Attachment G

List of Consultation Questions and Responses

6(a)(2) INFORMATION COLLECTION REQUEST
REGISTRANT RESPONSES
12/22/2006

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Respondent: Elizabeth Tannehill
Mason Chemical Company
800-362-1855
liz@maquat.com

Date: November 6, 2006

(A) 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? *No*

(2) 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?)

(B) Frequency of Collection

Can the Agency collect the information less frequently and still produce the same outcome? *I don't know.*

(C) 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 such data? *Yes*

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

(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? *No*

(4) Regarding the Voluntary Incident Reporting Forms, do you use them? Are they clear, logical, and easy to complete? *Yes. Yes*

(D) Electronic Reporting and Recordkeeping

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 we have no OMB-approved standard form for reporting incidents. There may also be concerns about protecting FIFRA CBI as well as personal information.

(1) 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? *I am always interested in electronic format. Unfortunately, there doesn't seem to be acceptance of electronic signatures at the Agency (meaning no "real" signature - instead a date/time stamp that can only be added to document with a password).*

(a) would you be more inclined to submit CBI on diskette than on paper? *Yes, as long as electronic signatures are acceptable on all levels at the Agency.*

(b) what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? *Paperless submission - also time saving measure.*

(E) Burden and Costs

(1) Are the labor rates accurate? *Yes*

(2) The Agency assumes there are no capital costs associated with this activity. Is that correct? *Yes*

(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. *Yes*

(4) Are there other costs that should be accounted for that may have been missed? *No*

Respondent: Teri Muchow
Osmose, Inc.
716-319-3255
tmuchow@osmose.com

Date: November 9, 2006

(A) 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? *No, it is not available from another source.*

(2) 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?) *N/A*

(B) Frequency of Collection

Can the Agency collect the information less frequently and still produce the same outcome? *Unsure as to what "outcome" the question is referring to.*

(C) 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 such data? *Using a combination of the regulations, PR Notices and industry documents (Voluntary Industry reporting forms), it is clear to me what I am required to do and how to submit the information.*

(b) If not, what suggestions do you have to clarify the instructions? *Areas that could use further clarification are how to determine the hazard classification in terms of human health hazard and what needs to be reported under the "catch all" provision of 40CFR 159.195.*

(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? *No, I utilize the industry developed Voluntary Incident Reporting Forms.*

(4) Regarding the Voluntary Incident Reporting Forms, do you use them? Are they clear, logical, and easy to complete? *Yes, I use the forms. I have found them to be very helpful, easy to understand and complete.*

(D) Electronic Reporting and Recordkeeping

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 we have no OMB-approved standard form for reporting incidents. There may also be concerns about protecting FIFRA CBI as well as personal information.

(2) 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? *Electronic reporting would only be a benefit to me if it were to save time. If the reporting could be made over the internet, it would be preferable. If the submission were to be made on a diskette or CD-ROM, there would be no time savings.*

I currently forward California and New York copies of all the reports submitted to EPA. If EPA were to use electronic reporting, it would be necessary for hard copies to still be generated.

(a) would you be more inclined to submit CBI on diskette than on paper? *No. There would be no time savings.*

(b) what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? *Benefits would include a time savings and a cost savings. I currently submit all reports via Federal Express Delivery to have a record of delivery. Electronic reporting would eliminate the mailing costs.*

(E) Burden and Costs

(1) Are the labor rates accurate? *The labor rates in the ICR appear to be accurate.*

(2) The Agency assumes there are no capital costs associated with this activity. Is that correct? *I agree.*

(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. *The*

estimated burden hours and labor rates appear to be accurate.

