Consultations Responses
2010 EUP ICR Renewal



**Fw: EUP Consultation Questions-Feedback**
Nicole Williams to: Lily Negash 05/21/2010 10:03 AM

History: This message has been replied to.

Nicole Williams
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----- Forwarded by Nicole Williams/DC/USEPA/US on 05/21/2010 10:03 AM -----

From: "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
To: Nicole Williams/DC/USEPA/US@EPA
Date: 05/21/2010 10:01 AM
Subject: FW: EUP Consultation Questions-Feedback

Nicole,

Below are our comments regarding biotechnology derived traits which are regulated by the Biopesticide and Pollution Prevention Division. I hope to have comments on the chemistry piece later today.

Russ

*Dr. Russell P. Schneider*
*Senior Director, Regulatory Affairs and Policy*
*Monsanto Company*
*1300 I St., NW*
*Suite 450 East*
*Washington, DC 20005*
*202/383-2866*

(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?

**Protein Safety/Event Characterization Data –**
For single events, this data is normally submitted to EPA for the EUP prior to submission to EPA for any other purpose. Vector information might be available for USDA regulated events in USDA notifications/permits prior to any EUP submission depending on the product and timing.

For stacked PIP products, the EPA may have already reviewed certain single events (by itself, or in the context of another stacked product) and therefore may have already collected necessary safety data that could just be cited in the EUP submission.

**Acreage data–**

Monsanto's response, p. 1

If event(s) is USDA de-regulated, not available from another public sources. If event (s) is USDA regulated, data acreage on event acreage may be available through USDA

$ 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?)

**Protein Safety/Event Characterization Data -**
If single event data has already been submitted to the agency, even in the context of another stack where the single event itself is not approved, it would be a duplication to resubmit this data instead of just citing.

**Acreage data-**
USDA acreage information is tracked differently, and may not meet EPAs needs. USDA notification process does not track PIP crosses in the field, or de-regulated non-PIP acres that are typically included in EUP acres.

(2) Frequency of Collection

$ Can the Agency collect the information less frequently and still Produce the same outcome?

**If this is referring to the collection of acreage data for PIPs:**
As the agency collects the acreage information in the initial submission, and then a final report is required at the end of the EUP, the frequency is acceptable.

(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?

Yes, it is mostly clear. We would like clarity on what is required for submission of an EUP for a new stack when a single event as part of the stack has already been reviewed by EPA (and EPA is in possession of the data) even if that single event is not yet approved, or won't be approved as a single.

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

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?

No, it is not difficult.

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

Yes, we use the Application form (8570-10) Data Citation form, Data Matrix form (8570-35), and Confidential Statement of Formula form (8570-4). These forms are not difficult to complete, although there is a redundancy of required information in filling them out (i.e. dates twice on the data matrix form, repeating the proteins and vectors on every page, etc). The forms could probably be streamlined for easier completion.

For EUP protocols/acreage information we do not fill out any forms, but this is OK as we import in our own tables from Excel.

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

Yes, we would be interested in an electronic reporting system for EUPs. We currently keep electronic records in Excel, Word, and other databases to manage all data. Eliminating the step of printing and submission of hard copies would be helpful, even if the same current format of submission was used. We would support the submissions of CBI CD-ROM, and would like to submit CBI electronically in the future.

> 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?

Yes. We generally provide a CD-ROM that contains both CBI and non-CBI files along with our paper copies anyway.

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

This would be a great benefit to us. We spend a lot of our time on the administrative portion of these activities (i.e. printing, binding, and shipping), and use a lot of paper in the process. Once the information is compiled, submission of only a CD-ROM (until there might be a true e-submission available) would greatly increase our efficiency.

**(5) Burden and Costs**

**$ Are the labor rates accurate?**

Monsanto's response, p3

$ The Agency assumes there is no capital cost associated with this activity. Is that correct?
$ 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.
Are there other costs that should be accounted for that may have been Missed?

We were not able to answer #5, as we are not clear on the cost estimates and labor rates to which you are referring. If you can provide that information, we will try to respond.

5 of 19

**Fw: EUP Consultation Questions-Feedback**
Nicole Williams to: Lily Negash 05/24/2010 10:06 AM

History: This message has been forwarded.

