

**Attachment B**  
**Consultation Questions for Human Studies ICR Renewal**

**Stakeholders contacted:**

- Carroll-Loye Biological Research
- Mancozeb Task Force
- Antimicrobial Exposure Assessment Task Force/American Chemistry Council
- Mimikai
- Citrefine International Limited
- Arctech Innovation

Responses from Stakeholders: **None**

**(1) Publicly Available Data**

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

**(2) Frequency of Collection**

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

**(3) Clarity of Instructions**

- A. The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.
- B. 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?
- C. Do you understand that you are required to maintain records?
- D. Considering that there is no required submission format, is it difficult to submit information in ways that are clear, logical and easy to complete?
- E. Are there forms associated with this process? Do you use them? Are they clear, logical, and easy to complete?

**(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.

- A. 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?
- B. Are you keeping your records electronically? If yes, in what format?
- C. Would you be more inclined to submit CBI on diskette (CD or DVD) than on paper?
- D. What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

**(5) Burden and Costs**

- A. Are the labor rates accurate?
- B. The Agency assumes there is no capital cost associated with this activity. Is that correct?
- C. 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.
- D. Are there other costs that should be accounted for that may have been missed?