**Consultation Contacts for OPP ICR Compliance Requirement for Child-Resistant Packaging____ Technology Sciences Group, Inc._____(OMB Control # 2070-0_052__)**

- List name, address and phone number (or e-mail) of at least 3 persons (entitles contacted) whose names will be listed in the ICR document. *(Make sure the contacts understand that their names and contact numbers will appear in a publically available document).* Amy Plato Roberts, Technology Sciences Group, Inc., 712 5th Street, Suite A, Davis, CA 95616, telephone (530) 757-1432, email ARoberts@TSGUSA.COM

**Updated ICR Document:**

**A list of the consultation questions asked and the responses thereto become a part of the electronic public comment docket for this ICR renewal. Thus, a list of questions asked the respondents and the responses received, either written comments, verbal responses or e-mail, etc. will become a part of the electronic public comment docket for this ICR renewal.**

**EPA Questions asked in Consultation**

(1) Publicly Available Data

$ Is the Child-Resistant Packaging (CRP) 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.

$ If yes, where can you find the CRP 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

$ Is submitting CRP certification with/without data when a change in packaging occurs too frequent? No.

(3) Clarity of Instructions

$ CRP regulations require respondents provide CRP certifications, CRP test data, and CRP exemption requests to ensure that the Agency can ascertain if CRP is protecting children from serious illness or injury resulting from handling, using, or ingesting certain products.

$ Based on the regulations, PR Notices, CRP webpage, etc., is it clear what type of CRP information you are required to submit (e.g. CRP certification with/without data, etc.) and how to submit such data? If not, what suggestions do you have to clarify the instructions? Yes it is clear.

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

$ There are no forms associated with CRP. Is the submission format for CRP certifications and/or CRP data, clear, logical, and easy to complete? Yes, however, it might be clearer if there was a specific form that is completed.

(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.

$ Currently CRP data may be submitted electronically in addition to a hard copy to expedited data analysis. What do you think about this option? Other electronic reporting alternatives include the use of Aweb forms@/XML based submissions via the Agency=s Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc. Electronic submission is helpful, however it would be easier if it was a directly electronic submission through a e-index builder type format.

$ Are you keeping your records electronically? If yes, in what format? Yes and generally in MSWord or PDF documents that are scanned in.

(5) Burden and Costs

- Are the clerical and technical burden hours in the 2 tables below accurate? These figures are based on 2009 projections. **Table I** associates the various types of CRP actions a respondent may do and the number of technical hours and clerical hours per event. Please note this table reflects 2006 comments regarding burden hours per CRP action and projections for an increase in burden hours per CRP action for 2009. Please remember this burden may cover more than one product registration. **Table II** spreads out a 5.6 hour burden per action in 0.1 hour increments. This not the time for self-certification without data or any other specific CRP type action. This is the time average based on registration actions spread out over self certification, certification with data, exemptions, etc. The time per action multiplied by the number of actions, and the sum of all registration actions time spent divided by the number of actions. **For example** using burden estimates say 10 registration actions with say 6 being self certifications @1.5 hr =9, 3 certification with data @ 11 hr =33, and 1 exemption at 5.9 hr. This would provide 47.9 hrs for 10 registration actions with an average time per action being 4.8 hr. **The question in Table II** is then **how would you divide** the 4.8 hr (**5.6 hr in the chart) between the various steps** in collection action such as read instructions, prepare submission etc. If you could please provide input to Table II I would appreciate it. The estimates seem accurate.

- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with CRP, e.g., the document does not include estimated burden hours and costs for conducting studies. If you provide burden estimates substantially different from EPA=s, please provide an explanation of how you arrived at your estimates.

Table I

| Type of Response | # Respondent | Technical Burden | | Clerical Burden | | Aggregate Burden |
|---|---|---|---|---|---|---|
| | | Hours Per Event | Total | Hours Per Event | Total | |
| CRP certification | 0 | 1 | 0 | 0.5 | 0 | 0 |
| CRP certification with data | 0 | 8 | 0 | 3 | 0 | 0 |
| exempt from CRP due large package size | 0 | 0 | 0 | 0 | 0 | 0 |
| exempt from CRP lack toxicity, packaging, no residential use, lower product toxicity | 3 | 4 | 12 | 1.9 | 5.7 | 17.7 |
| TOTAL | 3 | n/a | 12 | n/a | 5.7 | 17.7 |

