

From: [Negash, Lily](#)
To: [Gerret Van Duyn](#)
Subject: RE: 1995 OMB determination on label submission <> data
Date: Wednesday, August 12, 2015 7:44:38 AM

Dear Mr. Duyn,

Thank you for contacting the EPA with your questions. You requested a copy of an Office of Management and Budget (OMB) determination which is referenced on page 4 of the Information Collection Request (ICR) for "Application for New and Amended Pesticide Registration."

The OMB determination discussed in this section of the ICR is referring to the Paperwork Reduction Act (PRA) amendments of May 1995 and the OMB final regulations issued in August 1995, along with OMB's initial determinations implementing those regulations.

The threshold referenced in the same paragraph was in an OMB Action Notice that was issued on May 31, 1995 - before the OMB regulations were issued in August 1995, so it does not reflect the changes in the PRA & OMB regulations that were made later in 1995. In addition, Action Notices only apply for the time period specified unless the terms are specifically repeated in any subsequent Action Notice for the ICR. In this case, they were not repeated.

In general, when the EPA revises a regulation to require new, revised or additional labeling information, the Agency assesses the impact as part of that rulemaking package. When the Agency issues guidance (usually in the form of a PR Notice) that establishes new labeling policies, the EPA assesses the impact as part of developing that guidance. In both those cases, OMB has opportunities to review requirements before they go out for comment or in final form.

Based on your comment, we are planning to modify the ICR text in question to clarify the reference to the statute and OMB regulations (i.e., pesticide labels are not a "collection of information" under 5 CFR 1320.3(c)(2)). We will also review the ICR to provide clarifications elsewhere, as needed.

The Attachment H referenced in your questions is a consultations questionnaire and response document which will be posted once it has been compiled. This can be found posted with the second Federal Register Notice (FRN) which starts the second comment period. We anticipate the publication of the second FRN around December.

Let me know if I can be of further assistance.

Lily Negash
Policy & Regulatory Services Branch
Field & External Affairs Division
Office of Pesticide Programs
Environmental Protection Agency
Phone: 703-347-8515

From: Gerret Van Duyn [gerret.vanduynd@bayer.com]
Sent: Wednesday, July 22, 2015 9:46 AM
To: Negash, Lily
Subject: RE: 1995 OMB determination on label submission <> data

Dear Ms. Negash,

In addition to the OMB determination below, I also could not find your consultation reference (Attachment: H) mentioned in your supporting materials on Regulation.gov. Could you also provide a copy of this as well?

Thanks.

GVD

Sincerely,

S. Gerret Van Duyn
Regulatory Lifecycle Manager
2 T.W. Alexander Dr.
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e-mail: gerret.vanduyn@bayer.com<<mailto:gerret.vanduyn@bayer.com>>

From: Gerret Van Duyn
Sent: Wednesday, July 22, 2015 8:48 AM
To: 'negash.lily@epa.gov'
Subject: 1995 OMB determination on label submission <> data

Dear Ms. Negash,

Following up on my voice mail I just left I am interested in getting a copy of OMB's 1995 determination that label submission as part of the FIFRA Sec. 3 process is not a data submission. This determination is referenced in EPA's supporting documentation in section 3(d) for its ICR calculations for EPA-HQ-OPP-2015-0332.

"Pesticide labels: In accordance with a determination made by the Office of Management and Budget (OMB) in 1995, the third party disclosure requirement, which involves the registrant's disclosure of product specific information to potential users and the general public through the pesticide label, is not considered a collection of information. This is because the information that must be included as the product labeling is approved and provided to the registrant by EPA as part of the original registration (5 CFR 1320.3(c)(2)). As such, this ICR does not include any third party burden or cost estimates specifically associated with the labeling activities that are a part of the original registration. Please note, however, that whenever any general labeling changes initiated by the Agency result in an estimated burden of more than 5,000 burden hours, EPA must seek OMB concurrence. In such cases, EPA must provide OMB with a brief description of the general labeling change, along with the estimated burden and costs. OMB has agreed to notify EPA of any comments or questions within 10 days of receiving the information, after which EPA may proceed with the labeling change."

Do you have a copy of this determination you can send to me?

Thank you for any information you can provide.

GVD

Sincerely,

S. Gerret Van Duyn
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