(4) Are there other costs that should be accounted for that may have been missed? *Not that I am aware of.*

Respondent: Dana Clark
Clorox Company
925-425-6629
dana.d.clark@clorox.com

Date: November 28, 2006

(A) 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? *No, although we copy this data and pass it on to different state government agencies.*

(2) 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?) *N/A*

(B) Frequency of Collection

Can the Agency collect the information less frequently and still produce the same outcome? *The reports that are now generated monthly could be submitted quarterly, although the human death reports could still be reported on the 15 day basis.*

(C) 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 such data? *Yes, in general it is clear where to submit data and who must submit data. We do struggle at categorizing between major and moderate incidents for humans. We tend to be conservative and choose the higher classification where there is question.*

(b) If not, what suggestions do you have to clarify the instructions? *Clorox would like to have more clarification for deciding which symptoms fall into which levels of incident severity.*

(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? *No because we use the Voluntary Incident Reporting Forms. They are sufficient and cover the necessary reporting fields adequately. There is no limit to available space for text if one wants to add more information on the second page for an individual incident.*

(4) Regarding the Voluntary Incident Reporting Forms, do you use them? Are they clear, logical, and easy to complete? *Yes.*

(D) Electronic Reporting and Recordkeeping

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 we have no OMB-approved standard form for reporting incidents. There may also be concerns about protecting FIFRA CBI as well as personal information.

(1) 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? *Electronic reporting would be feasible. We receive incident reports as email from our poison control center. We print them out and submit them to EPA in paper format. It could be helpful to submit image files as email to the EPA. It would be more time consuming if we were going to have to fill in web based forms or databases to do reporting.*

(a) would you be more inclined to submit CBI on diskette than on paper? *It would not be a significant burden or advantage to submit CBI on diskette rather than on paper.*

(b) what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? *In the long run it could save us a step if we could QC an image sent to us from the poison control center and then submit it to EPA with a separate image providing any extra changes Clorox would like to make. These would be mainly housekeeping changes, and they usually would not need to go back to the Poison Control Center for revision.*

(E) Burden and Costs

(1) Are the labor rates accurate? *Yes.*

(2) The Agency assumes there are no capital costs associated with this activity. Is that correct? *Yes.*

(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? *Yes*

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. *N/A*

(4) Are there other costs that should be accounted for that may have been missed? *Internally, often our company uses the legal department to concur. Clorox uses a multidisciplinary team to decide whether studies and incidents are reportable or not.*

Respondent: Ms. Aludia B. Hernandez
Chase Products Company
708-865-1000
Ludi.Hernandez@chaseproducts.com

Date: December 6, 2006

(A) 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?

Poisindex (or National Poison Control Center) and other state/local Poison Control Centers in the country may have unreasonable adverse Health effects reports received directly from consumers. These are the agencies, other than those medical emergency contact toll free phone numbers listed on product labeling, that consumers are most familiar with to call, in case of medical emergency situations arising from the use of consumer products like, pesticides, household cleaners, automotive maintenance products, etc.

(2) 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?)

Above offices may have incident reports in their files but may not necessarily in the same format that EPA has. May or may not meet EPA's data needs. I am not sure about this.

(B) Frequency of Collection

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

I believe so, most especially for those who have very few incidents to report on a quarterly basis

(C) 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 such data?

Instructions on PR Notice 98-3 are clear.

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

(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?

Without standard format to use, I think each registrant will have its own format and this will be more difficult for EPA to evaluate and put together in order to draw conclusions from the data submitted by registrants.

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

Yes.

(D) Electronic Reporting and Recordkeeping

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 we have no OMB-approved standard form for reporting incidents. There may also be concerns about protecting FIFRA CBI as well as personal information.

(1) 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? *NO.*

Are you keeping your records electronically? *NO.*
If yes, in what format?

(a) would you be more inclined to submit CBI on diskette than on paper? *NO.*

(b) what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? *I do not see any benefit from electronic submission in compiling the information.*

(E) Burden and Costs

(1) Are the labor rates accurate?

(2) The Agency assumes there are no capital costs associated with this activity. Is that correct?

(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.

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

I am not in a position to give my comments on this as I am not familiar with other registrants' number & type of pesticide adverse effects incidences. As I verbally discussed with you over the phone, Chase's pesticides adverse effects incidences are very few. We do aggregate reporting on a quarterly basis. On the average we have 1 - 2 incident reports which all fall under H-D and H-E categories.

Respondent Gene Sturner
PBI Gordon Corp.
816-460-6289
gsturner@PBIGordon.com

Date: Dec. 7, 2006

(A) 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?

