

May 1, 2020

Meredith Williams, PhD
Director
Department of Toxic Substances Control
1001 I Street
P.O. Box 806
Sacramento, California 95812-0806

SUBJECT: Response to Public Comments on Alternative Analysis for Two Component Low- and High-pressure Spray Foam Systems Containing Unreacted MDI.

Dear Dr. Williams:

This letter outlines the Responsible Entities' (REs) consortium response to the public comments received by the California Department of Toxic Substances Control (DTSC) on the REs' Abridged Alternative Analysis Report (Report) for two-component low- and high-pressure spray foam insulation systems containing unreacted MDI (dated August 23, 2019). We note that DTSC has provided its own interpretation of the comments received, which in some cases appears to differ from what we perceive to be the public commenters' intention. For completeness, below we show the original public comment in numbered italic text followed by a summary of the Agency's interpretation in non-italic text and then our response.

DTSC opened two comment periods on the consortium's Abridged Alternative Analysis Report. One comment period for the REs that submitted the report in August 2019 and a second comment period for Rhino Linings' submission of the Report in November 2019. For simplicity, we have responded to all of the public comments in the revised Abridged Alternative Analysis. Accordingly, this letter and the revised Report include a response to the comment that DTSC requested from the Consumer Product Safety Commission.

Please contact me with any questions at 202-249-6617 or at stephen_wieroniey@americanchemistry.com.

Sincerely,



Stephen Wieroniey
Director

Attachment

Commenter – Natural Resource Defense Council

1. *“Making Affordable Multifamily Housing More Energy Efficient: A Guide to Healthier Upgrade Materials—for the record, our research highlights a robust analysis on alternatives SPF systems with unreacted MDI. Natural Resources Defense Council and Elevate Energy in collaboration with The Healthy Building Network (HBN), Vermont Energy Investment Corporation, Three3, and the International Living Future Institute. The Report offers a comprehensive and accessible compendium of alternative, safer products. Please see, Table 2 on pages 20 and 21 of the attached report for full list alternatives.”*

DTSC requested that more information be provided as to why the identified materials are not included as alternatives in the AA. These materials are cellulose, cork board, fiber glass, mineral wool, polyiso, expanded and extruded polystyrene.

Response: The comment does not request additional information from the REs. However, DTSC requested additional information. The Priority Product was defined as "spray polyurethane foam systems," not insulation generally. Therefore, it is the REs' position, as stated in the original report (Section 4.3), that the AA only needs to consider alternatives that are sprayable polyurethane. Although the REs believe DTSC has narrowly defined the product, thus effectively eliminating any requirements to review competitive insulation products, for completeness, the original report included a review of other insulation products, such as the ones mentioned by DTSC, except for cork board. We did not include a review of cork board insulation for walls and ceilings because it is relatively new and not commonly used in residential and commercial buildings for these purposes. Further, DTSC's "Alternatives Analysis Guide" (CalDTSC, 2017a) indicates that REs are not required to consider alternatives that fall outside their business manufacturing model (CalDTSC, 2017a, p. 26).

In response to DTSC's interpretation of the comment, the report has been revised to expand on the existing discussion of why non-spray polyurethane foam products do not meet the definition of the product at 22 CCR Chapter 55 §69511.2 and are outside of the REs' current business practices. These products are not appropriate alternatives for evaluation per the Safer Consumer Products (SCP) regulations. The REs did not change their position on cork board insulation.

Commenters – Clean Water Action (CWA), Breast Cancer Prevention Partners (BCPP)

2. *“This AA does not examine other materials that can fulfill that same function; nor does it articulate under what conditions, in exactly which applications, and for what reasons the alternative materials named in the DTSC Revised Priority Product Profile (September 2014) do not constitute viable alternatives.”*

Again, DTSC requested more information be provided as to why the identified materials are not included as alternatives in the AA.

Response: As noted above, it is the REs' position that non-spray polyurethane foam products are not alternatives within the scope of DTSC's rulemaking for this Priority Product. The reported materials can fulfill some but not all of the functions currently provided by pMDI-based polyurethane spray foam insulation. The report has been revised to expand on the existing discussion of why non-spray polyurethane foam products are not appropriate alternatives for evaluation per the SCP regulations.

