UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 05 2018

MEMORANDUM

SUBJECT: Response to comments received on the ICR Renewal entitled "Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports (Chemical Data Reporting)" (EPA-HQ-OPPT-2017-0648)

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Background

This information collection request (ICR) addresses the paperwork requirements contained in the most recent Chemical Data Reporting (CDR) rule (40 CFR Part 711) under the Toxic Substances Control Act (TSCA). Under TSCA section 8(a) (15 USC 2607(a)), the Environmental Protection Agency (EPA) is authorized to collect certain information on chemical substances manufactured (including imported) or processed in the United States. The CDR was formerly known as the Inventory Update Rule (IUR).

The CDR collection provides chemical manufacture, processing, and use information that helps EPA identify what chemicals the public may be exposed to as consumers or in commercial and industrial settings. The data also helps EPA assess routes of potential exposure to those chemicals. EPA has used the CDR rule to collect basic manufacturing information for selected chemical substances on the TSCA Inventory eight times beginning in 1986. More recent collections, beginning in 2006, included additional information relating to the manufacture, processing, and use of those chemical substances. The reporting requirements have been modified through rulemaking, most recently in 2011 when EPA promulgated the IUR Modifications Rule (76 FR 50815, August 16, 2011). The 2011 rule phased in some provisions; all changes were fully implemented with the 2016 CDR and are slated to continue for the next submission of data in 2020. The CDR collection is on a four-year reporting cycle and contains

detailed manufacturing and processing information drawn from the principal reporting year; the rule also contains basic information on production volume, by year, for the three years prior to the principal reporting year (e.g., for the 2020 reporting cycle, the principal reporting year will be 2019; the three years prior will be 2016, 2017, and 2018). In addition, changes have been made to the list of chemical substances (see 40 CFR 711.6(b)(ii)(4)) that are partially exempt, most recently in 2016 (81 FR 17395, March 29, 2016).

Certain other changes to CDR were put in place following enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA on June 22, 2016. For example, the CDR certification statement was updated in June 2016 to be consistent with the revised statutory requirements. The requirement for substantiation of claims of confidential business information (CBI) at the time the claim is made is being implemented though a separate action, initiated in 2017 (82 FR 6522, January 19, 2017). EPA is providing questions to help submitters develop their substantiation of CBI at the time of claim. These changes and the reporting burden estimates associated with them have been incorporated into this ICR supporting statement

The 2020 CDR collection is expected to involve an average of approximately 5,662 respondents at an annual cost of $57 million during the ICR period. The details of the paperwork burden and cost estimates are discussed in this document.

The ICR is identified by EPA ICR No. 1884.10 and OMB Control No. 2070-0162, and represents the renewal of an existing ICR that is scheduled to expire on October 31, 2018.

The Society of Chemical Manufacturers and Affiliates (SOCMA), the Color Pigments Manufacturers Association (CPMA), and the American Chemistry Council (ACC) responded to the Federal Register notice (83 FR 36928, July 31, 2018) announcing EPA's intent to submit the ICR renewal for Partial Update of the TSCA Section 8(b) Inventory Data Base, Production and Site Reports (Chemical Data Reporting) to OMB. A summary of their comments and EPA's responses are contained herein.

Public Comments

Society of Chemical Manufacturers and Affiliates (SOCMA)

{The complete comment can be found in docket EPA-HQ-OPPT-2017-0648}.

Comment Excerpt: **EPA must update the Section 8 small manufacturer or processor standards promptly.** Many manufacturers and processors within SOCMA's membership are small businesses, and as such, have a particular interest in EPA's revision of the CDR reporting requirements - namely, the TSCA section 8(a) standards for determining which manufacturers and processors qualify as small manufacturers and processors. To ensure that an update can be completed before the next CDR cycle commences, EPA should expeditiously initiate a rulemaking on these size standards. … the Agency's Spring 2018 Regulatory Agenda has deferred a proposed rule on the CDR size standards to September of this year and notes uncertainly that EPA "may include updates" to the standards. SOCMA is highly troubled by

these developments and by the Agency's lack of urgency regarding this matter. SOCMA, along with other stakeholders, have provided EPA with numerous comments in response to ICRs in 2016 and 2017 to assist the Agency in its update of the size standards. … These developments merit urgent action. EPA should promptly initiate a rulemaking to update its size standards for CDR, taking into particular account the most recent feedback provided to the Agency earlier this year in the TSCA user fees rulemaking.