With very few exceptions, the data provided by the individual or cumulative reports would not be available from any public source, nor would it be collected from any other section of the EPA or other agency.*

(2) 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?)

**Toxicity studies are routinely submitted as a part of initial product registrations and the reregistration process, but any change from an earlier study (specifically anything suggesting a more restrictive Signal Word or PPE recommendation…) would be construed as being applicable to the individual product, but would give no indication of a larger trend.*

(B) Frequency of Collection:
Can the Agency collect the information less frequently and still product the same outcome?

(1) *The quarterly cumulative period seems to be satisfactory. Internally, it provides an overview of areas of concern on a more or less seasonal basis. Any trends are readily captured, and any possible mitigating actions can be implemented more rapidly. A longer collection period would make the process considerably more cumbersome. I would assume that the Agency could glean the same information from reporting on a semi-annual or annual basis, but trends would take a commensurate longer time to discern.*

(2) *The acute nature of incidents that require more frequent (monthly or immediate) reporting justify that briefer reporting interval.*

(C) 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 Notice, etc.) is it clear what you are required to do and how to submit such data?

As with any Regulation, there is a learning curve, and a level of interpretation. There are straightforward, quantifiable definitions, and there are other more subjective areas that take a higher level of evaluation to determine whether an incident is reportable or not. The latter needs to be examined in light of the intent of the Adverse Incident reporting process, and that is to discern patterns or trends in types of incidents, and if indicated, determine ways to mitigate similar incidents (exposures) in the future.

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

Developing a Frequently Asked Question (FAQ) site may aid in determining the reportability of an incident. A list of examples (Reportable, or Not Reportable?) with the appropriate response may be helpful as well.

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

Internal protocol dictates maintaining a record of all reported incidents. As incidents are received, they are logged in sequential order (the number at 001 at the beginning of each calendar year, e.g., 6a-06-025 would be the 25th entry for the year 2006). Details of these individual incidents are maintained (either hard-copy, or digitally). This logging process is accomplished in a database, which can further be used to generate reports with any number of focal points [specific product, date range…]. At this point, all reports from initiation of the reporting process remain on file--storage space may dictate elimination of actual hard-copy reports older than three years however.

(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?

The final step of compiling the quarterly report in a format acceptable to the office remains a manual process, albeit a relatively straightforward one.

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

Reports that we utilize closely follow the Voluntary Incident Reporting Forms. Much of our information is gathered by contractors (ASPCA and Rocky Mountain Poison and Drug Center [RMPDC]). The format of the information they provide is specifically based on the Voluntary

Incident Reporting Forms. Our internal collection forms are patterned very similarly, to assure gathering the appropriate information from complainants/customers. The actual reporting process however (specifically the cumulative quarterly report), glosses over much of this information. In reporting only the raw numbers of incidents, review of the specifics ends with the respondent. As stated above, this does provide a process of internal detection of trends, and the opportunity to develop means of mitigation, but only on a very narrow basis. I presume the Agency can use just the raw number of incidents in determining patterns on a more global basis.

(D) Electronic Reporting and Recordkeeping

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 we have no OMB-approved standard form for reporting incidents. There may also be concerns about protecting FIFRA CBI as well as personal information.

(1) 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?

Our current method of recordkeeping includes primarily hard copy of the original allegation of an incident. These are gathered from a number of sources, including internally, from subregistrants, ASPCA and RMPDC (actually the latter are received in either HTML or PDF format, but usually printed out to hard copy-alternative methods of processing are under consideration). These are reviewed, and if determined to be reportable, entered into the database as described above.

a) would you be more inclined to submit CBI on diskette than on paper?

Depending on the process, electronic reporting may provide an advantage over the current paper-based process. Certainly, to accommodate a (nearly) direct entry into the Agency database would streamline the process from the Agency's standpoint, without any additional burden on the part of the respondent. I would only see this as being effective if the respondent filled out an online form (similar to shopping online, or online surveys) and that data passed directly into the appropriate data fields in the master database.