,

Table II
(Based on 2009 Projection Total Burden 5.6 Hrs/Respondent Acn)

| COLLECTION ACTIVITIES | Burden Hours | | | |
|---|---|---|---|---|
| | Tech. $60.39/hr. | % | Clerical $35.89/hr. | % |
| Read instructions | 0 | 0 | 0 | 0 |
| Plan activities | 0.71 | 0.13 | 0 | 0 |
| Create information including electronic format of data | 1.63 | 0.29 | 0 | 0 |
| Process, compile, and complete written compliance document | 1.45 | 0.26 | 1 | 0.18 |
| Review submission | 0.41 | 0.07 | 0 | 0 |
| Store, submit, file, or maintain data | 0 | 0 | 0.4 | 0.07 |
| TOTAL | 4.2 | 0.75 | 1.4 | 0.25 |

**Consultation Contacts for OPP ICR Compliance Requirement for Child-Resistant Packaging *Product & Regulatory Associates, LLC* (OMB Control # 2070-0_052__)**

- List name, address and phone number (or e-mail) of at least 3 persons (entitles contacted) whose names will be listed in the ICR document. *(Make sure the contacts understand that their names and contact numbers will appear in a publically available document).* John F. Wright Product & Regulatory Associates, LLC, P. O. Box 1683, Voorhees, NJ 08043-9998, telephone 856-424-1528, email JwrightCH@comcast.net

**Updated ICR Document:**

**A list of the consultation questions asked and the responses thereto become a part of the electronic public comment docket for this ICR renewal. Thus, a list of questions asked the respondents and the responses received, either written comments, verbal responses or e-mail, etc. will become a part of the electronic public comment docket for this ICR renewal.**

**EPA Questions asked in Consultation**

(1) Publicly Available Data

$ Is the Child-Resistant Packaging (CRP) 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.

$ If yes, where can you find the CRP 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

$ Is submitting CRP certification with/without data when a change in packaging occurs too frequent? No.

(3) Clarity of Instructions

$ CRP regulations require respondents provide CRP certifications, CRP test data, and CRP exemption requests to ensure that the Agency can ascertain if CRP is protecting children from serious illness or injury resulting from handling, using, or ingesting certain products.

$ Based on the regulations, PR Notices, CRP webpage, etc., is it clear what type of CRP information you are required to submit (e.g. CRP certification with/without data, etc.) and how to submit such data? My experience here has to be based on the type of submissions. For the small unit dose, prefilled, ready to use bait stations, yes there is sufficient information to prepare and submit the required certification or exemption. For CRP certification of multi use containers, I am not sure that I would full understand what is to be submitted. Or what data is to be generated. If not, what suggestions do you have to clarify the instructions? More examples of the pesticide formulations rather than general terms. For a small

container to hold a liquid or granular product, does the certificate need to be conducted with the actual product in place or will a generalized placebo be acceptable? The actual certificate is now required with the specific container and closure to be specified?

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

$ There are no forms associated with CRP. Is the submission format for CRP certifications and/or CRP data, clear, logical, and easy to complete? The submission of CRP certification is clear but not the format for the data. Since some CRP data is generated outside of the pesticide regulations, many vendors do not know how to conduct a study under GLP guidelines or prepare the final report in PR Notice 86-5 format. A section to clarify these points needs to be presented.

(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.

$ Currently CRP data may be submitted electronically in addition to a hard copy to expedited data analysis. What do you think about this option? This is an acceptable format. Most of the contract laboratories conducting the studies understand the proper formatting protocol. The registrant, however, would not have the general understanding of this format. Thus the data need to be in hard copy format for their storage requirements. Other electronic reporting alternatives include the use of Aweb forms@/XML based submissions via the Agency=s Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc.

$ Are you keeping your records electronically? No. Once the study is finalized, hard copies of the data are archived. In that hard copy archive, there will be a copy of CD submitted to the Agency. The reason for this is that most small companies do not have the infrastructure to maintain a GLP electronic archiving system. If yes, in what format?

