Attachment E Summary of Consultations

This attachment is available as part of the electronic **docket EPA-HQ-OPP-2015-0715** and is part of the ICR's Supporting Statement

I. Companies Contacted:

- A. Charlotte Sanson, Bayer Charlotte.sanson@bayer.com (919) 549-2824
- B. Dan Kunkel, Ph.D. IR-4 Program, Rutgers University kunkel@AESOP.Rutgers.edu 732-932-9575
- C. John Abbott, Syngenta john.abbott@syngenta.com

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	F	HOURS an	COSTS		
			(per petition)		
	Mgmt.	Tech.	Cler.	Total	
	\$141/hr	\$76/hr	\$39/hr	Hours	Total Costs
Review FFDCA regulations	25	48	24	97	
CFR citation; PRN 97-1					\$9,587
Conduct Field Trial	252	1,080	25	1,357	\$137,886
Prepare Petition	42	30	116	188	\$15,460
Read Notice of any petition	1	1	1	3	
deficiency					\$305
Prepare response	2	44	12	58	\$4,778
Maintain information	1	8	14	23	\$1,565
TOTAL BURDEN	323	1,211	192	1,726	\$169,581

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? By in large, our data are available to the public upon request. A listing of our data is available at our website. We submit most all of our data to EPA-OPP. It is not a duplication. Sometimes FOIA requests are used to get our information. IR-4 keeps archives for the life of an EPA registered product.
- 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?)

 In basic terms, we are a public institution and our research is funded by USDA. Therefore, yes our data are available publically.

(2) Frequency of Collection

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

No we make the submissions to request a pesticide tolerance. As growers request tolerances, IR-4 submits them to EPA.

(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?

 Yes
- Do you understand that you are required to maintain records for the life of the pesticide product registration?

 Yes and therefore, we maintain archives of all of our data for the life of the pesticide product. IR-4 follows the 8-60 guidelines for OPPTS (OCSPP).
- \$ Is the submission format clear, logical, and easy to complete? Yes

(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 and we submit all of our reports electronically to EPA. Prior to December 2015 all our submission were done on a CD. Now IR-4 is using the Portal for almost all submissions. The Portal is more forgiving and makes it easier to quickly correct mistakes of names and typos.

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

Most of our recent submissions (past 10 years) are available electronically, however we have paper copies of all data and reports in archives.

(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, they are pretty close to our estimates. Please see adjustments for preparing responses, our cost is less compared to industry since our data are directed to the area of pesticide residues on crops only.

• 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	I	HOURS an	COSTS		
			(per petition)		
	Mgmt.	Tech.	Cler.	Total	
	\$141/hr	\$76/hr	\$39/hr	Hours	Total Costs
Review FFDCA regulations	25	48	24	97	
CFR citation; PRN 97-1					
Conduct Field Trial	252	1,080	25	1,357	\$130,000
Prepare Petition	55	30	116	201	\$48,000
Read Notice of any petition	1	1	1	3	
deficiency					\$283
Prepare response	2	44	2	20	\$1700
Maintain information	1	8	14	23	\$1,500
TOTAL BURDEN	336	1,211	192	1,739	\$