

EPA ICR No. 2311.01

Supporting Statement ATTACHMENT D

FIFRA §18 - Consultation Contacts and Comments Received in the Consultation Process

- List of names, organizations, addresses and phone numbers of persons consulted, and whose names will be listed in the ICR document:

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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?

Responses:

- WI No, the data request is for specific information that comes from multiple sources (state pesticide regulatory agency, private industry, university/grower groups).
- NE No
- CA Yes

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?

Examples of this would include the USDA National Agricultural Statistics Service (NASS) data, State/County Crop Reports, State/Federal pesticide label databases, University Extension and scientific publications. However, how this data is interpreted and used is specific to each emergency situation being dealt with for the chemical/crop in question. Therefore, it is best to have the section 18 applicant submit the data in the context of the emergency explanation. EPA can then use these resources as verification.

(2) Frequency of Collection

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

Responses:

- WI No. The Agency's "one-time" data collection for each individual Section 18 emergency exemption request (application and follow-up report OR recertification request and follow-up report) is appropriate. The term "frequently" doesn't apply to this type of information collection except in the case of recertification requests. For granted exemptions that are eligible for recertification, the Agency has already provided a process for streamlined information collection should the applicant submit the same request the following year. Post-exemption reporting is appropriate for both new requests and recertifications as EPA would not otherwise have the information it needs to evaluate exemptions.
- NE Yes, under some situations. In cases of Section 18 requests submitted by the State for the first time, all information would be required, however, in cases where the emergency condition continued in additional years, much of the original information would be identical to the original request year. In these cases, EPA and States have agreed to reduce the information required to be submitted with any subsequent requests, and generally limit the information request to changes in the circumstances, such as amount of area to be treated, economics, or changes in pesticide use patterns.
- CA Yes, in the case of repeating section 18's, the recertification provision of the section 18 regulations is a good example of this. Emergencies that are likely to continue into the future may be re-certified in subsequent years with a reduced application package. This greatly

reduces duplication and streamlines the application process in most of these cases where the emergency situation is identical to the previous year(s). Additional information may be required to confirm the severity of the emergency and any alternatives that may have been registered since the original application.

The follow-up reporting of pesticide use information once the section 18 expires is important to this process; the frequency of which we would not recommend be reduced.

(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?

Responses:

- WI The requirements outlined in 40 CFR 166 are straightforward, for the most part, and I'm familiar with the process having worked in this program for four years. However, I'm unaware of guidance documents that 1) provide clarification or examples, 2) are current, and 3) are readily available (e.g. accessible from the Agency's Section 18 webpage). Such documents would especially benefit new persons involved with preparing/submitting Section 18 requests (e.g. state regulatory personnel, university staff/faculty). The Agency may consider 1) updating old guidance documents and/or developing new ones to reflect the current program, 2) distributing such documents to state agencies, 3) enhancing the Agency's webpage(s) to include such documents and/or other information (e.g. the Section 18 training tool currently under development by PREP). I'm aware of guidance documents from 1992 and the mid-2000s but these are not readily available online and, given the turnover at universities and state agencies, I would encourage an update and a (re-)distribution of such materials.

- NE While most of the instructions for data collection and submission are adequate to identify what type of data is required, what I find to be lacking is adequate instruction on how much detail and volume of information or data is needed by the agency. In previous years, I have utilized other state's exemption requests and data to assist me in my submission. I have observed that some states submit volumes of data and supporting documentation, while others provide a bare minimum. It appears to me that States could reduce their information submission significantly if they were provided additional guidance or instructions on exactly what EPA felt would suffice for the request.
- CA 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? As someone new to the section 18 program in our state over the past year and half, it was apparent that information to thoroughly complete and submit a well written section 18 application could not be found in one place. The main EPA section 18 website (<http://www.epa.gov/opprd001/section18/>) provides a general overview of what an emergency exemption is but does not provide the necessary detail to complete an application in the best manner possible. The link from this site to part 166 appears to only be partially working. Searching EPA's website for application criteria turns up 40 CFR part 166 (<http://www.epa.gov/opprd001/registrationmanual/chapter17.html#emergency>) which outlines the basic information required in an application. Other documents such as those distributed by the Section 18 Team - Risk Integration, Minor Use, and Emergency Response Branch, examples of successful applications from other states, and the March 28, 2006 revisions to 40 CFR part 166 help to fill in the missing pieces. The Section 18 Team, and members from other EPA branches have always been helpful, as well.

