduce the need for the multiple study deadline extension requests that were burdensome to List 1 recipients and presumably to EPA as well. Finally, even in cases where study deadline extensions are necessary, EPA should still accept a single submission of all required data to reduce the burden on both industry and EPA associated with multiple submissions. Since all studies are needed for the Agency to make a WoE determination, this should not significantly delay EPA in its decision making process.

(C) Clarity of Instructions

Based on the instructions, is it clear to the respondents what they may be required to do and how to submit such data? If not, what suggestions do they have to clarify the instructions?

The test order itself is not easily digested by the receiving registration manager in one reading. If the purpose is to readily understand what procedures need to be followed to respond rather than data related details, the document would benefit from some re-ordering (e.g., options for responding would be better early in the document so the reader can view the bulk of the information from the category he believes applies to him) and making some sections information related appendices (e.g. section III.A The Tier 1 battery along with Table 1 in III C could form an appendix) .

There is considerable mention in the test order about citing OSRI but we still have little insight on how EPA has and will in future review and determine OSRI acceptability. EPA indicated to industry that the Agency used a WoE approach for OSRI; a description of the OSRI WoE process would be greatly appreciated.

The 890 guidelines as issued contained numerous errors and misinformation. Industry appreciated the efforts of EPA to address the questions (EPA response to the EPF 2-7-2011 FAQ at EPA-HQ-OPP-2009-0634-0240). However, industry believes series 890 needs to be reissued in corrected form (after the decision is made on the utility of every screen in the battery and/or possible additions).

In some cases guidance was received late in the process, and therefore was not as useful as it should have been (SEPs, study profile templates, electronic data forms). In other cases, the guidance was insufficient (OSRI, Weight of Evidence). In at least one case, guidance has yet to be received (triggers for Tier 2 testing). Moving forward on List 2 Tier 1 and List 1 Tier 2, EPA needs to release guidance earlier in the process and solicit comments prior to finalization in order to maximize the usefulness and the compliance of test order recipients.

Did you understand what was required, where applicable, to submit or maintain in your records?

There was a level of clarity due to the fact that the test orders were issued under FIFRA. However, EPA will have to take additional steps to ensure the process is equally understood for test orders issued under alternate legislative mandates.

One point that did involve significant time and communication, both verbal and written, was the issue of adverse effect reporting, where there was uncertainty brought about by the 1998 Federal Register Notice on the proposed EDSP policy which stated in vitro assays would not be subject to FIFRA 6(a)(2) or TSCA 8(e) reporting requirements. The ultimate decision issued by EPA in response to the EPF's final written communication on April 29, 2011 was not received until July 2011, well after study results had begun to become available.

There is still the issue of conflicting requirements in the test guidelines/SEP/Study profile templates/DEST; is certain information truly required or is it viewed as "nice to have" and at the discretion of the lab/registrant whether to provide it (e.g., proficiency work, saturation binding). These discrepencies should be cleared up before the next test order issues.

Is the format of any reporting forms clear, logical, and easy to complete?

Once received, the forms were clear. The major issue was that forms generally came late in the process; in future, it would be preferred if everything is made available up front.

D) Electronic Reporting and Record Keeping

Would electronic alternatives to paper-based records and data submissions be preferred?

We did make electronic submissions, although our first e-submission was rejected necessitating some back and forth with the Agency and cost to resolve the problem. Values for certain ePrism fields were added to fill in EDSP specific information (i.e. Consortia information, EDSP number); internal effort to problem solve in addition to software development costs to adapt existing tools cost approximately $20K in one off costs. Once the needed modifications were made electronic submissions went smoothly.

(E) Burden and Costs

Are the labor rates EPA used to estimate burdens and costs accurate?

Clerical help is not widely available in many companies, including BCS, so clerical tasks are generally performed by managerial and technical staff except in the case of e-submissions, which involve documentation specialists whose hourly costs are more in line with the managerial costs suggested by EPA. The managerial and technical labor rates that EPA is applying in its ICR are considerably lower than those of BCS, particularly in the case of technical staff. It's possible that

general overhead costs for office space and systems and support that are part of labor costs (and will vary by company) are not taken into account in EPA estimates. Also, time and labor rates associated with legal and consulting services, both particularly important for consortia, are not represented.

