

Compliance Requirement for Child-Resistant Packaging;  
EPA-HQ-OPP-2016-0630

### Consultation for OPP ICR Renewals

#### Representative(s) Consulted

Name	: Mark Jernigan
Company Represented	: Bio-Lab, Inc.
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#### Questionnaire

(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? **I am not aware of another source.**
- 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? **Yes, a registrant should be able to submit a general CRP certification (certification without data) with the initial registration submission. With that certification, it is the responsibility of the registrant to ensure that any packaging used with the registration meets CRP standards. No additional submissions to EPA should be required of the registrant unless EPA specifically requests to see data.**

(3) Clarity of Instructions

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

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- Based on the instructions (certification guidance document, 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? PR Notice 97-9 needs to be updated as technology has changed regarding electronic data format. PR Notice 96-2 is inconsistent with the “Certification without data” in the document OMB No. 2070-0052; EPA No. 0616.12 in that PR Notice 96-2 appears to require a description of the package used (see pages 7 & 8 of the PR Notice). On Page 5 of OMB No. 2070-0052; EPA No. 0616.12 it states the “description of the packaging used” is requested, but not required. It is unclear what the requirement is for when to include a package description in the CRP certification. Additionally, there is no clear timeline for EPA review of a revised CR submission. CR submissions appear to take longer than other actions. Since registrant is certifying that the packaging is CRP compliant, EPA should consider accepting CRP submissions through the notification process.
- 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. As stated above, PR Notice 97-9 needs to be updated as technology has changed regarding electronic data format. PR Notice 96-2 is inconsistent with the “Certification without data” in the document OMB No. 2070-0052; EPA No. 0616.12 in that PR Notice 96-2 appears to require a description of the package used (see pages 7 & 8 of the PR Notice). On Page 5 of OMB No. 2070-0052; EPA No. 0616.12 it states the “description of the packaging used” is requested, but not required. It is unclear what the requirement is for when to include a package description in the CRP certification. Additionally, there is no clear timeline for EPA review of a revised CR submission. CR submissions appear to take longer than other actions. Since registrant is certifying that the packaging is CRP compliant, EPA should consider accepting CRP submissions through the notification process.
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- Are there forms associated with this process? No Do you use them? Not applicable. Are they clear, logical, and easy to complete? Not applicable.

(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 the OPP Pesticide Submission Portal via the Agency’s Internet site and magnetic media-based

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submissions, e.g., diskette, CD-ROM, etc. Would you be interested in pursuing electronic reporting? **Only if EPA can develop a more structured process for what is required to be submitted.**

- Are you keeping your records electronically? **Some.** If yes, in what format? **PDF**
- What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? **No benefit.**

(5) Burden and Costs

- Are the labor rates accurate? **I have no way to determine.**
- 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. **No comment.**
- Are there other costs that should be accounted for that may have been missed? **No comment.**

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## Consultation for OPP ICR Renewals

### Representative(s) Consulted

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### Questionnaire

(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? **No, currently the data is only collected at minimal time points (at initial registration and upon amendments). Therefore I would not expect this could be reduced.**

(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 (certification guidance document, 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 EPA website indicates that the certification statement should include information on the package and an overview of the testing information. This is not stated in 40CFR §157.34 Certification. Neither of these documents states the ASTM classification should also be submitted. It is not clear how much data the agency wants to review in regards to the packaging specification. As stated above, it is not clear from the instructions if CRP samples and how many should be submitted to the agency and to whose attention. A checklist or form for submission**

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would be helpful to ensure all required information is submitted for this data set, especially with the evolution of the CRP group within the EPA in the last couple of years. Any way the agency can share their current thinking is always helpful to registrants, whether it is guidance documents, PR Notices, webinars, or letters.

- 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? **I have been fortunate in working with experienced testing facilities that are in close contact with the Agency and understand the data submission requirements. It is not clear where the CRP certification needs to be submitted in the final package. It is also not clear when and how to submit CRP package samples for review, and how many samples are required. This is not outlined in the regs or guidance documents.**
- Are there forms associated with this process? Do you use them? Are they clear, logical, and easy to complete? **There are no formal CRP data submission forms. It would be nice to have a standard form for the certification.**

(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 the OPP Pesticide Submission Portal 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, I prefer to submit data electronically through the PSP on CDX.**
- Are you keeping your records electronically? If yes, in what format? **The original study data that was recorded on paper is kept in fireproof cabinets. The electronic study reports and EPA submissions are kept in pdf format on the company servers that are backed up at set frequencies.**
- What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? **Electronic submissions have reduced human resources needed to compile 3 copies of the study data and prepare for mailing. It has also reduced the cost of paper and copier maintenance as well as shipping costs. Electronic submission also reduces filing and follow-up times for employees with the Agency.**

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(5) Burden and Costs

- Are the labor rates accurate? **Yes**
- 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. **Yes**
- Are there other costs that should be accounted for that may have been missed? **No**

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### Consultation for OPP ICR Renewals

#### Representative(s) Consulted

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#### Questionnaire

(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? **When criteria are met for CRP per product, certification is collected. However the Agency needs to rely more on cited package data already reviewed and accepted.**

(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 (certification guidance document, 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.**
- Do you understand that you are required to maintain records? **Yes.**

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- 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.**
- Are there forms associated with this process? Do you use them? Are they clear, logical, and easy to complete? **No.**

(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 the OPP Pesticide Submission Portal 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? **Word and pdf files saved on server. Historically, the Agency required both paper and electronic format, especially for the raw data in spreadsheet.**
- What benefits would electronic submission bring you in terms of burden reduction or greater efficiency in compiling the information? **All documents for submission are currently prepared in electronic format.**

(5) Burden and Costs

- Are the labor rates accurate? **No. When the submission is managed and prepared using regulatory consultant(s) the labor costs are higher.**
- 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. **The burden hours seem appropriate, the labor rates seem low.**
- Are there other costs that should be accounted for that may have been missed? **Yes, historically additional burden and labor costs to provide further support**



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**information as response to Agency review and concerns, especially for Certification with Data applications.**