EPA Questions Asked in Consultation for the 6(a)(2) ICR:

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(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?

Incident and internally conducted study data is available only through Bayer CropScience. Some data, such as those conducted by universities, is publically available to the EPA upon request.

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?)

Some data is available publically. University data is located at the researching university. Other data is available through state poison control centers, or state administrative departments (*e.g.* Department of Agriculture). Also, information collected as part of litigation (both civil and criminal) can sometimes be located *via* court filings in the respective jurisdiction(s).

(2) Frequency of Collection

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

It is unusual to receive comments back from the agency on any incident (less than 20 requests for additional information since October 2007 usually to clear up administrative details.) Should this response rate be normal, all incidents can be reported on a quarterly basis with nearly the same results.

(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?

Instructions are usually clear as represented in 40 CFR 159, 40 CFR 152.50(f)(3) and guidance documents. However, some circumstances result in interpretations which need resolution. Examples are:

1. **Review of publically available information and requirement to submit to the EPA. The regulations currently read that information indexed in a database available to EPA is not reportable….however, these regulations have not been updated to account for the advent of the internet, search engines, or other information can be located now by EPA or any member of the public if desired.**
2. **The extent to which EPA consults or relies upon data from "Sister" agencies such as USDA, CDC, etc. and what information EPA is "assumed" to have (such as FDA detects of residues during routine inspections of food in the commercial channels) and the registrant's responsibilities as a result.**
3. **Clarification on H-C class incidents – which are generally intended to communicate to the agency more serious non-permanent incident symptoms or allergenic potential….however, should someone go to the hospital (an indication of the perceived seriousness of the symptoms) but have only a symptom which is minor in nature should the coding of the incident be on the perceived symptom or on the reported symptom?**

c) Do you understand that you are required to maintain records?

Yes. Bayer CropScience maintains 6(a)(2) records for the life of the registration, and beyond as specified in 40 CFR 169.

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?

Not usually. Incidents are placed in the standard reporting format, and studies are outlined in accordance with 40 CFR 159. The format of the report is only difficult when certain information is not available.

e) Regarding the Voluntary Incident Reporting Forms, do you use them? Are they clear, logical, and easy to complete?

Yes, voluntary incident reporting forms are the standard format which Bayer CropScience uses.

(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. The U.S. E.P.A. Office of Pesticide Programs has a program for electronic study submissions, and is currently developing plans for systems to support electronic incident reporting. The Agency is also concerned to protect FIFRA CBI as well as personal information.

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

1) Would you be more inclined to submit CBI on diskette, CD, or DVD, or via web rather than on paper?

Bayer supports the use of electronic submission. As an economically viable means of communicating CBI, submission of studies on a CD or portable electronic storage device (preferably with an encryption key) would be good. The current ePRISM system is also highly utilized and is good as metadata can automatically be assigned to study reports and other data to help the agency efficiently go through reports, CBI, and other materials to execute its duty.

Since the last ICR, Bayer has participated in ePRISM submissions for 6(a)(2) studies which continue to make both Bayer and the EPA more efficient through higher utilization of tools and processes.

Aside from studies, the provision of incident reports in electronic format (*e.g.* PDF files) would save considerable time, and allow for electronic archiving of data rather than both electronic and hardcopy archiving. The EPA would also not have to invest in scanning and electronically converting such information reducing costs and time to the US Government. Finally, should a system be generated where processes such as XML transfer or other means of communicating metadata be developed, Bayer could establish direct links to the EPA system to upload this information in its most current form with no respect to timeline making such information more current to the agency. It would also eliminate duplicative typing and potential typographical errors of data captured, and would allow for a broader number of data fields to be available to the agency. Such data could be converted into any number of useful products for registration activities, pre-screened CBI FOIA request, or other labor saving products.

2) What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

Benefits include but are not limited to:

i. **Reduction of formatting errors**
ii. **Reduction of paper / hardcopy form**
iii. **More timely compilation of data (no need to put data into standardized forms)**
iv. **More accurate data (reduction of copy/paste errors, typographical errors, or transcription errors)**
v. **Better archiving (electronic records vs. hardcopy logs)**

(5) Burden and Costs

a) Are the labor rates accurate?

Based upon EPA's estimate of 264,957 hours worked, and annual cost burden of $15,940,734, an hourly estimate of $60.16 / hour is calculated[1]. Bayer CropScience

[1] Excludes capital investment or maintenance and operational costs, as per 79 FR 6898

has calculated this same rate to be as low as $133.09 / hour and as high as $192.02 / hour depending on the function utilized to conduct 6(a)(2) screening. This labor rate is inclusive of overhead which includes capital expenditures, and other investments that EPA does not consider.

b) The Agency assumes there is no capital cost associated with this activity. Is that correct?

No. Bayer has significant investments in capital in the form of electronic reporting requirements, data servers, and dedicated trending / analysis programs which add significantly to the hourly rate and therefore the total cost. Additionally there is the cost of transportation (vehicles) and other expenses with having personnel in the field to investigate incidents, and coordinate responses to these incidents. For its comments here, Bayer takes the average hourly rate amongst all divisions involved in 6(a)(2) screening to calculate its costs at 70% of the capital inclusive labor rate at the low end to be $93.16 / hour.

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.

No. Bayer's estimate only bears the cost of electronic infrastructure capital (not counting vehicles and other capital investments) and time for incident input and investigation, as well as adverse effects screening of studies. Bayer calculated the cost of compliance using the data below. Data was collected through survey of the responsible individuals, as well as reporting from electronic archiving systems, which capture and control information to ensure compliance with 6(a)(2) requirements. Bayer has made improvements to its infrastructure which has cut down on the manual labor required to process 6(a)(2) incidents versus comments made during the last ICR.

Hours per year for study review[2]:	**556**
Hours per year for Incidents[3]:	**262**
Capital costs of data systems:	**$617,500**
Labor Costs:	**$76,204**
Total Costs:	**$693,704**
Total Hours:	**818**
Cost per Hour:	**$693,704 / 818 = $93.16**

[2] Average of number of internal studies reviewed from 1/1/2009 to 12/31/2013 (2,241 studies) multiplied by the average time provided by R&D functions to review such studies (43 minutes / study). This cost excludes publication reviews and other non-BCS "study" information.

[3] Average of number of incidents reviewed and investigated from 1/1/2009 to 12/31/2013 multiplied by an average review time of 7 minutes + all outside vendor and other associated costs with collection of such data, but excluding capital investments which are accounted for in Bayer's labor rate.

d) Are there other costs that should be accounted for that may have been missed?

Working Cost of Capital[4]:	**7.8%**
Annual Costs:	**$693,704**
Opportunity Costs:	**$693,704 x 7.8% = $54,108**

This is a conservative estimate, as it only calculates the cost of the funding dedicated to compliance activities, if it were invested in a vehicle returning an expected rate of return for the marketplace.

[4] BCS expected rate of return based on 2009 Bayer AG annual report