Nicole Williams
Information Technology Specialist
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http://www.epa.gov/pesticides
----- Forwarded by Nicole Williams/DC/USEPA/US on 05/24/2010 10:06 AM -----

From: "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
To: Nicole Williams/DC/USEPA/US@EPA
Date: 05/21/2010 04:39 PM
Subject: EUP Consultation Questions-Feedback

This is Monsanto's response for the chemistry portion of EUPs.

Russ

Dr. Russell P. Schneider
Senior Director, Regulatory Affairs and Policy
Monsanto Company
1300 I St., NW
Suite 450 East
Washington, DC 20005
202/383-2866
-----Original Message-----
From: WATSON, GREGORY R [AG/1000]
Sent: Friday, May 21, 2010 2:57 PM
To: MURPHY, JENNY [AG/1000]; SCHNEIDER, RUSSELL P [AG/1920]
Cc: HEYDENS, WILLIAM F [AG/1000]
Subject: RE: EUP Consultation Questions-Feedback



EUP Burden Estimate Response May 2010.docx

Monsantos Response, p. 5

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?

**RD Response:**
Information that would be needed to complete an EUP application is not readily available from a single resource. While some information needed to organize for an EUP submission would be available in public records (i.e., key production regions where trials should be placed to provide meaningful results), the overwhelmingly majority of information needed must be generated and assembled by the EUP applicant.

**BPPD Response:**
**Protein Safety/Event Characterization Data –**
For single events, this data is normally submitted to EPA for the EUP prior to submission to EPA for any other purpose. Vector information might be available for USDA regulated events in USDA notifications/permits prior to any EUP submission depending on the product and timing.

For stacked PIP products, the EPA may have already reviewed certain single events (by itself, or in the context of another stacked product) and therefore may have already collected necessary safety data that could just be cited in the EUP submission.

**Acreage data—**
If event(s) is USDA de-regulated, not available from another public sources.
If event (s) is USDA regulated, data acreage on event acreage may be available through USDA

$ 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?)

**RD Response:**
As stated above, the overwhelming majority of information needed for an EUP submission must be generated and assembled by the EUP applicant. Under PRIA, an EUP application can be part of an application for registration; in these specific applications, the information that would be required for an EUP would be duplicative.

**BPPD Response:**
**Protein Safety/Event Characterization Data –**
If single event data has already been submitted to the agency, even in the context of another stack where the single event itself is not approved, it would be a duplication to resubmit this data instead of just citing.

**Acreage data—**
USDA acreage information is tracked differently, and may not meet EPAs needs. USDA notification process does not track PIP crosses in the field, or de-regulated non-PIP acres that are typically included in EUP acres.

(2) Frequency of Collection

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

**RD Response:**
In EUPs that are multi-year, collection of information should be limited to the completion of the EUP period. Annual reporting of total acres treated or the amount of product utilized does not provide meaningful information to the regulatory process. Existing potential adverse effect reporting requirements would allow for early indications of issues that could potential require amendment of an approved EUP.

**BPPD Response:**
**If this is referring to the collection of acreage data for PIPs:**
As the agency collects the acreage information in the initial submission, and then a final report is required at the end of the EUP, the frequency is acceptable.

(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?

**RD Response:**
The advent of PRIA has brought back to companies the potential option of conducting an EUP; the previous priority system of ranking OPP applications created a situation where EUPs were not going to be reviewed by EPA and therefore they were not part of the development plan for a pesticide chemical. Existing guidance on what is required for an EUP submission can be interpreted correctly by an experience regulatory manager; they could not be interpreted correctly by a person without experience in pesticide regulatory matters. Also, the separation of the data guideline requirements for EUPs has made it more clear what data is required for an EUP; submission of studies for an EUP are required to follow PR Notice 86-5 format. However, the addition of new data requirements has placed an EUP application later in the development process for a new active ingredient than would have been desired.

**BPPD Response:**
Yes, it is mostly clear. We would like clarity on what is required for submission of an EUP for a new stack when a single event as part of the stack has already been reviewed by EPA (and EPA is in possession of the data) even if that single event is not yet approved, or won't be approved as a single.

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

**RD & BPPD Response:**
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?

**RD Response:**
There is a required format for certain EUP submissions for chemical pesticides, particularly if there is a desire to establish a time limited tolerance in association with the use of the pesticide under an EUP on food crops (i.e., commonly referred to as a 'sales EUP'). Generally the format for EUP submissions can be discerned from the available guidance; however, it is extremely likely that consultation with the appropriate PM Team in RD would be needed to assure that the proper documentation and submission format prior to the submission.

