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Date: 02/09/2012 09:31 AM
Subject: RE: Consultation process for the New and Amended Registration ICR

Rob,

On behalf of the Biopesticide Industry Alliance (BPIA) - here's our response and input on the ICR Attachment G.

Please note - this response is the combined input of 3 BPIA members and the document has been shared with the BPIA Regulatory Committee (and Bill Stoneman) for their input. So, I am wondering if the more appropriate point of contact to be listed would be Bill Stoneman, BPIA Executive Director – as indicated below. **Bill are you OK with this?**

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Best Regards,
Fred

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ICR ATTACHMENT G

Consultation Questions

1. **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?

In some instances (such as commodity chemicals that are widely used for a variety of purposes), certain data may be available in the public literature. However for the most part, such information is not available publically or collected by another agency.

(2) If yes, where can you find the data?

Public literature, MSDS, chemical manufacturer of commodity chemicals, government and university databases.

2. **Frequency of Collection**

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

No. Studies and information for new and amended registrations are generally submitted once to fulfill data requirements; EPA keeps the data on file (MRIDs) and the registrant can cite the MRID in future as needed (e.g., for another new registration or amendment of the same product/active ingredient).

3. **Clarity of Instructions**

(1) The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.

(a) Based on the instructions (regulations, PR Notices, etc.), is it clear what you are required to do and how to submit the data?

Generally yes, but there is significant room for improvement and more detailed guidance.

(b) If not, what suggestions do you have to clarify the instructions?

List out and discuss status and progress to initiate / complete process improvements. Update and publish (on website) existing checklists; compile additional checklists as needed. Update and complete the DER templates; publish on EPA website. Evaluate role of Ombudsman and how the position might add further value. Update EPA website and review organization to make more user friendly.

(2) Do you understand that you are required to maintain records? YES

(3) Considering that there is no required submission format, is it difficult to submit information in ways that are clear, logical and easy to complete?

There is a required submission format – set forth in PR Notice 2011-3. There are GLP regulations that address specific formatting requirements for studies submitted to fulfill data requirements for registrations and amendments. DER and waiver templates, etc. most of which is

guidance – some required. Most requirements for formatting are published, but not all; making specific, user-friendly formatting requirements (guidance) would be very helpful.

(4) Regarding the any [specific program] forms, do you use them? YES. Are they clear, logical, and easy to complete? Can be challenging and many issues often arise. CSF for example. EPA – Industry CSF workgroup has recently updated and upgraded the documents and likely much improved. It would be great if all forms could be available in MS Word format.

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.

(1) What do you think about electronic alternatives to paper-based records and data submissions? Full electronic submissions are long overdue and much needed. 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? YES. Are you keeping your records electronically? Yes for company internal records – that we also submit in paper. If yes, in what format? Various formats – but ultimately all documents saved as PDF (searchable if possible).

(2) Although the Agency does not offer an electronic reporting option for CBI-related data at this time, would you be more inclined to submit CBI on diskette than on paper? YES if a secure option were available. And options MUST be out there – given all the secure information that flows over the internet. Not being able to transmit electronically is a significant and unnecessary burden on information collection. The Canadian PMRA has successfully used electronic submissions for years. It would be useful to learn what is liked and not liked with the PMRA system.

(3) What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? Ease and speed of initial submission. Durable and easily transmitted record. Ease and speed to discuss, update, revise and resend to Agency. Saves significant time and money for both sides.

5. **Burden and Costs**

(1) Are the labor rates accurate? NO. The rates are too low – total costs about half of typical. Current regulatory consultants charge at least $150 - $250/hr that would cover both the Management and Technical (Table 1-B). Clerical may be fine. The number of hours are also close to what is required at 194.Consultant experience indicates a minimum of 160 hrs is required for an entire package, including oversight of all regulatory studies. 160 hours is a reasonable estimate for a microbial because there are likely to be many requirements that warrant "waiver requests" (satisfaction of data requirement by rationale/literature). but at least 50% more time (240 hours) should be

the time estimate for a biochemical product (Type A). Also, 4 hours management time to compile a label (de novo) is substantially underestimated. The time required is typically closer to 30 to 40 hours.

(2) The Agency assumes there is no capital cost associated with this activity. Is that correct? NO. At a minimum, there must be office space, regardless if it is a company or a regulatory consultant working from home, an office is required. If a company generates its own product chemistry data – that requires a laboratory; equipped to do work in accordance with GLP – which is a significant additional investment beyond normal lab operations. That said it's understood that the latter capital cost (laboratory) is out of the scope considered in this question.

(3) 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. From above, item (5.1), the 160 to 240 hrs is not CONDUCTING a study, but all the paperwork and oversight required to conduct a study. The 160 to 240 hrs is for a company where all the studies were done at external labs.

(4) Are there other costs that should be accounted for that may have been missed? The only extra is material costs – paper, binders, printing costs (ink, etc.), but that is pretty minimal.