

From:
To: [Samek, Karen](#)
Cc: [Alwood, Jim](#); [Sleasman, Katherine](#)
Subject: RE: Information Collection Request (ICR) Consultation
Date: Tuesday, February 6, 2024 12:16:34 PM
Attachments:

Dear Ms. Samek,

Thank you for contacting us regarding the ICR for nanoscale materials. We do not have any comments or input to provide on this ICR, but appreciate EPA keeping us in mind on these issues.

Best regards,



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From: Samek, Karen <Samek.Karen@epa.gov>
Sent: Monday, February 5, 2024 8:22 AM
To:
Cc: Alwood, Jim <Alwood.Jim@epa.gov>; Sleasman, Katherine <Sleasman.Katherine@epa.gov>
Subject: Information Collection Request (ICR) Consultati

I am contacting you to solicit your input on the renewal of the Information Collection Request (ICR). Enclosed, please find a list of several questions we hope you might consider during your review. (see attached questions). The existing ICR expires on September 30, 2024, for requirements pursuant to TSCA section 8(a) titled, “Chemical-Specific Rules under the Toxic Substances Control Act (TSCA) Section 8(a); Certain Nanoscale Materials,” it is identified by OMB Control No. 2070-0194. OMB requires federal agencies to consult with nine or fewer

potential respondents prior to submitting the ICR renewal to OMB for review and approval. This consultation requirement is in addition to providing the public with 60 days to comment on the proposed collection activity. The meaningful and timely comments the Agency receives from you will help us during the development of this renewal ICR. The notice announcing the ICR renewal and solicitation of comments was published in the Federal Register on February 1, 2024, ([89 FR 6520](#)) See <http://www.regulations.gov/>, docket ID EPA-HQ-OPPT-2010-0572, and the ICR supporting statement for this renewal located is in that docket for additional information.

The Paperwork Reduction Act (PRA) requires that agencies receive Office of Management and Budget (OMB) clearance before requesting most types of information from the public. In order to receive OMB clearance, federal agencies prepare draft ICRs providing an overview of the information collection and estimates of the cost and time for the public to respond. The agencies consult with potential respondents and the public about the ICR and, where appropriate, incorporate comments received. The draft ICR is then sent to OMB for its review and approval. These ICRs are periodically renewed. This ICR renewal covers reporting and recordkeeping requirements for persons who manufacture or process chemical substances as nanoscale materials under the authority of section 8(a) of the Toxic Substances Control Act (TSCA) and implementing regulations in [40 CFR part 704.20](#).

Please note that, if you take this opportunity to provide input, your name, affiliation, and phone number and any information you provide (e.g., copies of emails) will be incorporated and attached to the ICR supporting statement which will be a public document. In addition, you may be contacted by the OMB Desk Examiner for the ICR to verify the accuracy of any comments as reported in the ICR by EPA.

Your response will be greatly appreciated. If you have any comments in response to the attached questions, or with respect to any other part of the information collection, please respond by return e-mail by April 1, 2024. EPA will consider those responses, as well as any public comment received in response to the Federal Register Notice identified above, in preparing a final document for OMB review.

Thank you for your assistance.

Sincerely yours,

Karen Samek

Karen Samek, Program Manger
Environmental Protection Agency
Office of Pollution Prevention and Toxics
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(202) 564-4968
samek.karen@epa.gov



February 12, 2024

Ms. Karen Samek
Chemical Control Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

Re: Information Collection Request (ICR) Consultation

Dear Karen,

The NanoBusiness Commercialization Association (NanoBCA) is pleased to respond to the U.S. Environmental Protection Agency's (EPA) request to provide our views on the information collection request under TSCA Section 8(a) pertinent to nanoscale materials. Our responses to the questions you asked are appended.

EPA has not asked a more fundamental question than the one that relates to the ongoing need for this reporting obligation. NanoBCA questions the need for its continuation. The final rule compelling this one-time reporting obligation was issued in January 2017. Since then, it is quite unclear what benefit, if any, these reports have provided. If EPA has outlined the utility of the information reported, how many reports have been submitted, and how EPA is using the reported information, we are unaware of this information.

While no single reporting obligation is unduly burdensome, collectively, federal and state reporting obligations impose a heavy burden on U.S. businesses. This is especially true of small businesses and start-ups. NanoBCA members include many businesses in both categories.

We urge EPA to consider sunseting the obligation or helping the regulated community understand why it should continue.

NanoBCA welcomes this opportunity to assist EPA. We value our collaboration and are pleased to assist.

Sincerely,

cc: Mr. Raymond J. Alwood (via e-mail) (w/attachment)
Ms. Katherine Sleasman (via e-mail) (w/attachment)

From:
To: [Samek, Karen](#)
Cc: [Alwood, Jim](#); [Sleasman, Katherine](#)
Subject: Information Collection Request (ICR) Consultation - NanoBCA
Date: Monday, February 12, 2024 2:50:38 PM
Attachments: [EPA Questionnaire 2-12-24.pdf](#)


Dear Karen,

Per your request, attached you will find the completed questionnaire and a letter explaining the viewpoint of the NanoBCA.

Thank you for the opportunity to express our viewpoint.

Regards,

Consultation Questions for the Information Collection Request (ICR) for Chemical-Specific Rules under the Toxic Substances Control Act (TSCA) Section 8(a); Certain Nanoscale Materials

(1) Publicly Available Data

- A. Is the data that the Agency seeks available from any public source, or already collected by another office at EPA or by another agency?

Not to our knowledge, but the U.S. Environmental Protection Agency (EPA) would likely know better.

Data reportable under this rule are unlikely to be available publicly. Even if a submitter's product is described in a journal article or patent, EPA would not know the submitter is manufacturing or importing for a commercial purpose.

- B. 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 do not meet our data needs very well?)

(2) Clarity of Instructions

The ICR covers the requirement under the PBT rule for respondents to maintain records.

- A. Based on the instructions (regulations, FR Notices, etc.), is it clear what you are required to do? If not, what suggestions do you have to clarify the instructions?

If an entity understands it has a reporting obligation, the instructions are clear. If it is not clear, or even widely known, however, entities still have a reporting obligation.

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

Most entities appreciate that when reporting to a federal agency, record retention is required.

(3) 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.

- A. What do you think about electronic alternatives to paper-based records and data submissions? Would you be interested in pursuing keeping records electronically?

Electronic records are superior, assuming that EPA's system is working properly. EPA must be properly resourced to develop, test, deploy, and maintain its Central Data Exchange (CDX) data systems.

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

CDX allows download of the complete Copy of Record in a single archive. The Copy of Record includes all the submitted information and the critical metadata (the individual who signed the document and the date of submission).

(4) Burden and Costs

- A. Are the labor rates accurate?

Labor rates typically underestimate true costs and industry burden.

- 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.

EPA estimates 106.7 hours of burden per report. This is probably correct.

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

EPA does not include cost for retaining third-party assistance in determining whether the reporting obligation applies and how best to submit the report.

EPA's estimate of \$7,688 per submission (based on total annual burden of \$69,197 divided by 9 submissions) clearly excludes third-party assistance -- it corresponds to about \$72 per hour. That pay rate may be reasonable for a reporter's direct employee, but it is significantly below market rate for an outside TSCA consultant. NanoBCA's view is that only a company that has extensive experience with nano reporting would prepare a nanomaterial report without outside assistance.