**BPPD Response:**
No, it is not difficult.

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

**RD & BPPD Response:**
Yes, we use the Application form (8570-10) Data Citation form, Data Matrix form (8570-35), and Confidential Statement of Formula form (8570-4). These forms are not difficult to complete, although there is a redundancy of required information in filling them out (i.e. dates twice on the data matrix form, repeating the proteins and vectors on every page, etc). The forms could probably be streamlined for easier completion.

For EUP protocols/acreage information we do not fill out any forms, but this is OK as we import in our own tables from Excel.

(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?

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

**RD Response:**

Monsanto is fully supportive of continued development of electronic submissions and electronic reporting of information to EPA; we believe this improves efficiencies within the applicant and the regulator communities. Our regulatory archive is maintained in electronic form utilizing Documentum; we also store electronic records utilizing commercially available electronic submission software. This software allows us to store individual regulatory submissions and continue to add to the record of a submission if additional submissions and follow up is needed. We believe that it is possible to develop systems that would protect CBI and would still allow for electronic submission to OPP.

**BPPD Response:**
Yes, we would be interested in an electronic reporting system for EUPs. We currently keep electronic records in Excel, Word, and other databases to manage all data. Eliminating the step of printing and submission of hard copies would be helpful, even if the same current format of submission was used. We would support the submissions of CBI CD-ROM, and would like to submit CBI electronically in the future.

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?

**RD Response:**
In lieu of an internet portal for submissions to OPP (as exists with Canadian PMRA), we would support providing CBI and non-CBI on a CD or DVD.

**BPPD Response:**
Yes. We generally provide a CD-ROM that contains both CBI and non-CBI files along with our paper copies anyway.

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

**RD Response:**
While the preparation of an electronic submission may require additional resources to create, the archiving benefits of electronic records are very valuable and greatly reduce the burden of record storage. Further, much of the information and documentation needed for an EUP submission can be valuable in the preparation of a formal registration submission; therefore, previously generated electronic documents and forms could be utilized to assist in these follow up submissions.

**BPPD Response:**
This would be a great benefit to us. We spend a lot of our time on the administrative portion of these activities (i.e. printing, binding, and shipping), and use a lot of paper in the process. Once the information is compiled, submission of only a CD-ROM (until there might be a true e-submission available) would greatly increase our efficiency.

(5) Burden and Costs

$ Are the labor rates accurate?
**RD Response:**

The estimates that are given are reasonable if only salary is meant to be included; these figures are too low if benefits (i.e., health and other insurance) are meant to be included in the estimates.

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

**RD Response:**

Completion of an EUP submission may include the need to produce the chemical pesticide product; depending on the nature of the chemistry, a capital project may be needed to complete the production and / or packaging of the product. For example, one of the major costs in an EUP for a chemical pesticide is getting the product produced, packaged, and shipped to those conducting the EUP trials.

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

**RD Response:**

We have included the EPA burden estimates and our revised numbers in the following format: EPA Estimate / Monsanto Estimate. The major differences in our estimates comes from our experience with the time needed to assemble the information needed to plan the EUP and the submission of the documentation to EPA. A major part of a chemistry EUP submission that we are presenting below is the preparation and formatting of study volumes submitted to OPP (i.e., PR Notice 86-5 requirements including the transmittal document)

| ANNUAL RESPONDENT BURDEN/COST ESTIMATES COLLECTION ACTIVITIES | Burden Hours (per year) | | | TOTAL | |
|---|---|---|---|---|---|
| | Management ($109.82/hr) | Technical ($60.39/hr) | Clerical ($35.89/hr) | Hours | Costs |
| Read regulations | 0.5 / 2 | 0.5 / 4[1] | 0.0 | 1.0 / 6 | |
| Plan activities | 0.0 | 1.0 / 4 | 0.0 | 1.0 / 4 | |
| Create information | 0.0 | 2.0 / 4 | 0.0 / 4 | 2.0 / 8 | |
| Gather information | 0.0 | 2.5 / 6 | 0.0 / 8 | 2.5 / 14 | |
| Compile and review | 0.0 / 4[2] | 2.0 / 10 | 0.0 / 4 | 2.0 / 18 | |
| Complete paperwork | 0.1 / 0.5 | 0.5 / 1 | 0.0 / 4 | 0.6 / 5.5 | |
| Store/maintain data | 0.0 | 0.0 / 1 | 1.0 | 2.0 | |

[1] - includes review of data requirements for EUP for chemical pesticides

[2] - management review of the submission and its content would needed to assure compliance obligations have been met.