> **EPA Response**: EPA appreciates these comments and the interest from SOCMA in revising reporting requirements for small businesses. As noted by the commenter, EPA's Regulatory Agenda describes a forthcoming action that will propose to revise the size standards for small manufacturers under section 8(a), including reporting under CDR. This follows the publication of a determination by EPA that revision of the section 8(a) size standards for small manufacturers is warranted in a Federal Register notice published November 30, 2017 (82 FR 56824). EPA's determination, supporting documents, and comments received can be found at regulations.gov under docket number EPA-HQ-OPPT-2016-0675.
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> While EPA will consider these comments in the context of development of the proposed rule to revise the size standards under section 8(a), EPA does not view these comments as providing a basis for modifying this ICR renewal.

Comment Excerpt: **EPA should re-evaluate the impact of the 2,500 lb. reporting threshold for chemicals subject to Section 5 orders or rules in light of the dramatic increase in such restrictions.** In addition to updating the Section 8(a) size standards, EPA should also begin reevaluating its existing reporting threshold for chemical substances that are the subject of Section 5 rules or orders. The lowering of the threshold from 25,000 lbs. to 2,500 lbs. for chemicals subject to legal restrictions occurred before the 2016 TSCA amendments, at a time when the roughly 90% of new chemicals passed EPA review without a consent order or Significant New Use Rule (SNUR). Now, approximately 80% of new chemicals result in a SNUR, meaning that a regulatory burden that was once being applied judiciously to chemicals raising particular concerns is now routinely being applied to virtually all new chemicals. As EPA itself admits, "Promulgation of a significant new use rule (SNUR) can be an effective and efficient way to address reasonably foreseen conditions of use about which EPA has concerns, as part of the basis for EPA to conclude that the chemical is not likely to present an unreasonable risk of injury to health and the environment under the conditions of use under section 5(a)(3)(C)." If EPA has decided that nearly all new chemicals entering U.S. commerce will be subject to the regulatory burden of a SNUR, it must reevaluate the reasoning by which it determined that the 2,500 lbs threshold was reasonable for chemicals subject to Section 5 restrictions. This will ensure that chemicals that "are not likely to present an unreasonable risk" are not subject to the same degree of reporting as chemicals that EPA has found "present an unreasonable risk" or are "imminently hazardous."

> **EPA Response**: EPA appreciates the comments regarding reporting thresholds for chemicals subject to section 5 rules or orders. EPA continues to have an interest in this lower reporting threshold for chemicals that meet the criteria set forth in 40 CFR 711.8(b), which includes those subject to a SNUR under section 5. For example, in

accordance with TSCA section 6(b)(1)(A), as part of risk evaluation under section 6, EPA is required to consider the conditions of use, including significant changes in conditions of use, and the production volume, including significant changes in production volume.

EPA uses the data reported pursuant to the CDR rule to support health, safety, and environmental protection activities related to chemical manufacturing and use. Manufacturing, processing and use information about chemicals in commerce helps EPA understand exposure to these chemicals and screen and prioritize chemicals to identify potential human health and environmental effects. EPA uses the data reported under the CDR rule to support many activities under TSCA and to provide overall support for EPA and other federal, state, local, and tribal health, safety, and environmental protection activities ((83 FR 36928), July 31, 2018 (EPA-HQ-OPPT-2017-0648)). The 2,500-lb. reporting threshold for these chemicals of interest contributes to the support of these activities.

While EPA recognizes the commenter's strong interest in changing the lower reporting threshold, there is no information provided that provides a basis for modifying this ICR renewal. EPA agrees that this issue merits discussion in view of the modifications to section 5 under the Lautenberg amendments, and will consider these comments as part of the Agency efforts to update the CDR rule more broadly.

Color Pigments Manufacturers Association (CPMA)

{The complete comments can be found in docket EPA-HQ-OPPT-2017-0648}.

Comment Excerpt: EPA should not continue to use the CDR to collect information on chemicals and processes which cannot reasonably be anticipated to pose a hazard of concern. There is simply no benefit to continuously collecting use and exposure information for these types of materials since exposures are limited to long established and regulated industrial processes. Furthermore, in many cases, these chemical substances are integrated into the matrices that make up the final product. This encapsulation dramatically limits or eliminates further commercial or consumer exposure. … Overall, we find no benefit commensurate with the costs of reporting under the CDR for non-hazardous substances which cannot reasonably be anticipated to cause an exposure of concern. Even if EPA is required to collect identification and volume data for these types of chemicals, there is no discernable benefit to requiring the additional reporting of manufacturing process, industrial use and consumer information. EPA should use its broad discretion with respect to CDR reporting to focus the CDR on fewer chemicals which represent a potential risk. For those chemicals which pose a potential risk and are subject to EPA risk evaluation, a more detailed data collection should include processors to more accurately approximate the entire chain of commerce.

