

ICR 2311.02 -- Attachment D

2014 Section 18 ICR Consultation Questions/Responses:

1) Please provide your official contact information below:

CA: *Margaret Reiff, Environmental Program Manager I
California Department of Pesticide Regulation
Pesticide Registration Branch
1001 I Street, P.O. Box 4015
Sacramento, California 95812-4015
Phone: (916) 445-5977
Margaret.Reiff@cdpr.ca.gov*

TX: Dale R. Scott
Coordinator for Pesticide Product Evaluation and Registration
Texas Department of Agriculture
PO Box 12847
Austin, TX 78711
(512) 936-2535
Dale.scott@TexasAgriculture.gov

2) 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?

CA: *Some of the general data the Agency seeks, such as crop economics, pest definition, FQPA status, and alternative methods of control is available (in part) from public sources accessible through the internet.*

TX: Because a Section 18 registration can be an unregistered pesticide, the data is not always publically available or has not been previously submitted to EPA. In the cases where the product is registered for another use by EPA, the data would be available. However, much of the data is collected directly from the pesticide manufacturer. This data includes the Ecological Toxicity data, the Environmental Fate data, as well as residue data. Other data such as efficacy data is collected from either the company or universities, or both.

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 do not meet our data needs very well?)

CA: *If the data is not considered confidential, it is available in the public sector. 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.

Confidential data may be possible to obtain from a registrant.

TX: If a pesticide has been submitted to EPA for registration, much of the data can be taken from the EPA Risk Assessment. If the pesticide is unregistered, the data will have to come from either the manufacturer or other sources.

3) Frequency of Collection

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

CA: *Emergency Exemption information is collected once when the state submits a section 18 to U.S. EPA for approval. Less frequent collection is not possible in this regard. Additionally, the follow up reporting of pesticide use information once the section 18 expires is important to this process; the frequency of which should not be reduced.*

However, in the case of repeating section 18's, the recertification provision of the section 18 regulations is a good example of reduced information producing the same outcome. 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.

TX: The data is specific to the Section 18 registration in most cases, therefore is not collected multiple times.

4) Clarity of Instructions

a. 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?

CA: *Yes. The Pesticide Regulatory Education Program (PREP), in conjunction with U.S. EPA, University of California Davis, and State Lead Agencies developed a Section 18 Online Training Tool which clarifies the application information in detail (http://www.epa.gov/pesticides/regulating/section18_training/). This assists 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 also find this tool helps to better understand the purposes and processes of the Section 18 program.

TX: Yes

b. Do you understand that you are required to maintain records?

CA: Yes

TX: Yes

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

CA: *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. The PREP Section 18 Online Training Tool clarifies the application information further. The difficulty encountered is in gathering the economic loss information because it is not always available to that level of detail. However, once obtained, formatting is not an issue.*

TX: Although there is no required submission format, §40 CFR lays out the requirements that must be included in each submission. TDA does not have any problems with the submission procedure.

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

CA: *See previous question. We do use what formats are available. Our state has elaborated on the 2001 EPA form.*

TX: There are no forms for Section 18 submissions.

5) 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.

- 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?**

CA: Yes, to the point that it coincides with our Departments capabilities.

TX: Yes

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

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, unless the registrant has submitted them on CD. Our electronic files for Section 18's are kept in Microsoft Word, Excel, Power Point, and Adobe Acrobat. Database information is kept in Oracle 11G with the application written in cold fusion 9.*

TX: TDA currently keeps copies of all documents on our system. Most documents are either in Microsoft Word or pdf formats.

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

i. Would you be more inclined to submit CBI on diskette (CD or DVD) than on paper?

CA: *We do not have an inclination at this time.*

TX: Yes

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

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.*

TX: By allowing electronic submission, it would cut down on the cost and amount of paperwork and the cost of courier service. It would also allow for the submissions to be sent and reviewed in a timelier manner.

6) Burden and Costs

a. **Are the labor rates accurate?** CA: Yes TX: No response

b. **The Agency assumes there is no capital cost associated with this activity. Is that correct?** CA: Yes TX: Correct

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.

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.*

TX: No Response

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

CA: *Not that we are aware of.*

TX: No response

7) Miscellaneous – Response to Emergency Exemption Process Revisions

a. How has the streamlined application process impacted your division as it pertains to the following:

i. Recertification of certain repeat emergency exemptions?

CA: *See question #2. It has greatly reduced the amount of time needed to submit the request in subsequent years.*

TX: These submissions are submitted to EPA in a more efficient manner. Because the emergency and the need for the pesticide use still exists, TDA is able to get the submission to EPA in a timely manner. It also cuts down on the duplication of documents submitted.

ii. 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?

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.*

TX: The streamlined significant economic loss requirements allows for quick calculations for determining whether TDA should spend resources pursuing a section 18 or if the submission is not going to qualify based upon the economic loss data.

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

CA: Yes

TX: I have only been involved in Product Registrations since 2009. However, from discussions with other staff members, the application and review process has improved with the new regulation.