Monsanto's response, p. 10

| | | | | | |
|---|---|---|---|---|---|
| TOTAL | 0.6 / 6.5 | 8.5 / 30 | 1.0 / 21 | 10.1 / 57.5 | |

**Fw: EUP Consultation Questions-Feedback**
Nicole Williams to: Lily Negash 05/24/2010 10:07 AM

History: This message has been forwarded.

Nicole Williams
Information Technology Specialist
Registration Division
U.S. Environmental Protection Agency
(703)308-5551
williams.nicole@epa.gov
http://www.epa.gov/pesticides
----- Forwarded by Nicole Williams/DC/USEPA/US on 05/24/2010 10:06 AM -----

From: "SCHNEIDER, RUSSELL P [AG/1920]" <russell.p.schneider@monsanto.com>
To: Nicole Williams/DC/USEPA/US@EPA
Date: 05/21/2010 04:40 PM
Subject: EUP Consultation Questions-Feedback

Nicole,

This is additional information regarding the costs associated with PIP EUPs.

Regards,

Russ

Dr. Russell P. Schneider
Senior Director, Regulatory Affairs and Policy
Monsanto Company
1300 I St., NW
Suite 450 East
Washington, DC 20005
202/383-2866



EUP Question 5..docx

Monsanto's response, p. 12

(5) Burden and Costs

**$ Are the labor rates accurate?**

The estimates that are given are reasonable if only salary is meant to be included; these figures are too low if benefits (i.e., health and other insurance) are meant to be included in the estimates.

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

Correct, no capital requierd

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

We have included the EPA burden estimates and our revised numbers in the following format: EPA Estimate / Monsanto Estimate. The major differences in our estimates come from our experience with the time needed to assemble the information needed to plan the PIP EUP and the submission of the documentation to EPA. A major part of a PIP EUP submission that we are presenting below is the preparation and formatting of all of the different combinations of acreage and active ingredient calculations required to be broken down in different ways (i.e. by protocol tables, by PIP tables, etc).

| ANNUAL RESPONDENT BURDEN/COST ESTIMATES COLLECTION ACTIVITIES | Burden Hours (per year) | | | TOTAL | |
|---|---|---|---|---|---|
| | Management ($109.82/hr) | Technical ($60.39/hr) | Clerical ($35.89/hr) | Hours | Costs |
| Read regulations | 0.5 / 2 | 0.5 / 4[1] | 0.0 | 1.0 / 6 | |
| Plan activities | 0.0 | 1.0 / 20 | 0.0 | 1.0 / 20 | |
| Create information | 0.0 | 2.0 / 40 | 0.0 / 4 | 2.0 / 44 | |
| Gather information | 0.0 | 2.5 / 6 | 0.0 / 8 | 2.5 / 14 | |
| Compile and | 0.0 / 4[2] | 2.0 / 40 | 0.0 / 4 | 2.0 / 48 | |

[1] - includes review of data requirements for EUP for chemical pesticides

[2] - management review of the submission and its content would needed to assure compliance obligations have been met.

| | | | | | |
|---|---|---|---|---|---|
| review | | | | | |
| Complete paperwork | 0.1 / 1 | 0.5 / 8 | 0.0 / 4 | 0.6 / 13 | |
| Store/maintain data | 0.0 | 0.0 / 1 | 1.0 | 2.0 | |
| TOTAL | 0.6 / 6.5 | 8.5 / 30 | 1.0 / 21 | 10.1 / 147 | |

Monsanto's response, p.14

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**RE: EOP Information Collection Request Review and Consultation Process**
wendelyn.jones to: Mike Mendelsohn 07/06/2010 10:18 AM
Cc: Lily Negash, Robert Forrest, lawrence.zeph

Mike,

Greetings! Please see attached. If you have any questions, please feel free to contact either Larry or myself.

Hope you had a great 4th!
Wendelyn

Wendelyn Jones, Ph.D.
Syngenta Biotechnology, Inc.
mobile: +1 443-631-7261
email: wendelyn.jones@syngenta.com

-----Original Message-----
From: Mendelsohn.Mike@epamail.epa.gov [mailto:Mendelsohn.Mike@epamail.epa.gov ]
Sent: Wednesday, June 30, 2010 8:21 AM
To: Jones Wendelyn USRE
Cc: Negash.Lily@epamail.epa.gov; Forrest.Robert@epamail.epa.gov; Zeph Lawrence USRE
Subject: Fw: EOP Information Collection Request Review and Consultation Process

Wendelyn,

I talked with Lily on Monday and wanted to check to see whether Syngenta would be able to provide feedback on the reporting burden for EUPs. Some of the information, we have received thus far has been unexpected and we would greatly value your input. Please feel free to give me a call if you would like to discuss. Thanks.