(5) Burden and Costs

- Are the clerical and technical burden hours in the 2 tables below accurate? These figures are based on 2009 projections. **Table I** associates the various types of CRP actions a respondent may do and the number of technical hours and clerical hours per event. Please note this table reflects 2006 comments regarding burden hours per CRP action and projections for an increase in burden hours per CRP action for 2009. Please remember this burden may cover more than one product registration. **Table II** spreads out a 5.6 hour burden per action in 0.1 hour increments. This not the time for self-certification without data or any other specific CRP type action. This is the time average based on registration actions spread out over self certification, certification with data, exemptions, etc. The time per action multiplied by the number of actions, and the sum of all registration actions time spent divided by the number of actions. **For example** using

burden estimates say 10 registration actions with say 6 being self certifications @1.5 hr =9, 3 certification with data @ 11 hr =33, and 1 exemption at 5.9 hr. This would provide 47.9 hrs for 10 registration actions with an average time per action being 4.8 hr. **The question in Table II** is then **how would you divide** the 4.8 hr (**5.6 hr in the chart) between the various steps** in collection action such as read instructions, prepare submission etc. If you could please provide input to Table II I would appreciate it.

- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with CRP, e.g., the document does not include estimated burden hours and costs for conducting studies. If you provide burden estimates substantially different from EPA=s, please provide an explanation of how you arrived at your estimates.

Table I

| Type of Response | # Respondent | Technical Burden | | Clerical Burden | | Aggregate Burden |
|---|---|---|---|---|---|---|
| | | Hours Per Event | Total | Hours Per Event | Total | |
| CRP certification | 352 | 1 | 352 | 0.5 | 176 | 528 |
| CRP certification with data | 295 | 8 | 2360 | 3 | 885 | 3245 |
| exempt from CRP due large package size | 28 | 1[A] | 0 | 0 | 0 | 0 |
| exempt from CRP lack toxicity, packaging, no residential use, lower product toxicity | 28 | 8 [A] | 112 | 1.9 | 53.2 | 165.2 |
| TOTAL | 703 | n/a | 2824 | n/a | 1114.2 | 3938.2 |

[A] The time to document these items is too low. One must provide a review of the pesticide label, manufacturing records, marketing options or research data to support the justifications for the exemption.

Table II
(Based on 2009 Projection Total Burden 5.6 Hrs/Respondent Acn)

| COLLECTION ACTIVITIES | Burden Hours | | | |
|---|---|---|---|---|
| | Tech. $60.39/hr. | % | Clerical $35.89/hr. | % |
| Read instructions | 0 | 0 | 0 | 0 |
| Plan activities[B] | 0.71 | 0.13 | 0 | 0 |
| Create information including electronic format of data | 1.63 | 0.29 | 0 | 0 |
| Process, compile, and complete written compliance document | 1.45 | 0.26 | 1 | 0.18 |

Attachment C

| COLLECTION ACTIVITIES | Burden Hours | | | |
|---|---|---|---|---|
| | **Tech. $60.39/hr.** | **%** | **Clerical $35.89/hr.** | **%** |
| Review submission | 0.41 | 0.07 | 0 | 0 |
| Store, submit, file, or maintain data | 0 | 0 | 0.4 | 0.07 |
| TOTAL | 4.2 | 0.75 | 1.4 | 0.25 |

[B] When a registrant evaluates the need for or an exemption of the CRP data requirements for the registration, the time in assembling and documenting all the facts is missing from the activities above. Also the planning option is significantly low when one needs to configure the various marketing options and their implications. This should be at least 3-4 X higher.

**Consultation Contacts for OPP ICR Compliance Requirement for Child-Resistant Packaging__*name*_____(OMB Control # 2070-0_052__)**

- List name, address and phone number (or e-mail) of at least 3 persons (entitles contacted) whose names will be listed in the ICR document. *(Make sure the contacts understand that their names and contact numbers will appear in a publically available document).*

  Merial Limited, 3239 Satellite Blvd., Duluth, GA 30096,

  Contributors
  1. Karen C. Cunningham, Head, Regulatory Affairs Lifecycle Management, Phone: 678-638-3138, Email: karen.cunningham@merial.com

  2. Karen Mardis, Senior Manager Regulatory Affairs Lifecycle Management, Phone: 678-638-3706, Email: karen.Mardis@Merial.com

  3. Timothy A. Dotson, Director, Regulatory Affairs New Products, Phone: 678-638-3713, Email: timothy.dotson@merial.com

**Updated ICR Document:**

**A list of the consultation questions asked and the responses thereto become a part of the electronic public comment docket for this ICR renewal. Thus, a list of questions asked the respondents and the responses received, either written comments, verbal responses or e-mail, etc. will become a part of the electronic public comment docket for this ICR renewal.**

**EPA Questions asked in Consultation**

(1) Publicly Available Data

$ Is the Child-Resistant Packaging (CRP) 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.

