#### Attachment E

**Consultation Summary** 

## **Office of Pesticide Program ICR Renewal**

#### Pesticide Data Call-In (EPA ICR No. 2288.04; OMB Control No. 2070-0174)

#### **Consultation Questions**

- (1) 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? <u>RESPONSE: Yes</u> sometimes publicly available or with another agency, but often not.
  - If yes, where can you find the data? (Does your answer indicate a true duplication, or does the input indicate that certain data elements are available, but that they don't meet our data needs very well?) <u>RESPONSE: Literature searches may provide</u> <u>publicly available data as well as references to where data may be available with other agencies, including state or foreign governments. However, it is likely that this would not be easy for the Agency to conduct on all ingredients undergoing a reevaluation and necessitating new data to conduct risk assessments.
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## (2) **Frequency of Collection**

• Can the Agency collect the information less frequently and still produce the same outcome? <u>RESPONSE</u>: Possibly but unlikely. The key determinant in the DCI process is that the burden of production of new information for risk assessment is applied to all registrants of the subject ingredient(s) equally, at the same time, leveling the playing field such that one registrant is not forced to make changes or submit additional data when others who came before are not also subject to the same with the same response deadlines.

## (3) **Clarity of Instructions**

- The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.
- Based on the instructions (regulations, PR Notices, etc.), is it clear what you are required to do and how to submit such data? If not, what suggestions do you have to clarify the instructions? <u>RESPONSE: The directions are generally clear with clearly defined response due dates.</u>
- Do you understand that you are required to maintain records? <u>RESPONSE: Yes,</u> 40 CFR Parts 167, Subpart E, and 169 outline the requirements for maintenance of books and records of pesticide production and distribution under FIFRA Section 7, while 40 CFR Part 160, Subpart J, outlines the requirements for maintenance of

documentation supporting studies submitted to EPA in support of registration. Interestingly, there is no requirement in the statute or the regulations to maintain any records concerning correspondence, including approval or rejection letters, for any active or cancelled registration.

- Considering that there is no required submission format, is it difficult to submit information in ways that are clear, logical, and easy to complete? <u>RESPONSE: EPA</u> has formatting requirements for studies (currently PRN 2011-3) that are sufficient to meet this.
- Are there forms associated with this process? Do you use them? Are they clear, logical, and easy to complete? <u>RESPONSE</u>; DCI Forms 6300-3 and 6300-4 are clear and now can be filled out electronically through the CDX PSP without the need to physically print out, fill out, and sign the documents, which is most helpful. It would be useful if other forms could also be prepared and submitted electronically. As to Forms 8570-36 and 8570-37, they are in essence useless as they cannot be filled out strictly as "forms" but must then be formatted into a study per PRN 2011-3 and submitted thusly. If the Agency truly wishes for these forms to be used as forms, the requirement to then incorporate them into a "study" for submission needs to be reconsidered and eliminated.

# (4) Electronic Reporting and Record keeping

The Government Paperwork Elimination Act requires agencies make available to the public electronic reporting alternatives to paper-based submissions by 2003, unless there is a strong reason for not doing so. One such reason is that, at the present time, the Agency is unable to ensure the security of CBI that might be transmitted over the Internet.

- What do you think about electronic alternatives to paper-based records and data submissions? Current electronic reporting alternatives include the use of web forms @/XML based submissions via the Agency's Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc. Would you be interested in pursuing electronic reporting? <u>RESPONSE: Registrants submit CBI right now</u> through the CDX PSP so this is not accurate. What would be helpful is if OPP would allow electronic signatures (generated through CDX or similar) on forms other than 6300-3 and 6300-4, which are already doing that. (Section 7 reporting through CDX SSTS also generates an electronic signature upon filing through the portal.)
- Are you keeping your records electronically? If yes, in what format? <u>RESPONSE: Yes, in PDF format.</u>

## Although the Agency does not offer an electronic reporting option because of CBIrelated security concerns at this time,

- Would you be more inclined to submit CBI on diskette (CD or DVD) than on paper? <u>RESPONSE: As answered above, this is not an issue anymore as CBI can be and is being submitted electronically through the CDX PSP.</u>
- What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? <u>RESPONSE: See above.</u>

#### (5) Burden and Costs

- Are the labor rates accurate? <u>RESPONSE: I haven't had an opportunity to fully</u> vet those costs and can provide no comment on the accuracy.
- The Agency assumes there is no capital cost associated with this activity. Is that correct? <u>RESPONSE: That's most likely correct, but there is the possibility that for some "special studies," specialized equipment or other capital purchases (potentially including construction, but not generally) may be necessary to address them.</u>
- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with this ICR, e.g., the ICR does not include estimated burden hours and costs for conducting studies, are the estimated burden hours and labor rates accurate? If you provide burden and cost estimates that are substantially different from EPA's, please provide an explanation of how you arrived at your estimates. <u>RESPONSE: I think they are reasonable but have not fully vetted the time estimates</u>.
- Are there other costs that should be accounted for that may have been missed? <u>RESPONSE: I think these are likely reasonable as is.</u>