Best Regards,

Mike Mendelsohn
Senior Regulatory Specialist
Office of Pesticide Programs/ Biopesticides and Pollution Prevention Division (7511P) U.S. Environmental Protection Agency 1200 Pennsylvania Avenue NW
Washington DC 20460
(703) 308-8715
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http://www.epa.gov/pesticides/biopesticides

----- Forwarded by Lily Negash/DC/USEPA/US on 06/28/2010 10:46 AM -----
|------------>
| From: |
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|Robert Forrest/DC/USEPA/US
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Syngenta's response, p. 1

16 of 19

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| To: |
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|wendelyn.jones@syngenta.com
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| Date: |
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|06/04/2010 01:28 PM
|

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| Subject: |
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|EOP Informatiion Collection Request Review and Consultation Process
|

>----------

Dr. Wendelyn Jones
Syngenta Biotechnology, Inc

Dr. Jones,

It was good to talk to you today and we very much appreciate your participation in this Application for Experimental Use Permit (EUP) Information Collection Request (ICR) review and consultation process. Below you will find additional information regarding background, action outline, relevant attachments, link to the docket, and a contact name and number.

Background

The Environmental Protection Agency's (EPA), Office of Pesticide Program (OPP) is proposing to renew for another three years the ICR for Application for Experimental Use Permit (EUP) to Ship and Use a Pesticide for Experimental Purposes Only, OMB number 2070-0040, EPA No. 0276.14. ICR's are required to be renewed every three years and we re-estimate burden based on any new information available to the Agency

Action

In an effort to actively seek input from registrant associations and the public, EPA is contacting you to ask for your feedback regarding this Information Collection Request (ICR). Please use the " Consultation Questions" form attached when crafting your response. Also, please note that your comments/feedback will appear in a publicly available document along with your name and e-mail address ( the Docket for this ICR action). Your response to this request would be most appreciated within the next week (by June 10, if

Syngenta's response, p.2

possible), however, if your response comes in after that time frame, the Agency will enter your response directly into the Docket.

Attachments

I am attaching the following documents:

the list of consultation questions
(See attached file: Consultation Questions.doc

(See attached file: Consultation Questions.doc)

an excerpt of the proposed burden section 6 of the ICR renewal
(See attached file: Section 6 Excerpt-Consultations-EUP.doc

(See attached file: Section 6 Excerpt - Consultations - EUP.doc)

and a copy of the proposed ICR (the same copy that is in the docket)

(See attached file: Published draft_EUP_2010_EPA-HQ-OPP-2009-0883-0002 [1].doc)

"The Agency has established a public docket for this ICR under Docket NO. EPA-HQ-OPP-2009-0883, which is available for on line viewing at www.regulations.gov. The docket contains links to the attachments cited in the ICR proposal."

Direct link to the Federal Register Notice:
http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480ab35fe



Syngenta's response, p. 3

**Sample Consultation Questions OPP ICR Renewals**

**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?
  no

- 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?)

(2) Frequency of Collection

- Can the Agency collect the information less frequently and still produce the same outcome?
  Not sure

(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?

  The proposed rule on data requirements for PIPs would help. We would advocate for clear PIP specific guidance. The maturity of the industry is such that fitting biotechnology derived products into chemical paradigms creates undue confusion.

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

  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?
  yes

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

  Have own internal processes developed – there are minimal EPA forms

(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



Syngenta's response, p. 4

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?
  Yes

- Are you keeping your records electronically? If yes, in what format?
  Yes – in various formats

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?
  NO. Paper copies are tangible and can be controlled. CD and DVDs have files that can be copied readily and in advertantly used in inappropriate manners.

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

(5) Burden and Costs

- Are the labor rates accurate?
  NO

- The Agency assumes there is no capital cost associated with this activity. Is that correct?
  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.
  The data information needs for PIPs is very complex given the current industry pipeline trends and the number of varieties tested to enable commercial registration.

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



Syngenta's response, p.5