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

Any indirect method (diskette/CD/DVD) would seem more trouble than it is worth. The respondent would still need to compile the data, write/burn it to the media and send it off to the Agency. The Agency, in turn would need to a) process the incoming mail/courier package, b) open the package, c) process the information from (hundreds? thousands?) of pieces of media. Then there is the question of storage/disposal of these items of media. Any time saved on physical data entry would seemingly only be transferred to the physical processing of this data in a different form. Should formatting not be precisely correct, that of course results in a timely determination and rectification of error, yet another very time-consuming process. **Direct entry into a self-correcting online form would seem to me to be the only practical consideration for data gathering.** *As stated above, with the options being a) fill in an online form with the final data, or b) compile a hard copy or electronic version of the data and mailing it off, a) would seem to be the most straightforward for the respondent, and most certainly to the advantage of the Agency.*

(E) Burden and Costs

(1) Are the labor rates accurate?

The 3.2 hours per Study is probably right on target. The estimate of 2.1 hours average per Incident probably works– some are very straightforward and require little more than a cursory glance, while others entail significant investigation.

(2) The Agency assumes there are no capital costs associated with this activity. Is that correct?

There is the cost of contractors such as ASPCA and Rocky Mountain Poison and Drug Center, but these provide a valuable service to consumers, particularly in a time of need, and would probably be engaged regardless of Adverse Reporting requirements.

(3) Bearing in mind that the burden and cost estimates include only burden hours and costs associate with the paperwork involved with this CIR, 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.

Not really applicable-many of the Customer Service calls/contacts processed do not involve adverse reports, but consume a considerable amount of time regardless.

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

There is also the significant time (as well as the expense) spent by contractors such as ASPCA and Rocky Mountain Poison and Drug Center in gathering information and compiling reports, but their involvement is justified in (3) above.

Respondent Dennis Hackett
Syngenta Crop Protection, Inc.
336-632-2535
Dennis.Hackett@syngenta.com

Date: 12/8/2006

(A) 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?

Syngenta uses established internal processes to collect potentially adverse effects information concerning its products. We also employ contract firms to collect adverse effects information resulting from incidents involving Syngenta products. None of this information is publicly available.

(2) 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?)

(Not applicable)

(B) Frequency of Collection

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

In Syngenta's opinion, the EPA could collect adverse effects information less frequently and still have an effective process. This would be especially true in cases involving less critical information that would not be of immediate concern for health or welfare.

(C) 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 such data?

Syngenta has a clear view of process and requirements for submission of new adverse effects information. On occasion, guidance is needed to clarify reporting requirements for unique circumstances. Access to an EPA expert or web site with detailed background is often helpful. Syngenta also utilizes internal or external legal counsel to ensure compliance with FIFRA 6a2 legal requirements.

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

Improved content on the EPA FIFRA 6(a)(2) web page would be very helpful, including recent FIFRA 6(a)(2) submissions and a Frequently Asked Questions section. The TSCA 8e website is a good example.

(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?

Syngenta has adopted a style of submitting adverse effects information utilizing standard letter correspondence and on occasion using a formal regulatory submission for study reports. We have sought guidance from the FIFRA 6a2 Office when we have had questions. To our knowledge these practices have met with EPA's approval.

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

Syngenta and its agents use the Voluntary Incident Reporting Forms without any significant problem.

(D) Electronic Reporting and Recordkeeping

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 we have no OMB-approved standard form for reporting incidents. There may also be concerns about protecting FIFRA CBI as well as personal information.

(1) 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?

Syngenta is interested in using an electronic submission process for adverse effects reports. We are currently using an electronic submission process for major active ingredient registration submissions. We have the capability to use many industry-standard technologies and we would be willing to work with the EPA to implement such a process for future reports. Currently Syngenta maintains its official adverse effects information files in a paper format. Correspondence related to new adverse effects

reports is generally communicated within the company in electronic format, mostly via email. We are initiating the use of a Documentum-based document management system to store regulatory correspondence to supplement our paper records storage system.

(a) would you be more inclined to submit CBI on diskette than on paper? *No*

(b) what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?