3. *“the AA could have, and our view should have, analyzed in which applications and circumstances these other materials could be substituted for spray polyurethane foam, thereby reduce hazardous exposures.”*

DTSC requested that more information be provided on alternatives that may reduce exposure or discussion of why such products are not alternatives to be included in the AA.

Response: The commenters and DTSC appear to be asking somewhat different questions. The commenters are asking about non-spray polyurethane foam alternatives in various applications whereas DTSC seems to be asking

specifically about alternatives (presumably those including MDI) that could reduce exposure. Concerning the commenters' question, as already stated, the report has been revised to expand on the existing discussion of why non-spray polyurethane foam products are not appropriate alternatives for evaluation per the SCP regulations. Further, the REs believe that any alternative must match all the performance requirements of spray polyurethane foam (SPF). The SCP regulations do not require the REs to identify and recommend alternative materials that only match some individual performance characteristics of SPF products. Although DTSC has previously rejected engineering controls as an option to protect workers, a discussion of alternative technologies that could reduce exposure potential was in the original Report, but has been expanded.

4. *"the AA did not provide any justification as to why these other materials are unsuitable; instead, the materials were dismissed out of hand."*

DTSC requested that more information be provided on why these products are unsuitable for evaluation in the AA.

Response: Again, the report has been revised to expand on the existing discussion of why non-spray polyurethane foam products are not appropriate alternatives for evaluation per the SCP regulations.

5. *"The AA also did not consider options to reduce the level of unreacted MDI in spray polyurethane foams or other ways to reduce exposures to workers and consumers. The result is a perfunctory review that provides little added value to SSCP's goal. By contrast, a thorough detailed comparison of the strengths and weaknesses of other materials relative to SPFs would have been a constructive contribution."*

DTSC cites the relevant part of the SCP regulations concerning alternatives that reduce exposure and mentions pMDI, the Profill system, and a "BASF nozzle" as examples that should be discussed.

Response: The commenters seem to expect that the AA would speculate on, or investigate, new technologies for reducing exposure to MDI. Speculation alone would not be sufficient to serve as a basis for recommending a regulatory action. A research investigation of alternative technologies could be conducted as part of an alternatives study, but this is not part of an AA as defined by the SCP regulations, which limit the AA to existing information that is publicly available.

DTSC mentions several products including pMDI, Profill, and a "BASF nozzle" and requests a "robust discussion" of possible product changes designed to reduce exposure. Although DTSC has previously rejected engineering controls as an option to protect workers, a discussion has been added to the revised Report (Section 4.4.2). In brief, the MDI used in current SPF systems is pMDI, which consists of a blend of molecular weights/chain lengths of MDI, monomeric and oligomeric forms. Moving towards higher molecular weight versions of MDI would inherently decrease the expansion and increase curing time leading to a product incapable of fulfilling its intended purpose. The Profill product was discussed in the original Report (in a footnote); this discussion has been expanded in Section 4.4.2.1 in the revised Report. The BASF nozzle applies polyurethane foam as a froth, similar to low pressure SPF. Currently, this nozzle related equipment (i.e., AutoFroth®) is primarily used for insulation applied in a factory (e.g., during refrigerator or freezer manufacture). The equipment used to apply the foam is heavy and difficult to move. Additionally, the gun is generally mounted to other equipment to assist with moving. These limitations do not make it an ideal product for field application since applicators typically hold the spray gun for extended periods of time. According to BASF, AutoFroth® has not been used as insulation for commercial and residential walls, basements, and roofs to date and more research is needed in order to adapt said technology for these purposes. This information has been included in the revised Report.

6. *"The ACC-SFC's Alternatives Analysis report argues that performance and cost are critical elements for an initial AA and should be an early consideration within the process; however, they were unable to include this analysis due to lack of information on potential spray foam alternatives [page 20]. From our*

perspective, lack of information on alternative foams makes it all the more important to undertake a full comparison of the alternative materials, which the ACC-SFC elected not to do.”

DTSC requests additional information on performance and cost to justify the statement that there are no suitable alternatives available.

