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.) Dr. Russell P. Schneider, Senior Director, Regulatory Affair and Policy, Monsanto Company, russell.p.schneider@monsanto.com
2.) Mr. Nick Storer, Dow AgroSciences, nstorer@dow.com
3.) Tracy Rood, Senior Regulatory Manager, Pioneer Hi Bred, INC., A Dupont Company, tracy.rood@pioneer.com

Fw: Plant Incorporated Protectant ICR Reveiw and consultation

Robert Forrest to: Scott Drewes 06/15/2010 08:17 AM
Cc: Mike Mendelsohn, Alan Reynolds

Scott, this is Dow's response.
----- Forwarded by Robert Forrest/DC/USEPA/US on 06/15/2010 08:15 AM -----

From:	"Storer, Nicholas (N)" <nstorer@dow.com>
To:	Robert Forrest/DC/USEPA/US@EPA
Date:	06/14/2010 01:53 PM
Subject:	RE: Plant Incorporated Protectant ICR Reveiw and consultation

Mr. Forrest

I have sent these documents around our biotech regulatory leaders. Unfortunately, we do not feel able to provide meaningful input. We feel that the CBI time estimates appear to be about right, though we do not have good estimates ourselves. For the adverse effects reporting, we have not had experience with this in relation to the types of products covered; however, based on experience with other adverse effects reporting, we feel the time estimates are likely to be low.

I am sorry that we are not able to provide anything more informative on these. Please feel free to get in touch again if you have additional questions.

Best regards

Nick Storer
Dow AgroSciences LLC

-----Original Message-----
From: Forrest.Robert@epamail.epa.gov
[mailto:Forrest.Robert@epamail.epa.gov]
Sent: Monday, 07 June, 2010 12:41 PM
To: Storer, Nicholas (N)
Subject: Plant Incorporated Protectant ICR Reveiw and consultation

Mr. Nick Storer
Dow AgroSciences

Mr. Storer

It was good to talk to you today and we very much appreciate your participation in consultation for the Information Collection Request (ICR) for Plant Incorporated Protectant (PIP), Confidential Business Information (CBI) Substantiation and Adverse Effects Reporting. Below you will find additional information regarding background, action outline, relevant attachments, link to the docket, and a contact name and number.

Background

The Environmental Protection Agency's (EPA), Office of Pesticide Program (OPP) is proposing to renew for another three years the ICR for PIPs CBI Substantiation and Adverse Effects Reporting (OMB No. 2070-0142, EPA

No.1693.06). ICR's are required to be renewed every three years and we re-estimate burden based on any new information available to the Agency.

Action

In an effort to actively seek input from respondents to this ICR, EPA is contacting you to ask for your feedback regarding this Information Collection Request (ICR). Please use the " Consultation Questions" form attached when crafting your response. Also, please note that your comments/feedback along with your name and e-mail address, will appear in a publicly available document along with your name and e-mail address (the Docket for this ICR action). Your response to this request would be most appreciated within the next week or two (by June 24, if possible), however, if your response comes in after that time frame, the Agency will enter your response directly into the Docket.

Attachments

I am attaching the following documents:

1. the list of consultation questions
(See attached file: Consultation Questions.doc

(See attached file: consultation questions.doc)

2. an excerpt of the proposed burden section 6 of the ICR renewal
(See attached file: Section 6 Excerpt-Consultations-doc

(See attached file: ICR_Section 6.doc)

3. and a copy of the proposed ICR (the same copy that is in the docket)

(See attached file: DRAFT_PIP_ICR_Supporting Statement_2010 03 30.doc)

"The Agency has established a public docket for this ICR under Docket NO. EPA-HQ-OPP-2010-0281, which is available for on line viewing at www.regulations.gov. The docket contains links to the attachments cited in the ICR proposal."

Direct link to the Federal Register Notice: http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480ab35fe

If you have any additional questions, you may contact me via e-mail Forrest.Robert@EPA.gov or by phone at (703) 308-9376

Sample Consultation Questions OPP ICR Renewals

EPA Questions asked in Consultation

(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?

- $ 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

- $ Is the submission of CBI Substantiation Claims or Adverse Effects Reports too frequent?

(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?

- $ Do you understand that you are required to maintain records?

- $ 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.

- $ 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?
- $ Are you keeping your records electronically? If yes, in what format?

Although the Agency does not offer an electronic reporting option because of CBI-related security concerns at this time,

- $ Would you be more inclined to submit CBI on diskette (CD or DVD) than on paper?
- $ What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

(5) Burden and Costs

The following questions refer to Tables 1 and 2 in Section 6 of the ICR (see the Section 6 excerpt that is attached). Tables 1 and 2 provide EPA's estimate of the average respondent burden and cost estimates for Substantiation of CBI Claims and Adverse Effects Reporting, respectively

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- $ The Agency assumes there is no capital cost associated with this activity. Is that correct?
- $ 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.
- $ Are there other costs that should be accounted for that may have been missed?