$ If yes, where can you find the CRP 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

$ Is submitting CRP certification with/without data when a change in packaging occurs too frequent? No.

(3) Clarity of Instructions

$ CRP regulations require respondents provide CRP certifications, CRP test data, and CRP exemption requests to ensure that the Agency can ascertain if CRP is protecting children from serious illness or injury resulting from handling, using, or ingesting certain products.

$ Based on the regulations, PR Notices, CRP webpage, etc., is it clear what type of CRP information you are required to submit (e.g. CRP certification with/without data, etc.) and how to submit such data? If not, what suggestions do you have to clarify the instructions? It is clear.

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

$ There are no forms associated with CRP. Is the submission format for CRP certifications and/or CRP data, 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.

$ Currently CRP data may be submitted electronically in addition to a hard copy to expedited data analysis. What do you think about this option? Other electronic reporting alternatives include the use of Aweb forms@/XML based submissions via the Agency=s Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc. The only alternative Merial is aware of is submitting data on durable media like CD-ROM. A separate cost is incurred in this case and it is not clear if there is a benefit to this.

$ Are you keeping your records electronically? Yes. If yes, in what format? All hard copy reports are scanned into *.pdf format and placed in a central database, and copies of CRP data on CD-ROM are also kept.

(5) Burden and Costs

- Are the clerical and technical burden hours in the 2 tables below accurate? These figures are based on 2009 projections. **Table I** associates the various types of CRP actions a respondent may do and the number of technical hours and clerical hours per event. Please note this table reflects 2006 comments regarding burden hours per CRP action and projections for an increase in burden hours per CRP action for 2009. Please remember this burden may cover more than one product registration. **Table II** spreads out a 5.6 hour burden per action in 0.1 hour increments. This not the time for self-certification without data or any other specific CRP type action. This is the time average based on registration actions spread out over self certification, certification with data, exemptions, etc. The time per action multiplied by the number of actions, and the sum of all registration actions time spent divided by the number of actions. **For example** using burden estimates say 10 registration actions with say 6 being self certifications @1.5 hr =9, 3 certification with data @ 11 hr =33, and 1 exemption at 5.9 hr. This would provide 47.9 hrs for 10 registration actions with an average time per action being 4.8 hr. **The question in Table II** is then **how would you divide** the 4.8 hr (**5.6 hr in the chart) between the various steps** in collection action such as read instructions, prepare submission etc. If you could please provide input to Table II I would appreciate it. No

comments for either table.

- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with CRP, e.g., the document does not include estimated burden hours and costs for conducting studies. If you provide burden estimates substantially different from EPA=s, please provide an explanation of how you arrived at your estimates.

Table I

| Type of Response | # Respondent | Technical Burden | | Clerical Burden | | Aggregate Burden |
|---|---|---|---|---|---|---|
| | | Hours Per Event | Total | Hours Per Event | Total | |
| CRP certification | 352 | 1 | 352 | 0.5 | 176 | 528 |
| CRP certification with data | 295 | 8 | 2360 | 3 | 885 | 3245 |
| exempt from CRP due large package size | 28 | 0 | 0 | 0 | 0 | 0 |
| exempt from CRP lack toxicity, packaging, no residential use, lower product toxicity | 28 | 4 | 112 | 1.9 | 53.2 | 165.2 |
| TOTAL | 703 | n/a | 2824 | n/a | 1114.2 | 3938.2 |

Table II
(Based on 2009 Projection Total Burden 5.6 Hrs/Respondent Acn)

| COLLECTION ACTIVITIES | Burden Hours | | | |
|---|---|---|---|---|
| | Tech. $60.39/hr. | % | Clerical $35.89/hr. | % |
| Read instructions | 0 | 0 | 0 | 0 |
| Plan activities | 0.71 | 0.13 | 0 | 0 |
| Create information including electronic format of data | 1.63 | 0.29 | 0 | 0 |
| Process, compile, and complete written compliance document | 1.45 | 0.26 | 1 | 0.18 |
| Review submission | 0.41 | 0.07 | 0 | 0 |

