

Attachment E
Summary of Consultations

This attachment is available as part of the electronic **docket EPA-HQ-OPP-2012-0744** and is part of the ICR's Supporting Statement

I. Companies Contacted:

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II. Consultation Questions:

(1) Publicly Available Data

- \$ Is the data that the Agency seeks for your product(s) available from any public source, or already collected by another office at EPA or by another agency?
- \$ 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 are not specific to your package/bait station?)

(2) Frequency of Collection

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

(3) Clarity of Instructions

- \$ Based on the regulations, PR Notices, Agency webpages, etc., is it clear what type of information you are required to submit and how to submit such data? If not, what suggestions do you have to clarify the instructions?
- \$ Do you understand that you are required to maintain records for the life of the pesticide product registration?
- \$ Is the submission format clear, logical, and easy to complete?

(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.

- \$ Can the information be submitted electronically? If not, would you be interested in this option?
- \$ Are you keeping your records electronically? If yes, in what format?

(5) Burden and Costs

- Are the burden hours in the table below accurate? The table provides EPA's estimate of management, technical, and clerical burden hours per petition. In each row, the total cost is the sum of the estimated burden hours times the hourly rate for each personnel category.
- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with submitting tolerance petitions. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This

includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. If you provide burden estimates different from EPA's, please provide an explanation of how you arrived at your estimates.

Table I

ACTIVITIES	HOURS and RATES				COSTS (per petition)
	Mgmt. \$141/hr	Tech. \$76/hr	Cler. \$39/hr	Total Hours	Total Costs
Review FFDCA regulations CFR citation; PRN 97-1	25	48	24	97	\$8,109
Conduct Field Trial	252	1,080	25	1,357	\$118,587
Prepare Petition	55	30	116	201	\$14,559
Read Notice of any petition deficiency	1	1	1	3	\$256
Prepare response	2	44	12	58	\$4,094
Maintain information	1	8	14	23	\$1,295
TOTAL BURDEN	336	1,211	192	1,739	\$146,900

III. Response provided by Dan Kunkel, IR-4

(1) Publicly Available Data

\$ Is the data that the Agency seeks for your product(s) available from any public source, or already collected by another office at EPA or by another agency?
No, essentially all of the data IR-4 submits (to registration division) is generated by IR-4. IR-4 generates and submits data to request pesticide tolerances. The IR-4 Biopesticide program may cite data that are already available through public sources and submits those data to the Biopesticide Pollution and Prevention Division at EPA, but this would be a very minor portion of the overall data IR-4 submits to EPA.

\$ 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 are not specific to your package/bait station?)

(2) Frequency of Collection

\$ Can the Agency collect this information less frequently and still produce the same outcome?
No IR-4 submits data for each new use requested. On an annual basis, EPA reviews about 95 IR-4 data packages on 30 active ingredients.

(3) Clarity of Instructions

\$ Based on the regulations, PR Notices, Agency webpages, etc., is it clear what type of information you are required to submit and how to submit such data? If not, what suggestions do you have to clarify the instructions?
The guidelines are fairly clear on the requirements for the studies we conduct. I do anticipate that there will be changes associated with the Regulatory Cooperation Council (between US and Canadian regulatory authorities) that will change some of the guidelines in the coming years.

\$ Do you understand that you are required to maintain records for the life of the pesticide product registration?
Yes – absolutely. We maintain long term archives.

\$ Is the submission format clear, logical, and easy to complete?
Yes and the recent update - Pesticide Registration (PR) Notice 2011-3, has been of great assistance. We also expect that the electronic submissions process will make the process easier in the long run.

(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.

\$ Can the information be submitted electronically? If not, would you be interested in this option?

Yes – we are in the process changing to making all of our submissions electronically.

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

No, we are still keeping paper copies and will likely continue with paper archiving for the next few years.

(5) Burden and Costs

- Are the burden hours in the table below accurate? The table provides EPA’s estimate of management, technical, and clerical burden hours per petition. In each row, the total cost is the sum of the estimated burden hours times the hourly rate for each personnel category.

Yes these numbers follow fairly closely to what we estimate our cost to be for each study that we complete. The overall cost is similar, but we would likely have more hours under Technical compared to Management (and management hours would be somewhat lower). This applies to the studies that we do, pesticide Magnitude of the Residues on particular commodities.

- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with submitting tolerance petitions. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements which have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. If you provide burden estimates different from EPA’s, please provide an explanation of how you arrived at your estimates.

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