Over the past year we have often heard that EPA has found certain steps/review to be more resource intensive or more complicated than they had anticipated. BCS is interested in whether EPA estimates of Agency burden have been accurate. In the interest of transparency, will the Agency be furnishing an accounting of their burden in comparison to what was predicted for the first 3 years?

Are there other costs that should be accounted for that may have been missed, such as capital/start-up/M&O expenditures/etc.?

Start-up costs and capital expenditures are a consideration for every lab when implementing new testing designs. In addition, the costs of developing OSRI were not included in EPA's burden estimates. The Endocrine Policy Forum has developed cost-burden information for the test order to OSRI phase of the program (and are working on estmates that would encompass from OSRI to submission including testing and data interpretation) and these reflect the real burden to industry for this phase of the EDSP.

Another consideration is the accuracy of the costs that EPA put forward in 2009, which were well below the estimate EPA has in its current ICR renewal request. The estimates that EPA has recently put forward regarding the cost burden to test order recipients has come closer to the costs that industry expects to bear to comply with the EDSP than were reflected in the original ICR. If one considers the difference between the data generation activity estimates EPA put forward in 2009 (approximately $540,000) as compared to today's estimates (approximately $860,000) there was close to a 40% underestimation made in the initial ICR. It is understandable that at the beginning of a program estimates must be based on hypotheses and/or less robust information, increasing the likelihood that estimates will be significantly skewed. Looking ahead to List 2 Tier 1 and especially List 1 Tier 2, EPA should consider the difference between the 2009 and 2012 estimates as other ICRs are developed for the endocrine program and determine an uncertainty factor to apply that would better predict the actual costs when the program matures. Perhaps cooperative consultation between industry and EPA could help determine some reasonable uncertainty factors.

Appendix 2
Written Response From ACC Acetone EDSP Testing Consortium

EPA ICR Renewal Survey
Response of the ACC Acetone EDSP Testing Consortium
October 12, 2012

(A) Publicly Available Data

Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

Please see the response of the American Chemistry Council (ACC) submitted separately.

(B) Frequency of Collection

Can the Agency collect the information less frequently and still produce the same outcome?

Please see the response of the American Chemistry Council (ACC) submitted separately.

(C) Clarity of Instructions

Based on the instructions, is it clear to the respondents what they may be required to do and how to submit such data? If not, what suggestions do they have to clarify the instructions?

Please see the response of the American Chemistry Council (ACC) submitted separately.

Did you understand what was required, where applicable, to submit or maintain in your records?

Please see the response of the American Chemistry Council (ACC) submitted separately.

Is the format of any reporting forms clear, logical, and easy to complete?

Is there any information on the initial response form, the 1 year progress that we can relate from Panels?

Please see the response of the American Chemistry Council (ACC) submitted separately.

(D) Electronic Reporting and Record Keeping

Would electronic alternatives to paper-based records and data submissions be preferred?

Please see the response of the American Chemistry Council (ACC) submitted separately.

(E) Burden and Costs

Are the labor rates EPA used to estimate burdens and costs accurate?

Depending on the experience of the Consortium manger and dynamics of the particular industry Consortium, a typical trade association rate for management services of $150 to $250 per hour would apply to the EDSP. Typically, the same hourly rate ($150 to 250 per hour) also would apply to a PhD scientific consultant retained by a Consortium. The hourly rates for both management and consultant fees for the Acetone EDSP Testing Consortium fit within the ranges presented here.

Are there other costs that should be accounted for that may have been missed, such as capital/start-up/M&O expenditures/etc.? (Management and Overhead)

For the Acetone EDSP Testing Consortium:

--Laboratory Costs: The assay-by-assay break down is provided in the attachment. The EPA table that was sent as part of the survey did not allow input for analytical costs, range-finding study costs, or for GLP purity assessment costs. These are significant costs. When you take these three costs, and the total assay-by-assay costs for testing at a commercial laboratory, the total laboratory costs thus far for acetone testing are **$666,615.**

--Scientific Consulting Costs: To assist the acetone Consortium for such activities as protocol and report review, lab site visits, and communications with lab and sponsors on technical issues, the scientific consulting costs are approximately: **$85,000**

--Trade Association Management Costs (for a 2 year testing program): **$80,000**—This approximate figure covers in part such items as: the manager's direct time on the project; time of administrative assistant; and legal and accounting services.