Attachment C

| COLLECTION ACTIVITIES | Burden Hours | | | |
|---|---|---|---|---|
| | **Tech. $60.39/hr.** | **%** | **Clerical $35.89/hr.** | **%** |
| Store, submit, file, or maintain data | 0 | 0 | 0.4 | 0.07 |
| TOTAL | 4.2 | 0.75 | 1.4 | 0.25 |

Attachment C

**Response from: Mark Jernigan, Bio-Lab, Inc. (EPA Company # 5185)**
**Consultation Contacts for OPP ICR Compliance Requirement for Child-Resistant Packaging_ _____(OMB Control # 2070-0_052__)**

- List name, address and phone number (or e-mail) of at least 3 persons (entitles contacted) whose names will be listed in the ICR document. *(Make sure the contacts understand that their names and contact numbers will appear in a publically available document).*

**Updated ICR Document:**

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**EPA Questions asked in Consultation**

(1) Publicly Available Data

$ Is the Child-Resistant Packaging (CRP) 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

$ If yes, where can you find the CRP 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

$ Is submitting CRP certification with/without data when a change in packaging occurs too frequent? No

(3) Clarity of Instructions

$ CRP regulations require respondents provide CRP certifications, CRP test data, and CRP exemption requests to ensure that the Agency can ascertain if CRP is protecting children from serious illness or injury resulting from handling, using, or ingesting certain products.

$ Based on the regulations, PR Notices, CRP webpage, etc., is it clear what type of CRP information you are required to submit (e.g. CRP certification with/without data, etc.) 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 CRP records for the life of the pesticide product registration? Yes

$ There are no forms associated with CRP. Is the submission format for CRP certifications and/or CRP data, clear, logical, and easy to complete? Yes, although a form may be helpful so that responses are structured.

(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.

$ Currently CRP data may be submitted electronically in addition to a hard copy to expedited data analysis. What do you think about this option? Other electronic reporting alternatives include the use of Aweb forms@/XML based submissions via the Agency=s Internet site and magnetic media-based submissions, e.g., diskette, CD-ROM, etc.

$ Are you keeping your records electronically? If yes, in what format? No

(5) Burden and Costs

- Are the clerical and technical burden hours in the 2 tables below accurate? These figures are based on 2009 projections. **Table I** associates the various types of CRP actions a respondent may do and the number of technical hours and clerical hours per event. Please note this table reflects 2006 comments regarding burden hours per CRP action and projections for an increase in burden hours per CRP action for 2009. Please remember this burden may cover more than one product registration. **Table II** spreads out a 5.6 hour burden per action in 0.1 hour increments. This not the time for self-certification without data or any other specific CRP type action. This is the time average based on registration actions spread out over self certification, certification with data, exemptions, etc. The time per action multiplied by the number of actions, and the sum of all registration actions time spent divided by the number of actions. **For example** using burden estimates say 10 registration actions with say 6 being self certifications @1.5 hr =9, 3 certification with data @ 11 hr =33, and 1 exemption at 5.9 hr. This would provide 47.9 hrs for 10 registration actions with an average time per action being 4.8 hr. **The question in Table II** is then **how would you divide** the 4.8 hr (**5.6 hr in the chart) between the various steps** in collection action such as read instructions, prepare submission etc. If you could please provide input to Table II I would appreciate it.

- Bearing in mind that the burden and cost estimates include only burden hours and costs associated with the paperwork involved with CRP, e.g., the document does not include estimated burden hours and costs for conducting studies. If you provide burden estimates substantially different from EPA=s, please provide an explanation of how you arrived at your estimates.

  Numbers presented in tables I and II for Burden Hours appear reasonable.

Attachment C

Table I

| Type of Response | # Respondent | Technical Burden | | Clerical Burden | | Aggregate Burden |
|---|---|---|---|---|---|---|
| | | Hours Per Event | Total | Hours Per Event | Total | |
| CRP certification | 352 | 1 | 352 | 0.5 | 176 | 528 |
| CRP certification with data | 295 | 8 | 2360 | 3 | 885 | 3245 |
| exempt from CRP due large package size | 28 | 1 | 0 | 0 | 0 | 0 |
| exempt from CRP lack toxicity, packaging, no residential use, lower product toxicity | 28 | 8 | 112 | 1.9 | 53.2 | 165.2 |
| TOTAL | 703 | n/a | 2824 | n/a | 1114.2 | 3938.2 |