Response: As stated in the Abridged AA, the identified alternatives that may be a possible replacement for MDI-based polyurethane spray foams are not commercialized. There is very limited publicly available performance data (summarized in patents only) and not the full set of testing that would be required to determine if they are appropriate replacements. The minimum set of performance tests required have been added to the discussion of each non-MDI alternative. The SCP regulations do not require REs to generate new information. Moreover, if additional information is available, it is likely proprietary to each company and thus not available for consideration. Companies evaluate potential formulations and technologies as part of their product development programs and, as shown by the patents discovered, cost, along with poor safety profiles and other factors, frequently make an alternative technology non-viable in the market place, forcing it to remain non-commercialized. It is possible that cost played a role in the decision to not bring the research products noted in the AA to market. As they are not yet commercialized, there are no useful, publicly available, data on costs. Regarding performance data, the REs included a table in the original and revised Reports on what performance information would be required compared to information in the patents to demonstrate the lack of sufficient data for non-MDI SPF materials. Exposure data relating to Profill have been added to the revised Report.

7. *“Finally, contrary to the ACC-SFC’s position, the lack of already commercialized alternatives to MDI for foams is not a reason to shut the AA process down, especially since in order to become commercialized, the suppliers of new materials must work with foam manufacturers to develop new products and markets. Foam insulation producers should work with material innovators in this field to fully explore foam compatible materials under development, when and how it might come to the market, and the potential of making their finished product safer in order to stay on the market in California.”*

DTSC requests that the REs include “known alternatives that have not been commercialized and the information considered to evaluate these alternatives.”

Response: The commenters appear to be requesting a research program to explore alternatives (“work with material innovators in this field to fully explore ...”). AAs under the SCP regulations are tools to compare existing products and, in circumstances where a comparison is not possible, the regulations allow DTSC to require REs to conduct research after AA process. DTSC appears to be requesting patent information, which is the information that was provided in the original Report. In response to the comments above, we documented our information gathering approach, including patent searches and RE queries to see if other patents are available. This information has been included in Section 4.4 of the revised report.

Commenter – Toxic Use Reduction Institute (TURI)

8. *“{A}lternatives assessments are designed to include consideration of the full range of alternatives to a process or product, ranging from drop-in substitutes to adoption of safer technologies or processes. We understand that the responding entities may have been limited in part by the narrow focus of the priority product profile. However, it is important not to lose sight of the larger picture: safer alternatives exist for many applications of polyurethane spray foam, and adoption of those safer alternatives wherever practicable would help to protect workers and the public from preventable disease and disability. In TURI’s work to assess alternatives, we are careful not to limit the discussion to a single technology; rather, we begin with a broad consideration of the cases in which the material is used and the full range of alternative products and processes that are available.”*

As above, DTSC requests the REs consider the full range of alternatives and provide more information as to why the identified materials are not included as alternatives in the AA.

Response: DTSC has narrowed the scope of the Priority Product designation from all polyurethane spray foams to only two- component spray foams. Moreover, the designation is focused on spray *polyurethane* foams used for building insulation, not the “many applications of polyurethane spray foam.” DTSC has asked for an AA of a specific product and it would not be responsive to the regulatory requirement to conduct a broad AA of the entire spray foam industry. As noted above, revised Report has been expanded to explain why non-spray polyurethane foam technologies are outside the scope of the AA.

9. *“We were surprised that the assessment of acceptable/feasible alternatives was rather limited. Many of the responsible entities are themselves formulators. Therefore, it is not clear why the search for alternatives was limited to existing formulations.”*

DTSC notes that although the SCP regulations do not require the responsible entity to create new data or formulations as part of the AA process, DTSC request the REs to provide information on potential formulations being researched which may assist in recommending possible Regulatory Responses (Cal. Code of Regs., tit. 22, § 69505.7(k)(2)(B)).

Response: We are puzzled by this comment. The AA clearly included a discussion of patents that have been filed for alternative formulations which represent the “potential formulations being researched.” We have expanded the patent search in section 4.4 of the revised Report to include the patent search criteria we used in the Abridged AA Report.