EPA Response: EPA has carefully considered this comment and disagrees that there is no benefit to reporting under CDR for the substances described by CPMA. Under Section 6(b) of TSCA, as amended, EPA is required to prioritize and evaluate the risks of existing chemical substances. EPA uses the data reported to CDR to support health, safety, and

environmental protection activities related to chemical manufacturing and use. Manufacturing, processing and use information about chemicals in commerce helps EPA understand exposure to these chemicals and screen and prioritize chemicals to identify potential human health and environmental effects. As an example, data submitted under CDR was an important part of the scope and problem formulation documents for the first ten chemicals undergoing risk evaluation under section 6(b).

CPMA asks that EPA focus the CDR on fewer chemicals that represent a potential risk. A determination of risk, however, is made after an evaluation of a chemical substance's hazard and exposure to determine whether the chemical presents risk. The prioritization and risk evaluation processes under TSCA section 6 are EPA's primary means for determining whether an existing chemical substance merits risk evaluation or poses potential risk. Through the prioritization process, chemical substances are designated as either high-priority or low-priority for risk evaluation. However, low-priority designations are not necessarily indications of safety, but rather that the chemicals do not meet the "may present risk" standard for a high-priority designation. As such, there is reason to believe that EPA may still find value in CDR information for low-priority chemicals because there is the potential that EPA may have interests in these chemicals beyond the risk evaluations conducted under TSCA. For example, CDR information can be used to determine if the exposure conditions change. In addition, there are many other uses of CDR information, as described in the ICR, that may involve chemicals other than those designated as high priority.

CPMA may be interested in the petition process for chemicals for which an individual believes the CDR processing and use information to be of low current interest to EPA. If such petition is granted by EPA, then manufacturers of the chemical substance would be exempt from reporting the processing and use information required by CDR. A petition for this kind of partial exemption from reporting may be submitted by any person, regardless of whether the person manufacturers, imports, or uses the chemical, or is otherwise interested in the chemical. When evaluating the petition, EPA will consider the production volume and use information for all manufacturing or importing sites and all uses. The considerations used by EPA when deciding whether to grant the petition are listed at 40 CFR 711.6(b)(2).

In its comment, CPMA also suggests that for chemicals subject to EPA risk evaluation, a more detailed data collection should include processors, in order to more accurately approximate the entire chain of commerce. EPA intends to use information reasonably available to the Agency as part of the prioritization and risk evaluation processes. Currently, CDR provides the production volume, the production volume over time, and changes in the volumes under different conditions of use. Such longitudinal information contributes to improved understanding of the chemical, including during the prioritization process. EPA agrees that more detailed information on chemicals undergoing risk evaluation may benefit EPA's evaluation of such chemicals. EPA continues to consider all available tools to get the most relevant information on chemicals undergoing risk evaluation.

American Chemistry Council (ACC)

EPA Overall Response: EPA appreciates the detailed and thoughtful comments from ACC regarding the CDR reporting experience and the specific challenges encountered by reporters using the e-CDR web tool, particularly during the 2016 submission period. While EPA does not find the comments from ACC to provide a basis for modifying the burden estimates or other components of this ICR renewal, EPA would like to respond to the detailed feedback provided and explain what steps will be taken to improve the reporting tool for future submission periods.

Comment: **The e-CDR web tool**

The e-CDR web tool requires significant upgrades for a variety of reasons in order to ensure a less burdensome, more accurate CDR reporting process.

First, the web tool was difficult to use for an average user, and too slow for reporting sites with a high number of chemical substances to be reported. For example, for each chemical substance, the tool opens four separate web pages, taking minutes to load each time.