--OSRI Costs for Acetone: $0 (no OSRI data were submitted for acetone)

--Estimated Archiving Cost of Study Materials for 15-year FIFRA Period: These are estimated costs because they have not been incurred yet: (a) $15,000 (or $1,000 per year x 15 years for the four mammalian studies = $15,000), plus (b) $800 per year for the seven non-mammalian/*in vitro* studies ($800 per year x 15 years = $12,000). Total estimated archiving cost = **$27,000** for the 15-year required FIFRA retention.

--Consortium Funding Agreement: **$10,000** must be retained by Consortium after completion of testing program in event the trade association must assist with data compensation issues.

--Quality assurance costs (budgeted): **$65,000**

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TOTAL of all of the above for the acetone EDSP costs: **$933,615.** The acetone testing is currently in progress, so there is always the chance that costs could increase.

Information provided by:

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Appendix 3
Written Response From American Chemistry Council

EPA List 1 ICR Renewal Survey
American Chemistry Council Response
October 15, 2012

(A) Publicly Available Data

Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

For a number of substances, the data from substantially similar assays to the Tier 1 screening and Tier 2 testing assays may be available in the scientific literature.

For some substances, the data from substantially similar assays to the Tier 2 test assays may be available as information EPA has already collected for pesticide registrations, for the HPV Challenge program and from TSCA test rules, TSCA enforceable consent agreements and other submissions in accordance with TSCA rules and requirements.

For the substances selected for List 1 Tier 1 screening, there was data available therefore from public sources that EPA had access to. The Agency did not perform adequate due diligence in determining what was available, before asking industry to provide it. In addition, the OSRI process was so strict that the available data was often rejected or under-utilized. EPA should have evaluated the information available before requesting all 11 screens.

If yes, where can you find the data?

- Data required for pesticide registration
- Data collected under the HPV Challenge program
- TSCA test rules, consent agreements and other TSCA submissions
- ToxCast results, if such methods can be shown to meet the requisite validation benchmarks of "relevant, reliable, sensitive and specific for the intended purpose of use." At present, we are not in support of using assays such as these until they have been shown to be valid for their intended use.
- Positive/negative controls in development and validation work for EDSP Tier 1 and Tier 2 Test guidelines.
- Scientific literature

Many 870 series test guideline studies required for pesticide registration of active ingredients include evaluations of endpoints that are sensitive to effects on E, A, T and can also be used in weight of evidence evaluations.

(B) Frequency of Collection

Can the Agency collect the information less frequently and still produce the same outcome?

EPA asked for too much "other" information that was not needed as part of the test order. This took additional time and resources, and increased the paper-work burden on industry

There were several tasks for the information collection requirements that required time and effort but added very little value e.g. the interim report which was of limited value due to the fact that most respondents simply stated that testing and responses were in progress.

The agency can collect information less frequently and still produce the same outcome by giving industry the ability to submit all studies at once. This would allow the results to be understood in the context of the full battery and any positive response in a particular assay would be potentially tempered by the overall results of the entire battery. This would also enable companies to make a WoE determination.

(C) Clarity of Instructions

Based on the instructions, is it clear to the respondents what they may be required to do and how to submit such data? If not, what suggestions do they have to clarify the instructions?

The 890 guidelines contained numerous errors and misinformation, and there is still no guidance available to industry on what will trigger Tier 2 testing.

Filling out Study templates wasn't completely clear because there are discrepancies between the test guidelines, Standard Evaluation Procedures (SEP) and Data Entry Spreadsheet Templates (DEST) and guidance was received late in the process.

It is not clear what data should be submitted for OSRI and the form such submissions should take. Despite repeated requests, EPA has still not provided guidance on development of OSRI. Experience with OSRI for EDSP List 1 substances shows that a lack of guidance leads to considerable transaction costs by test order recipients. The lack of uniformity in what is submitted and the level of documentation required causes major delays in reviews of OSRI submissions and decisions from the Agency as to whether to grant a waiver from 1 or more EDSP Tier 1 assays for a given substance. The lack of guidance and thus the lack of uniformity in what is submitted increases the burden for the Agency.