When submitting a recertification request, the Association of American Pesticide Control Officials (AAPCO) Section 18 Task Force developed the following format as a helpful guideline (<http://aapco.ceris.purdue.edu/doc/min2006/attach/06oct02/attach1.html>)

The Pesticide Regulatory Education Program (PREP), in conjunction with EPA, University of California Davis, and State Lead Agencies is currently working to develop a Section 18 Online Training Tool in response to the need for clarification of application information. The focus is to assist requesting State, tribal, and federal agencies in determining situations where it is appropriate to submit a Section 18 application, and when doing so, to submit a robust Section 18 package that is as complete and accurate as possible to facilitate a timely and effective review by EPA. Other

stakeholders in this process may also find this tool helps to better understand the purposes and processes of the Section 18 program.

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

Responses:

- WI Yes. We also must meet state record disposal requirements.
 - NE Yes
 - CA 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?

Responses:

- WI On occasion applicants have difficulty adequately explaining a particular emergency situation and could use some guidance on what information would help support an emergency condition. In Wisconsin, our technical experts (university researchers, sister state agencies, etc.) prepare the applications for submission to the Agency. We have them use the requirements in 40 CFR 166 as an outline for the application. This helps organize the application but from a review standpoint the description of the emergency situation, which is an essential component, is buried far too deep into the application.
- NE Yes. Referencing my response in the second bullet above, the variety of formats and volume of information submitted by states is considerable. Some states have developed and use outline formats that are quite easy to follow and read, while others use different nomenclature and formats that make it quite difficult to read and find relevant information.
- CA We wouldn't characterize it as difficult; however, it would be more helpful if instructional guidelines were available for some of the required application information (economic loss and emergency criteria) so the best application possible could be submitted to EPA.

Submitting a robust application improves EPA's review efficiency, and has a greater chance of reducing their review and approval time frames which increases the success of meeting the emergency need in the field.

In regards to formatting, an application format was provided in the November 8, 2001 U.S. EPA document titled, Emergency Exemptions Under Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, Instructions for Submission of Emergency Exemption Applications which helped organize the required information and is an excellent base to work from. The March 28, 2006 revisions to 40 CFR part 166 provided

more detail and structure for what EPA is looking for relative to economic loss information. Providing information to supplement the required information is not hard to format clearly. The difficulty encountered is in gathering the economic loss information because it is not always available to that level of detail.

This is being addressed in the Section 18 Training Tool that is being developed by PREP.

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

Responses:

- WI I'm unaware of any federal forms. Wisconsin has not developed any forms to date but will evaluate this possibility in the near future to streamline the review, processing, and submission of applications and reports.
- NE To my knowledge, there are no standardized forms for this process. It would be very helpful if there were, so long as they provided the States the needed flexibility to expand or defer some sections that do not apply to their specific emergency situation.
- CA We do use what formats are available. Our state has elaborated on the 2001 EPA form.

(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?

Responses:

- WI Yes, I would be interested in further pursuing electronic reporting. I've been submitting applications and reports electronically for some time now, possibly for over two years. I've found that it saves time and money. Submitting materials via magnetic media would not save as much time,

and would not save nearly as much money, as other alternatives such as web forms/XML or even e-mail. To my knowledge, inclusion of CBI in our Section 18 requests is uncommon but I do acknowledge this complication in moving forward with alternatives to paper submissions.

- NE Yes. We have already submitted a few Section 18 repeat requests in electronic format, since they only consisted of text documents.
- CA Yes, to the point that it coincides with our Departments capabilities.
- Are you keeping your records electronically? If yes, in what format?

Responses:

- WI Partially, yes (paper and/or electronic). Formats include e-mail, word processing documents, and pdf documents.
- NE All text documents are developed and maintained in electronic format. We use Microsoft Word for our all-agency word processing program, and Microsoft platform database and spreadsheet programs.
- CA In California, we do maintain electronic files of most of the Section 18 documents that are submitted to the Agency, in addition to paper-based records. Large volumes of data are submitted to the Agency via overnight mail and not kept electronically. Our electronic files are in Microsoft Word, Excel, Power Point, and Adobe Acrobat. Database information is kept in Microsoft Access. Currently, we are in the process of developing a new state Section 18 database in Oracle 11G with the application written in cold fusion 9.

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?

Responses:

- WI Yes
- NE We would likely not submit CBI directly to EPA, rather, we would ask the registrant/owner of the CBI to do so directly. I personally would not have concerns about submission of the CBI on digital media.
- CA We do not have an inclination at this time.