> **EPA Response**: EPA appreciates the comment from ACC on this regard, and recognizes that this feedback has been provided by several commenters through multiple venues outside this comment period. EPA has been making efforts to improve the user experience to the e-CDR web tool; submitter feedback is essential to further improvements.
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> EPA would like to note that during the 2016 reporting period, two events occurred that affected the response or speed of the application and submission process:
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> - An outside entity or user was continuously querying the Substance Registry Services (SRS) website, which is used to identify the chemical substance being reported. This continual querying interfered with data transfers between the site and the e-reporting form by the eCDRweb application during data entry and validation. This issue has been addressed.
> - The vast majority of submitters waited until the final two weeks to complete and submit their data, which resulted in the use of the application during this time was much higher than ever previously monitored.
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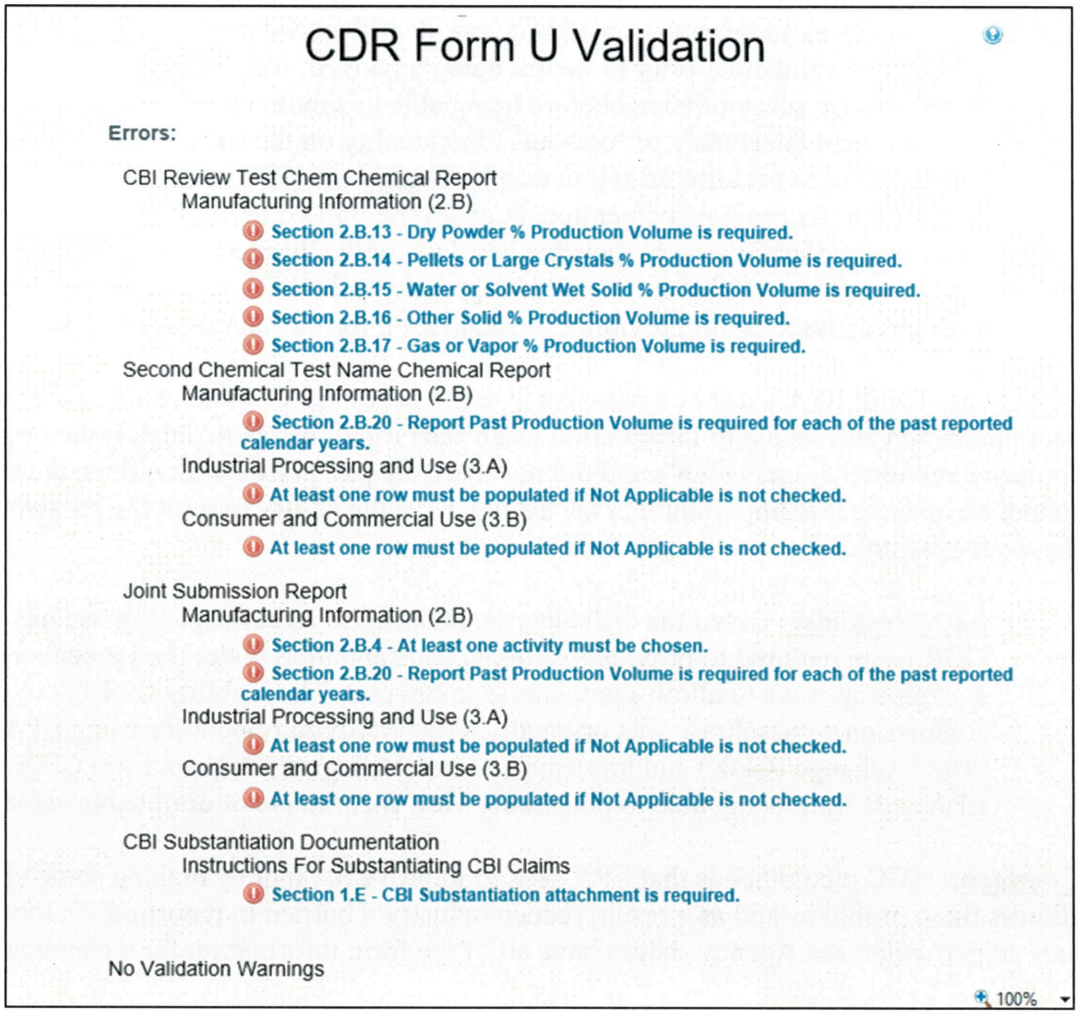
> For the 2020 CDR reporting period, EPA plans to address these items by streamlining the reporting process and updating the application platform to operate more efficiently.

Comment: Once each page loads the volume of information required to fill out the validation forms, page time-outs resulted. Once those validations were completed, the system did not identify the actual chemical that had associated errors. Throughout this process, navigating within the form was difficult, and time consuming because advancing between the pages of the form was delayed.

EPA Response: EPA will examine ways to address this issue with the application and will update the User Guide and instructions with information about how to change the period of inactivity for common browsers.

