OMB Control Number 2070-0142; EPA ICR Number 1693.05

ICR ATTACHMENT D

Record of Consultations Between the U.S. Environmental Protection Agency and Respondents to the Information Collection Request: "Plant-Incorporated Protectants; CBI Substantiation and Adverse Effects Reporting" (Consultations conducted September, 2006)

1. Myrna Q. Sevilla, Ph. D.; BHN Research
2. Penny Hunst; Dow Agrosciences
3. Russell Schneider; Monsanto Co.

15 September 2006

Dear Mr. Torla:
Here are my answers to the questions

1. Are the data EPA asks for available from another source?

No, I do not think that EPA is asking for data that is available from another source. In the case of adverse effects, I believe that each experience is unique for each submitter and that although there may be similar studies published in scientific journals, the conditions and parameters at which such are conducted will still be different from that ofany submitter's.

2. Are the instructions for submission clear?-Please include any comments on frequency of information collection here.

The instructions are clear for the reporting of the adverse effects. I would suggest a similar format for CBI, i.e. there should be a standard form as to what information should be included in the claim.
Frequency - At the time of submission and any time the CBI status changes from CBI to non-CBI; Adverse effects - within 30 days and status report every month until all PIPS sold/distributed are accounted for.

3. Would you be interested in electronic reporting of data?

Yes, this will make the process faster but only if EPA can guarantee absolute secure transmission and data storage.

4. Do you find the burden and costs estimates in the ICR realistic? See the attached tables.

I think the estimates are realistic.

Hope this helps. Let me know if you have any other questions.

Sincerely,

Myrna Sevilla

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18 September 2006
Penny Hunst
Dow Agrosciences

We are renewing the ICR (information collection request) for the PIP; CBI Substantiation and Adverse Effects Reporting rule OMB No.:2070-0142 EPA ICR No.: 1693.03). ICR's are required to be renewed every three years and we re-estimate burden based on any new information available to the Agency. Note that the burden/cost tables are labeled draft and if we change the estimates prior to submission to the Office of Management and Budget, we will provide you copies of the new estimates and an opportunity to comment again.

Part of this renewal requires EPA to contact at least three persons whose names and contact numbers will be listed in the ICR document. I propose to list email addresses rather than phone numbers. Please let me know which you prefer. You may have access to another phone number or email address to which such responses would be routed to. Please do not list my e-mail or phone. Instead, use the following e-mail address:
felusrg@dow.com

Summarized comments will also be included in the ICR document without identification of the specific source. Registrants and the Agency now have had several years of CBI substantiation and several years of no adverse effects reports. The lack of adverse effects reports implies we have no information to better estimate the burden of adverse effects reporting on industry or the Agency.

We are repeating the original questions with the aim of seeing if the data required are available from another public source, how often the information should be collected, are the instructions for data collection sufficiently clear, thoughts on electronic reporting of data and the burden and costs of the information.

EPA has changed its method of estimating labor costs for both industry and EPA. The effect of this method change has been to lower the dollar burden estimates.

The CBI Substantiation requires registrants to substantiate and claims of CBI for PIP registration related submissions. The Adverse Effects Reporting requirement requires registrants to submit claims of adverse effects for exempted PIPs'. We have yet to receive an adverse effects report for an exempted PIP.

The questions follow:

1. Are the data EPA asks for available from another source? Not that I am aware of.

2. Are the instructions for submission clear?—Please include any comments on frequency of information collection here. Yes, the instructions are clear.

3. Would you be interested in electronic reporting of data? Yes, it would be of interest.

4. Do you find the burden and costs estimates in the ICR realistic? Yes, however, hourly rates may be a little “light”. See the attached tables.

Please let me thank you in advance for your review of this information.

Robert F. Torla,
Economist

20 September 2006
Russell Schneider
Monsanto Co.

We are renewing the ICR (information collection request) for the PIP; CBI Substantiation and Adverse Effects Reporting rule OMB No.:2070-0142 EPA ICR No.: 1693.03). ICR's are required to be renewed every three years and we re-estimate burden based on any new information available to the Agency. Note that the burden/cost tables are labeled draft and if we change the estimates prior to submission to the Office of Management and Budget, we will provide you copies of the new estimates and an opportunity to comment again.

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The questions follow:

1. Are the data EPA asks for available from another source? **NO**

5. Are the instructions for submission clear?—Please include any comments on frequency of information collection here. **YES**

6. Would you be interested in electronic reporting of data? **YES, IF CONFIDENTIAL INFORMATION COULD BE PROTECTED.**

7. Do you find the burden and costs estimates in the ICR realistic? See the attached tables. **THEY LOOK ACCEPTABLE. HOWEVER, IN THE ADVERSE REPORTING SECTION I THINK YOU NEED TO ADD THE COST OF DATA COLLECTION FOR POISON CONTROL CENTERS AND ANIMAL POISON CONTROL CENTER. OFTEN THESE SERVICES REQUIRE CONTRACTS AND COSTS CAN BE QUITE HIGH. IN OUR CASE WE SPEND ABOUT $150,000 PER YEAR TO HELP US WITH THIS EFFORT.**

Please let me thank you in advance for your review of this information.

Robert F. Torla,
Economist