Did you understand what was required, where applicable, to submit or maintain in your records?

There was much confusion on 6(a)(2) and 8(e) adverse reporting requirements and on April 29, 2011, the Endocrine Policy Forum sent a letter to the Agency requesting clear guidance on whether the results of Tier 1 screening must be reported pursuant to TSCA § 8(e) and FIFRA § 6(a)(2). Because the EDSP Tier 1 screening battery does not determine adverse effects, the EPF believes the results of Tier 1 screening (both the *in vitro* and *in vivo* assays*)* should not be subject to TSCA § 8(e) or FIFRA § 6(a)(2) reporting obligations. EPA eventually provided some clarification in a July15, 2011 response.

Is the format of any reporting forms clear, logical, and easy to complete?

EPA did not develop and disseminate all the Standard Evaluation Procedures/Data Entry Reports (SEP/DER) and Data Entry Spreadsheet Templates on time after the test orders were released. The SEPs were critical for reviewing results generated by each of the 11 EDSP screens. It would have been helpful to have had the DESTs at the beginning of the program so that data could have been collected and then submitted electronically.

(D) Electronic Reporting and Record Keeping

Would electronic alternatives to paper-based records and data submissions be preferred?

Yes, but with some caveats as some test order recipients did encounter problems related to electronic submissions. At least one Consortium prepared several reports prior to EPA's guidance on reporting results and then had to spend resources to amend three reports.

(E) Burden and Costs

Are the labor rates EPA used to estimate burdens and costs accurate?

EPA's process in the ICR supporting document for calculating the labor rate to arrive at the hourly rate figures for managerial, technical and clerical duties is difficult to follow. There are several layers of estimations and assumptions being factored into the equation, thus the method for arriving at the estimated respondent burden and costs is not readily apparent from the document. Labor categories appear to be missing (e.g. legal, accounting). Consultants are likely included in the technical category, suggesting that what is there is a significant underestimate. It would be good to get some greater accuracy and transparency about how the labor rates are generated.

Depending on the experience of a consortium manager and the dynamics of the particular industry consortium, a typical trade association rate for management services in the range of $150 to $250 per hour would be expected for the EDSP testing consortia activities. Typically, the same hourly rate ($150 to 250 per hour) also would apply to a PhD scientific consultant retained by a consortium. The hourly rates for both management and consultant fees for the Acetone EDSP Testing Consortium fit within these ranges. (See specific survey responses of the Acetone Consortium.)

Are there other costs that should be accounted for that may have been missed, such as capital/start-up/M&O expenditures/etc.? (Management and Overhead)

The one big item that EPA does not take into account is the initial cost to the consortia of screening the companies that received test orders but who may or may not ultimately join a consortium. Numerous test orders were issued for several of the inert substances, and a significant total time burden resulted- several hundred hours were spent tracking down all the companies receiving test orders.

As the EDSP moves onto List 2 chemicals, there will likely be considerable additional costs for setting up and managing consortia for the greater number of commodity chemicals that will likely be on EPA's final List 2. For example, toluene, which was added to EPA's proposed List 2 when it was proposed as an inert utilized in pesticide formulation, had a total of 308 test orders issued. This is at least an order of magnitude larger than the maximum number of test orders issued for a pesticide active ingredient.

Acetone EDSP testing and ACC management together cost around $933,615 for the entire 11 assays. No OSRI was submitted for acetone, so there was no cost related to that. Because there are some acetone assays still in progress, the total cost of $933,615 could eventually climb higher. The Isophorone Consortium did prepare an OSRI document initially which cost about $25,000.

Overall, EPA significantly under-estimated the Tier 1 costs in the List 1 Tier 1 ICR. See comments[1] submitted to the List 1 ICR Renewal by the Endocrine Policy Forum on October 9, 2012.

[1] Comments of the Endocrine Policy Forum on List 1 ICR Renewal, October 9, 2012 http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2011-0966-0013