Regarding the user experience with the application validation not identifying specific errors within the application, it is likely that the user's pop-up blocker interfered with the application validation. During the validation process, the application creates a pop-up window identifying each error with a link that takes the user to that specific page (see example below).

EPA will update the User Guide and instructions to regarding how to turn off the pop-up blocker for common browsers.



Comment: Second, recent additions to the tool such as the CBI substantiation summary do not work correctly. For example, the summary does not identify the elements of the submission that require substantiation.

EPA Response: EPA will update and improve this process for the 2020 reporting period. Given the limited timeframe for implementing the substantiation updates to the applications, limited functionality was included.

Comment: Additionally, while substantiation for chemical identity is built into the application, it does not always work correctly; the application does not always acknowledge that a user has provided CBI substantiation and may not validate the submission. For users uploading 300 or more chemical substances, this process is extremely tedious and time consuming.

EPA Response: EPA plans to include improved functionality for the 2020 reporting period. During the 2016 reporting period, a bug in the eCDRweb reporting tool was identified that allowed users to bypass the embedded chemical substantiation questions. This issue was addressed soon after it was identified. Submitters who were able to bypass the built-in validation, prior to the fix being deployed, were required to go back and provide those substantiations before being able to submit or resubmit. When dealing with the document attachment or 'opt-out' functionality on the substantiation screen, a user was required to perform an action despite already providing substantiation within the application. As previously mentioned, given the limited time available to update all reporting applications to support the new law, only a limited amount of functionality could be made available for the 2016 reporting cycle. EPA was unaware of any other widespread issues with providing substantiation for the submissions.

Comment: Third, EPA's use of a passphrase that Agency staff cannot reset causes problems in communication and access to information when staff roles change or shift. If the original company submitter is unavailable and did not share the passphrase with others, the submission cannot be opened. It is important that the agency have the ability to reset the password those these submissions.

EPA Response: Given the difficulty the inability to reset the passphrase has caused to CDR users required to provide additional substantiation under the Lautenberg Act, EPA is exploring ways to allow a passphrase to be reset. The inability for EPA to reset a submission's passphrase was originally a security requirement for using EPA's Central Data Exchange (CDX) and implemented in response to a request from CDX users to keep EPA staff from being able to potentially view incomplete or draft submissions.

Comment: ACC recommends that EPA seek to improve the tool by making some changes to address these problems and as a result, reduce industry's burden in reporting via the e-CDR web tool. In particular, the Agency should have all of the form information for a chemical substance on one web page, instead of four pages in order to save time entering data and clicking between each page. With this change, the tool should run faster, and pages should load faster from the user's perspective, while avoiding crashing.

EPA Response: EPA appreciates the interest from ACC and its members in improving the tool and the CDR reporting experience. In response to these comments, EPA will investigate updating the application to a new platform which should improve the speed

and flow of the data entry. EPA will also look at the layout of the pages to reassess the data entry process.

Comment: The XML Schema

ACC members have found that in comparison to the inventory reset reporting, which was Excel based, the XML schema made it more difficult to correct informational errors, track submissions, and edit the data. Furthermore, the size of some xml files led the CDX site to crash, and would not allow the upload to go through. These issues were exacerbated by late release of an operational schema. EPA should work to release a working and validated XML template ahead of the submission window to provide time for submitters to familiarize themselves with the schema and submit the necessary information without encountering errors.

EPA should allow users to utilize a Microsoft Excel based format. In addition, the system should allow multiple uploads for a particular reporting side, and allow partial uploads of information without overwriting prior uploads. This would decrease wait time and reduce the likelihood of crashing the application.

> **EPA Response**: For the 2020 reporting period, EPA is examining new ways to allow users to populate their forms more easily, including pulling information from the previous reporting period to pre-populate the new submission. EPA will review all routes to improve the data upload process.

Comment: Central Data Exchange User Experience

ACC members have discovered challenges in uploading data through the Central Data Exchange (CDX). Generally, submitting data through CDX involves long wait times when submitting a large number of reportable chemicals. Notably, the CDX transaction number generated is difficult to link to the actual form submitted. EPA should make this process easier and update the system to operate more efficiently, and alter the transaction IDs so that those numbers indicate the type of submission (CDR/PMN/Inventory NOA).