Table II
(Based on 2009 Projection Total Burden 5.6 Hrs/Respondent Acn)

| COLLECTION ACTIVITIES | Burden Hours | | | |
|---|---|---|---|---|
| | Tech. $60.39/hr. | % | Clerical $35.89/hr. | % |
| Read instructions | 0 | 0 | 0 | 0 |
| Plan activities | 0.71 | 0.13 | 0 | 0 |
| Create information including electronic format of data | 1.63 | 0.29 | 0 | 0 |
| Process, compile, and complete written compliance document | 1.45 | 0.26 | 1 | 0.18 |
| Review submission | 0.41 | 0.07 | 0 | 0 |
| Store, submit, file, or maintain data | 0 | 0 | 0.4 | 0.07 |
| TOTAL | 4.2 | 0.75 | 1.4 | 0.25 |

## RE: Child-Resistant Packaging, ICR

Jernigan, Mark to Scott Drewes 05/10/2010 01:21 PM

Cc: Ian Blackwell

History: This message has been replied to.

Dear Scott:

I have no additional comment based on your indicated change.

Best regards,

Mark

Mark Jernigan
Regulatory Affairs Manager
Bio-Lab, Inc., A Chemtura Company
678-502-4149 (voice)
678-502-4764 (fax)
Mark.Jernigan@chemtura.com

-----Original Message-----
From: Drewes.Scott@epamail.epa.gov [mailto:Drewes.Scott@epamail.epa.gov]
Sent: Monday, May 10, 2010 12:43 PM
To: Jernigan, Mark
Cc: blackwell.ian@epamail.epa.gov
Subject: Fw: Child-Resistant Packaging, ICR

Mark,

I was on the phone call with you and Ian Blackwell last week to discuss the burden hours for submitting CRP applications. I noticed later that there was an error in Table 1. I am sending this email to ask if you could take a few moments to review the corrected table below.

Table 1 should have appeared as it does below (and in the attached document). In particular, the burden hours for CRP exemptions due to large package size and exempt from CRP for lack of toxicity, etc. should have read 0 and 4 hrs per event respectively. In the table you reviewed they were listed as 1 and 8 hrs; these higher number were based on consultations with another registrant and may not reflect the amount of time that your organization spends, on average, processing CRP exemptions. EPA's estimates are based on the following assumptions: 1) Applicants exempt from CRP requirements based on large package size require no time because the CRP regulations require no action on their part and 2) Less data is required to be submitted for exemptions due to lack of toxicity, etc. We would appreciate it if you could comment on these corrected numbers. If your estimates differ, can you please provide your assumptions? Feel free to respond directly to this email, or enter your comments in the attached document. I would be happy to call you if I can provide further clarification.

Thanks again for your assistance. We appreciate the time you have already spent on this activity.

Table 1

| Type of Response | # Respondent | Technical Burden Hours Per Event | Total Hours | Clerical Burden Hours Per Event | Total Aggregate Burden |
|---|---|---|---|---|---|
| CRP certification | 352 | 1 | 352 | 0.5 | 176 | 528 |
| CRP certification with data | 295 | 8 | 2360 | 3 | 885 | 3245 |
| exempt from CRP due large package size | 28 | 0 | 0 | 0 | 0 | 0 |
| exempt from CRP lack toxicity, | 28 | 4 | 112 | 1.9 | 53.2 | 165.2 |

| | | | | | |
|---|---|---|---|---|---|
| packaging, no | | | | | |
| residential use, | | | | | |
| lower product | | | | | |
| toxicity | | | | | |
| TOTAL | 703 | n/a | 2824 | n/a | 1114 | 3938 |

(See attached file: consultationquest.doc)

Scott Drewes
Environmental Protection Specialist
Field and External Affairs Division
Office of Pesticide Programs
703-347-0107
----- Forwarded by Scott Drewes/DC/USEPA/US on 05/10/2010 12:07 PM -----

From: Ian Blackwell/DC/USEPA/US

To: "Jernigan, Mark" <Mark.Jernigan@chemtura.com>

Cc: Scott Drewes/DC/USEPA/US@EPA

Date: 04/30/2010 03:44 PM

Subject: Re: FW: Child-Resistant Packaging, ICR

Mark,

Thanks so much. I didn't expect this so soon. We really appreciate your help!

Sincerely,
Ian Blackwell
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention (OCSPP)
U.S. Environmental Protection Agency
2777 S. Crystal Drive
Arlington, VA 22202