

ICR ATTACHMENT E

Consultant Contacts and Comments Received in the Consultation Process

Dr. Brian J. Hughes  
Toxicologist/Pesticide Registration Manager  
Pesticide and Plant Pest Management Division 5th Floor, Constitution Hall North  
Lansing, Michigan 48933  
(517) 241-3267

Cynthia Crowley, Environmental Chemist I  
New York State Department of Environmental Conservation  
Bureau of Pesticides Management  
Division of Solid & Hazardous Materials  
625 Broadway  
Albany, New York 12233  
(518) 402-8768

Dr. Laura Quakenbush  
Colorado Department of Agriculture  
Division of Plant Industry  
700 Kipling Street, Suite 4000  
Lakewood, Colorado 80215  
(303) 239-4147

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? The states agreed that all of the necessary data the Agency seeks is not available anywhere else and that each application is unique. However, parts of the section 18 package can be pulled from other sources, such as reference to a previously submitted application from another state for the same use pattern.

CO No

MI No. The specifics of pest problems, range, and economic impacts vary from state to state. There are agencies that make parts of the information public. For example, the USDA Michigan Agricultural Statistic Service has amounts of acreage for a particular commodity by county, but the extent and magnitude of the economic impacts are different. Only partial data can be obtained through

alternate resources. It is usually the technical expertise to evaluate the data in the context of pest management that gives meaning to it.

NY No. While other resources are available for parts of the submission (Our state and national ag databases, extension agents), we still need to collate the information into a single submission

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 do not meet our data needs very well?)

NY Crop statistics are available publicly from the New York State Agriculture & Markets and the National Agriculture Statistical Service websites; this would include acreage planted and harvested as well as value of the crop. These sites also give the historical information for previous years. Cornell also uses data that are not publicly available. Many times we have to rely on grower information relative to crop inputs such as cost of materials, chemicals/fertilizers, harvesting, to determine the cost of producing a commodity on a per acre basis. Also, grower spray records are collected to evaluate resistance and the number of sprays being made

## (2) Frequency of Collection

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

CO Not without a federal rule change. Frequency is mandated by rule (CFR). We would support more regional and national submissions. For example, a national submission from USDA for soybean rust.

MI Yes, particularly when the section 18s are repeated from year to year.

NY We are probably constrained by the CFR, but could specific exemptions be for more than one use season? The streamlined re-certification process makes this less of an issue. Can more regional or national submissions be made? The states would certainly support a national submission (from USDA) for soybean rust quarantine exemptions

## (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?

CO Clarity of instructions is relatively good. I have built my own template for initial section 18 requests using the November 8, 2001 Instructions document from EPA.

MI The instructions are sufficient.

NY Instructions are detailed and clear. Cornell has an outline and instructions on their PMEP website that provides assistance to those wanting to create an emergency exemption.

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

CO Yes.

MI Yes, we maintain the records for 3 years in our files.

NY Yes

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

CO I understand what is required for submission, but the learning process was not that easy. Editing an example from another state or a previous submission is easier than using the EPA guidance. It would be useful if the 2001 "Instructions" were updated to reflect the recent changes.

MI There is an outline in 40 CFR 166.20 that provides adequate guidance on the information that must be in the section 18 applications.

NY No

- Are there forms associated with this process? Do you use them? Are they clear, logical, and easy to complete?

CO There are no EPA-provided forms associated with this process.

MI There are no forms associated with this process from EPA. AAPCO has created a format for the letters of recertification. However, states can choose to create their own format. In this case, I prefer my own submission format.

NY No

#### (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?

CO It would be useful to be able to submit initial requests, repeat requests, and use reports electronically. We would be interested in submitting via email, but with any information that might be considered CBI (under Colorado definitions) submitted has hardcopy and/or on CD. We would be less interested using any web-based systems.

MI The Michigan Department of Agriculture is in favor of electronic submission and would like to explore this opportunity. However, I think there should be some security measure if submissions are sent over the internet (encryption).

NY The New York Department of Environmental Conservation submitted re-certifications only electronically this year. We are moving towards having all of our information in electronic format and would support electronic submissions (email, FTP, or through an Agency web site).

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

CO The request is a word file (which we could easily submit as a .pdf file if preferred). However, some of the additional documents may not be provide to us in electronic format. We have increasingly been asking for electronic versions of section 3 labels, section 18 use directions, supporting efficacy data, residue study data, and other supporting documents.

We currently keep as many of the documents as possible needed for or related to a particular section 18 submission in electronic form. Each year has a folder with each candidate section 18 request having a sub-folder on a network drive. It is easier to find the documents on the network drive than digging out the hard file. Formats vary, including .doc (word), .xls (excel), .pdf and an occasional PowerPoint file of efficacy data.

Our section 18 responsibilities are considered a critical function under our emergency planning, and much of our planning resolves around access to information on the networked drives (not my hard files). I need to be able to continue on with section 18 activities within 12 hours of losing access to our building.

- MI The submissions are kept on the Department of Agriculture's server on the hard drive. The files are Word 2002 and in .pdf format. Yes, we maintain the records for 3 years in our files.
- NY WordPerfect, Word, PDF, Excel. Emergency exemptions are posted on the Cornell website for the current and previous year(s).