> **EPA Response**: EPA regrets the long wait times, particularly for submissions of large numbers of chemicals. As described earlier, during the 2016 reporting period, two events occurred that affected the response or speed of the submission process. The first was that an outside entity or user was continuously querying the SRS website. This interfered with data transfers between the site and the e-reporting form by the eCDRweb application during data entry and validation. That issue was addressed once it was identified. The second issue was that the expected volume at the end of the submission period exceeded EPA's predictions, likely due to the Lautenberg amendments to TSCA requiring submitters to take more time to ensure accurate reports or to revise previously submitted information to comply with the new law's substantiation requirements. The higher than normal usage is not expected for the next reporting cycle. Nevertheless, for the 2020 CDR reporting period, EPA plans to address these items by streamlining the reporting process and updating the application platform to operate more efficiently.

EPA understands that the Transaction ID may not be the easiest method for identifying a submission. Unfortunately, the Transaction ID is generated during the CROMERR submission process which is not submission-specific. EPA will explore adding explanatory information into the notification emails that are sent to the submitter's CDX email, such as site name and submission type, to make those submissions easier to identify.

Comment: EPA's Burden Cost Estimates

ACC member company experience with the CDR reporting process has generally been that the hours and chemicals per submission required of even experienced users is higher than EPA's stated estimates. However, ACC recognizes that not all user submissions are complex; some may involve only one or two chemicals. EPA should revise its burden cost estimate to clarify the level of effort expended by submitters with significantly more than 7.5 chemicals per submission. For example, EPA should provide separate burden estimates for submitters with 5, 10, 50, and 100 chemicals in a submission. These more granular estimates would explicitly take into account the widely varying burden that submitters may experience during the CDR reporting periods.

EPA Response: While EPA understands that submitters would prefer to identify burden on an individualized basis, the purpose of this ICR is to quantify the overall burden for reporting to CDR. EPA has estimated that the average submitter has 7.5 chemicals per submission and EPA uses the concise metric to obtain the total burden. Due to the diversity of situations when reporting to CDR, with burden related-factors measured and unmeasured, it is problematic to break out burden into smaller increments because the methodology is designed to provide total burden estimates. Such an exercise creates the potential for misapplication of the estimation method, and can also create a false sense of precision. EPA anticipates that submitters will be able to estimate their expected burden based on the number of chemicals in their submission using information provided in the ICR, but such granular estimates are outside of the scope of this ICR.

Comment: CDR and CDX applications are burdensome to use because the application is cumbersome, and information uploads and downloads can impose significant wait time on the user. This burden is exacerbated for new or inexperienced submitters unfamiliar the system, and in particular, with new CBI substantiation requirements. The agency should not assume that each submitter will be familiar with the reasons why the 2020 CDR will have more elements requiring substantiation, and should make the reasons for requiring that substantiation clear and available within the application. Particularly, in CDR submissions where a company is submitting information on hundreds of chemicals, the submitting company will now need to manually review the individual components of those submissions for substantiation. The agency should also create a public webpage explaining the CBI substantiation requirements in advance of the submission period so that submitters may familiarize themselves with the process and what level of substantiation is required for each element.

Furthermore, member companies have found that a significant burden arises where submitters are forced to re-substantiate elements in their CDR submission even if they have already provided that information elsewhere. Currently, the CDR application will not allow users to

continue a submission without providing substantiation. The Agency should implement a function within the CDR application so that the application will know whether the submitter has already provided substantiation for a particular element.

Finally, members have also found an increased burden in answering notices of deficiency where those notices are sent only to CDX inbox emails. This requires submitters to check additional email accounts, resulting in a significant burden for companies with large numbers of submissions. The Agency should send notice of deficiency emails to both the submitter's regular email and the CDX inboxes.

EPA Response:

EPA recognizes that many submitters will not be familiar with changes to the 2020 CDR elements requiring substantiation, and plans to engage with submitters through numerous means to prepare them for those changes, as well as to help submitters become more acquainted with the submission process in general. For the next submission period, EPA will update the CDR Instructions, website, and other sources of information helpful to CDR submitters. The updates will include information about substantiation requirements for confidentiality claims.

Because the eCDRweb reporting tool was built before the Lautenberg amendments to TSCA were enacted in June 2016, EPA was limited in its ability to update the application to support the collection of substantiations in a timely manner. The reporting tool was updated to require that a submitter either opt-out of providing additional substantiation (if all data was substantiated already) or attach a document substantiating all other CBI claims. EPA plans additional updates before the next submission period, and believes many of the concerns related to the substantiation and deficiency notice process will be addressed by these updates.