EPA Questions Asked in Consultation for the 6(a)(2) ICR:

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Date: March 12, 2014 ***e-mail address: nina.heard@syngenta.com***

(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?

Syngenta uses established internal processes to collect potentially adverse effects information concerning its products. We also employ contract firms to collect adverse effects information resulting from incidents involving Syngenta products. None of this information is publicly available.

a) 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 don't meet our data needs very well?)

(Not applicable)

(2) Frequency of Collection

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

In Syngenta's opinion, the EPA could collect adverse effects information less frequently and still have an effective process. This would be especially true *in* cases *involving* less *critical information that would not be of immediate concern for health* or *welfare.*

(3) Clarity of Instructions

a) The ICR is intended to require that respondents provide certain data so that the Agency can utilize them.

b) 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?

Syngenta has a clear view of process and requirements for submission of new adverse effects information. On occasion, guidance is needed to clarify reporting requirements for unique circumstances. Access to an EPA expert or web site with detailed background is often helpful. Syngenta also utilizes internal or external legal counsel to ensure compliance with FIFRA 6a2 legal requirements.

Improved content on the EPA FIFRA 6(a)(2) web page would be very helpful, including recent FIFRA 6(a)(2) submissions and a Frequently Asked Questions section. The TSCA Be website is a good example.

c) Do you understand that you are required to maintain records?
Yes

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

Syngenta has adopted a style of submitting adverse effects information utilizing standard letter correspondence and on occasion using a formal regulatory submission for study reports. We have sought guidance from the FIFRA 6a2 Office when we have had questions. To our knowledge these practices have met with EPA's approval.

e) Regarding the Voluntary Incident Reporting Forms, do you use them? Are they clear, logical, and easy to complete?

Syngenta and its agents use the Voluntary Incident Reporting Forms without any significant problem.

(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. The U.S. E.P.A. Office of Pesticide Programs has a program for electronic study submissions, and is currently developing plans for systems to support electronic incident reporting. The Agency is also concerned to protect FIFRA CBI as well as personal information.

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

Syngenta is interested in using an electronic submission process for adverse effects reports. We are currently using an electronic submission process for major active ingredient registration submissions. We have the capability to use many industry-standard technologies and we would be willing to work with the EPA to implement such a process for future reports. Currently Syngenta maintains its official adverse effects information files in a paper format. Correspondence related to new adverse effects reports is generally communicated within the company in electronic format, mostly via email.We are initiating the use of a Documentum-based document management system to store regulatory correspondence to supplement our paper records storage system.

1) Would you be more inclined to submit CBI on diskette, CD, or DVD, or via web rather than on paper? *No*

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

An electronic submission process would be more efficient and ease submission of information to EPA and aid distribution of information within Syngenta. At this time we do not have plans to eliminate our paper archive, which contains the official copies of adverse effects reports required by FIFRA 6(a)(2), but we have now instituted an electronic system as a back-up.

(5) Burden and Costs

a) Are the labor rates accurate?

The labor rates look reasonable, but no *attempt was made to verify accuracy.*

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

Yes

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.

Syngenta's costs for administering its adverse effects reporting process are generally higher than EPA's estimates, especially for studies. Syngenta conducts studies at several of its global R&D facilities around *the world. Results from these studies are reviewed by a committee of approximately 6 to 8 scientific* and *technical experts familiar with adverse effects reporting obligations from around the world. This committee typically* meets *twice per month to discuss pending issues. Scientific and regul.atory staff are involved in answering questions* and *preparing the notification letter to EPA. We estimate that this process takes approximately 6 to 10 hours per study to complete. EPA's estimate of the* amount *of time needed to report incidents (2.1 hours) is in alignment with our experience.*

Syngenta spends significant time training its staff in adverse effects reporting requirements. A typical training session takes up to 4 hours for a new employee and *approximately* 1 *hour for bi-annual refresher traini ng. It appears that EPA did not include the time trainees spend training programs as a cost. The cost for* Syngenta *is relatively high, compared to EPA estimates, because of the large number of people that must be trained.*

d) Are there other costs that should be accounted for that may have been missed?
No