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

Responses:

- WI Electronic submission in general may reduce the amount of paperwork generated and reduce or eliminate costs associated with mailing paper copies of the submissions. It is also easier to keep track of and follow up on electronic submissions.
- NE The cost and time needed to duplicate, collate, organize, mail and retain printed documents is significant. To do so electronically takes much less time, and is easier to access for future reference. The aspect of modifying an electronic document and saving it to a unique file name greatly reduces the amount of time it takes to create and submit repeat requests. Distribution to other states and agencies for review or utilization can happen quickly, whereas delivery of printed documents takes days or weeks using standard mail or parcel services.
- CA It would increase efficiency, reduce workload, and streamline paperwork. It would also facilitate a quicker response to information requests and the sharing of information between entities. In the case of repeat Section 18's, being able to recall an electronic version of previous documents and emails increases the efficiency of project completion.

(5) Burden and Costs

- Are the labor rates accurate?

Responses:

- WI Yes
- NE Yes, so long as the wage rates accurately reflect 2011 and beyond.
- CA Yes
- The Agency assumes there is no capital cost associated with this activity. Is that correct?

Responses:

- WI Yes
- NE Yes

- CA Yes
- 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.

Responses:

- WI It is very difficult to estimate burden hours per application for technical labor as each application has different circumstances that require different amounts/types of communication, research, review, etc. and we do not track hours spent per application. As mentioned above, though, it is the technical expert outside our agency that prepares the application materials for our review. Therefore, the burden hours for technical labor seem high, especially for recertification requests. Regarding burden hours for clerical workers, this number would be zero for Wisconsin. The burden hours for management labor appear to be accurate, although the activity is inaccurate. Management labor activities involve discussing the application with technical staff and reviewing application materials, as needed, with less emphasis on reading federal regulations.
- NE In cases of typical Section 18 emergency exemption requests, I would say the burden and cost estimates are accurate. In certain unique and rarely encountered cases, such as wide-spread infestations of plant or animal diseases, the States and EPA have utilized a process where one or two States with greater expertise and resources develop the request for all states, which then submit letters of request to be added to the larger request. For the States that volunteer to develop the multiple-state request, the time and cost burden is significantly higher. Taking for example the request developed for the control of Asian soybean rust, two states cooperated together to write the initial request that eventually was used by nearly 20 states, and included data for more than 15 fungicides. There were two state lead agencies and two state land grant colleges involved in the effort, which took more than 6 months time and perhaps as many as 15 people working nearly constantly on the request. This is a unique and rare situation, but is an example of how the estimated burden of cost and time would be inaccurate for all requests.
- CA Yes, we agree these figures are accurate for the standard section 18 request. It should be noted that there are times when a section 18 emergency situation is credible but the economic information to support the emergency is limited. In these situations, the "burden hours" can

increase significantly (>120) in order to obtain as much data as possible to satisfy EPA's review.

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

Responses:

- WI No
- NE No
- CA Not that we are aware of

(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

Responses:

- WI I began working in this program in 2007, after the changes occurred. I have received positive feedback from university partners regarding successful recertifications, particularly when they occur relatively quickly. The streamlined application process certainly saves time at our end and is preferable to submitting a full application every year.
- NE It has greatly reduced the amount of time needed to submit the request in subsequent repeat years. It is very convenient, when compared to the standard process.
- CA It has greatly reduced the amount of time needed to submit the request in subsequent years.
- 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.

Responses:

- WI Unclear impact. I began working in this program in 2007, after the changes occurred, and have had relatively few requests for new exemptions since then.
- NE It is more difficult to find appropriate and credible data to support the three-tiered economic analysis process currently in place. While the three-tiered approach is perhaps more relevant to the actual conditions of the

emergency, data that would be specific to the emergency situation are not always available, especially in the first year of the emergency. In the absence of real-time or relevant data, States are forced to expend considerable effort to find or generate credible data to support the economic analysis. It is not unusual for me to take 40 to 60 work hours just on the economic analysis, which includes the time it takes to contact experts that might be able to provide the data to support the request.

- CA The clarification of these criteria has been helpful. It provided more detail and structure to what EPA is looking for with this type of information. At the same time, it is often difficult to find data to support the three-tiered economic analysis process, especially for those crops that are ultra minor, such as fresh figs, where this level of detail has not been recorded. In an effort to comply with as much of this level of detail as possible a considerable amount of “burden hours” are expended.
- (7) Has the application and review process for submitting repeat emergency exemptions improved since the regulation went into effect March 28, 2006?

Responses:

- WI In general, yes. One area of improvement could be turnaround time for recertification requests. We have had several requests “fall through the cracks,” possibly due to higher priority requests from other states.
- NE Yes
- CA Yes