An electronic submission process would be more efficient and ease submission of information to EPA and aid distribution of information within Syngenta. At this time we do not have plans to eliminate our paper archive, which contains the official copies of adverse effects reports required by FIFRA 6(a)(2).

(E) Burden and Costs

(1) Are the labor rates accurate?

The labor rates look reasonable, but no attempt was made to verify accuracy.

(2) The Agency assumes there are no capital costs associated with this activity. Is that correct? *Yes*

(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.

1. *Syngenta's costs for administering its adverse effects reporting process are generally higher than EPA's estimates, especially for studies. Syngenta conducts studies at several of its global R&D facilities around the world. Results from these studies are reviewed by a committee of approximately 6 to 8 scientific and technical experts familiar with adverse effects reporting obligations from around the world. This committee typically meets twice per month to discuss pending issues. Scientific and regulatory staff are involved in answering questions and preparing the notification letter to EPA. We estimate that this process takes approximately 6 to 10 hours per study to complete.*
2. *EPA's estimate of the amount of time needed to report incidents (2.1 hours) is in alignment with our experience.*

3. *Syngenta spends significant time training its staff in adverse effects reporting requirements. A typical training session takes up to 4 hours for a new employee and approximately 1 hour for bi-annual refresher training. Syngenta has conducted adverse effects reporting training at 4 of its major global R&D sites. These training sessions have involved over 100 people. We expect to maintain an ongoing refresher training program in the future.*

(4) Are there other costs that should be accounted for that may have been missed? *No*

Respondent: Janet A. Dykes
Bayer CropScience LP
919-549-2000
Janet.Dykes@bayercropscience.com

Date: Dec. 18, 2006

(A) 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? *Rarely.*

(2) 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?)

(B) Frequency of Collection

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

(C) 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 such data? *I think that the reg and PR notices are vague. We often have to ask clarifying questions to agency representatives, research our history or consult with internal experts to find answers.*

(b) If not, what suggestions do you have to clarify the instructions? *It is difficult, I'm sure, to clarify instructions when there are so many types of incidents as well as timelines for incidents. It would be nice to have one comprehensive source for this information.*

(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? *Yes, particularly in the case of the aggregate reports.*

(4) Regarding the Voluntary Incident Reporting Forms, do you use them? Are they clear, logical, and easy to complete? *Yes we use them. For the most part they are easy to complete.*

Along these lines, I would very much like to see regular training sessions and dialog with the agency regarding 6(a)(2) regulations and instructions. I can only speak for my company but with frequent turnover the way it is here, there are fewer and fewer experts available as sources and

there are new people coming in that could use regular reviews.

(D) Electronic Reporting and Recordkeeping

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 we have no OMB-approved standard form for reporting incidents. There may also be concerns about protecting FIFRA CBI as well as personal information.

(1) 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? *I am very interested in pursuing electronic reporting. I think it would save a lot of time and costs associated with paper printing, mailing and storing. Yes, I keep electronic records in several formats, depending on internal needs and uses, Excel, Word and most often, Adobe Acrobat PDF.*

(a) would you be more inclined to submit CBI on diskette than on paper? *Yes, if protection of CBI was guaranteed.*

(b) what benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? *Since I receive reports from several sources, compiling time would show some efficiency. But, reducing the need for printing and courier service would be significant.*

(E) Burden and Costs

(1) Are the labor rates accurate? *Labor rates are fairly accurate but don't take overhead costs into account.*

(2) The Agency assumes there are no capital costs associated with this activity. Is that correct? *Yes*

(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. *I would estimate 160 hours annually for the paperwork side of this process. This is due to the number of products, types of*

incidents, and numerous sources and business units that provide reporting data to me. It is very difficult to only narrow the responsibility down to paperwork since it involves so much more, e.g., consultations, meetings, etc.

(4) Are there other costs that should be accounted for that may have been missed? *I keep both paper and electronic records. We do not throw away our paper in regulatory and once it gets to be a certain age we archive it off-site with a local storage vendor. There are definite costs associated with boxing, storing, indexing and retrieving our paper as relates to 6(a)(2). Storage costs alone are $.33 per 1.5 cf per month.*