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?
- CO Most section 18 submissions do not involve submission of CBI. In a few rare cases, detailed economic data may be provided by a business. This is kept as a separate attachment instead of including it as part of the section 18 request document. We would be more inclined to submit CBI as a hard-copy than electronic. Papers are shredded and it is less clear how to destroy information on electronic media. We currently send back CD's when submitted by our state pesticide registration registrants for this reason (they may stick the CSF on a CD along with labels and MSDS's.)
- MI We would more than likely transmit CBI via CD.
- NY New York State does not have any CBI concerns for Sec 18 submissions.
- What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information?
- CO The major benefit for an electronic submission to EPA would be the assurance that the submission reached the correct person more quickly and more dependably. There would also be a cost savings. We wouldn't need to pay for shipment via federal express, wouldn't have photocopying costs, and would require less staff time for copying and mailing. Electronic submissions would not provide a benefit in terms of compiling the information.
- MI There is no overall burden reduction or efficiency in compiling the data.
- NY Reduction of duplication and shipping costs (both time and \$). Also no postage is necessary as there is no "snail" mail along with easy storage and access. It is also easier to post to a website since there is no need for xeroxing and duplicating. Email has made the turnaround time much quicker relative to getting information from the registrant.

(5) Burden and Costs

- Are the labor rates accurate?

CO The labor rates for Mgmt. and Tech are reasonable, but the clerical rate is high. We would estimate only \$24/hour for clerical, not \$42.

MI EPA labor rates may reflect national average. However, costs to the state in Michigan may be less.

NY Yes

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

CO Yes, there are no capital costs associated with this activity.

MI Yes, there are no capital costs associated with this activity.

NY Yes, there are no capital costs associated with this activity.

- 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.

CO The burden hours for Clerical should be higher.

The amount of time required from clerical will depend on how many applicators use the section 18 product. For many of our section 18 requests, we require each applicator to be a licensed applicator, obtain a special permit from us, and submit a final use report providing the information we need to supply to EPA in our use report. Clerical staff talks to each applicator on the phone, issues a permit number, sends them an application package, makes sure each permittee returns their permit application and the final use report, and compiles a summary of the total amount and area of use. This is the source of the information we send to EPA in our final use report.

The burden hours for "technical" is too high, we estimate 40 hours for CDA staff; not 93. We also consult with University extension people and also grower groups and industries that want a section 18. If we include their time as well (not including effort to conduct efficacy studies or summarize studies that they would be doing regardless of use in a section 18 request) it might add an additional 15 hours. (= 55 hours total for technical).

How this was determined: In a typical year, the pesticide registration coordinator prepares about 10 section 18 requests. During previous years, this would occupy 50% of her time for one month

and 25% for an additional 2 months on section 18's during the winter months. That works out to 40 hours.

MI Cost burdens are not vastly different.

**New York State Burden/Cost Estimates**

COLLECTION ACTIVITY	Burden Hours (per application)			Total	
	Mgmt. \$65/hr	Tech. \$54/hr	Cler. \$42/hr	Hours	Costs (\$)
Read FIFRA and FQPA requirements and CFR regulations.	2	4	0	6	346
Process, compile, and review the requested data for accuracy and appropriateness.	4	15.6	0	15.6	1,102
Generate application correspondence and follow-up summary report.	0	4	0	4	216
Store/maintain/submit information	0	0	3.5	3.5	147
<b>Totals</b>	<b>6</b>	<b>23.6</b>	<b>3.5</b>	<b>33.1</b>	<b>1,811</b>

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

CO There have been training costs incurred as we learned the new streamlined submission process, and participated in various meetings and discussions prior to the final rule change.

MI Are you including the costs of only issuing the Section 18 without any enforcement or follow-up costs? If so, these are costs with the section 18 that are potentially missed. Also if there is any special conditions in the granting document (eg monitoring).

NY No costs have been missed.

(6) Miscellaneous – Response to Emergency Exemption Process Revisions

How has the streamlined application process impacted your Division?

- As it pertains to recertification of certain repeat emergency exemptions

CO The streamlined process has greatly reduced the effort required to prepare repeat requests. This year we put together four of these in one day (2 hours each). Under the old system repeat requests would take less time and effort than the initial application, perhaps 24 hours instead of the 40 hour average.

MI The streamlined process has actually lessened the time of the technical expert in responding to section 18 requests.

NY The streamlined process has been a significant savings in time and money.

- As it pertains to the criteria used to determine when a potential emergency condition is expected to cause a significant economic loss and the data requirements used to document the loss

Has the application and review process for submitting repeat emergency exemptions improved since the regulation went into effect March 28, 2006?

CO This has also made preparation of section 18 requests substantially easier. It also makes it easy to know when a situation will not qualify and clarifies for extension specialists what type of information is needed. This may reduce EPA's workload in ways that they may not be directly aware of, since we will not submit a request if it doesn't meet the very clear criteria that have now been spelled out for us.

The application process for submitting repeat exemptions has improved since the regulations took effect in March of 2006. It is still too early to see if the turn-around time on EPA's side has been reduced.

MI In a few instances, we have needed to seek the help of an agricultural economist to deal with a tier 3 economic analysis. Since the new regulation went into effect we have been able to turn around section 18 submissions faster and receive approval quicker from EPA.

NY As it pertains to the criteria used to determine when a potential emergency condition is expected to cause a significant economic loss and the data requirements used to document the loss. The information and time required for this is similar to what was required previously. Yes, the application and review process for submitting repeat emergency exemptions have improved since the regulation went into effect March 28, 2006.