10. *“The title of Table 5.1 states, “Does Not Represent Hazard or Risk Associated with Final Product(s)”. This wording is misleading since the final products are not tested for hazard. In addition, the wording introduces the concept of risk, which is not the focus of the assessment. It is important to be clear that ingredient information is the source for understanding inherent hazard.”*

DTSC suggests leaving the first half of the title “Table 5.1: Data for Relevant Factors – Ingredients-specific Hazards (Primarily from Pharos)” and deleting the second half of the title “does not represent hazard or risk associated with the final products” by moving it into the discussion section instead.

Response: We understand TURI’s comment, yet it is a fact that the hazard of the final product may not be reflected by the hazards of its ingredients. As a neat material, MDI is a respiratory and dermal sensitizer while the reacted and cured foam is polyurethane, which does not contain MDI and is not a sensitizer. We believe it is equally misleading to leave readers with the impression that hazards of ingredients translate into equivalent hazards of final products. Second, TURI’s comment regarding risk directly contradicts prior DTSC statements that risk IS a part of the Alternative Analysis process (note the concept of alternatives analysis vs. assessment). We have moved “does not represent hazard or risk associated with the final products” to a footnote and, as DTSC suggested, added the concept that ingredient hazards do not represent hazard or risk associated with the final products in the discussion section.

11. *“There may be more flexibility in certain functional requirements than has been acknowledged in the abridged alternatives assessment. For example, specifications for slump and cure time are designed around the existing polyurethane foam products. These specifications may be important in many applications, but other specifications could also be effective for many applications. For example, a different material could be used to serve the same functional use with a somewhat longer cure time, if the material is less prone to slump.”*

DTSC requests a more robust discussion on the Priority Product’s functional requirements along with performance attributes and other applicable efficacy requirements.

Response: We agree that specifications for current SPF may not be entirely applicable to alternatives, but because there are no viable alternatives, how these might change cannot be known. However, the existing functional requirements and performance attributes of SPF are described in Section 3.6 of the revised Report. Clearly, if an alternative has different properties (slower curing, but less slump potential) it would make sense that it may require different specifications to achieve the same level of ultimate performance.

12. *“Even without considering alternative formulations, the responsible entities could have provided valuable information by considering ways to reduce the total amount of unreacted MDI in the product. This is an important component of the analysis, given that the regulation was written to focus on unreacted MDI specifically. There is room for improvement in processing and installation of MDI-containing spray foam polyurethane insulation. To the extent that the responding entities are unable to identify any safer alternatives, it would be helpful to see more information in the assessment about ways they are working to improve their products and equipment to address the on-going hazard. It would be helpful if the responding entities provided information on how they plan to protect workers from on-going health hazards and how they will employ green chemistry techniques to improve upon their existing product.”*

DTSC notes that reformulation or redesign to reduce or eliminate the concentration of Chemicals of Concern is an option that must be addressed under the SCP regulations. DTSC requests further information on whether this type of information is available. And if available, DTSC requested justification why potential alternatives are not functionally acceptable, technically feasible, and economically feasible.

Response: The revised Report includes a new section, section 4.4.2, which discusses products and patents focused on lower MDI exposure, including ProFill and the “BASF nozzle.” The REs are unaware of any other technical research related to exposure reduction (but note the extensive applicator training and certification that the industry provides). The commenter seems to expect that the AA itself would speculate on, or investigate, new technologies for reducing exposure to MDI. A research investigation of alternative technologies could be conducted as part of an alternatives study, but this is not part of an AA as defined by the SCP regulations, which limit the AA to existing information that is publicly available. Speculation alone would also not be sufficient to serve as a basis for recommending a regulatory action (the intended outcome of the AA).

13. *“The responsible entities appear to have relied upon simple internet searches of product specifications, supplemented by a search of patents for available documentation. This superficial level of research would miss what is likely a rich set of innovative solutions being developed by some of the RE’s. For example, two patents identified are from Dupont, a member of the applicant consortium and a company that is widely recognized for its innovative materials research. At a minimum, additional information could have been provided on these products.”*

DTSC requests a discussion of the two DuPont patents and any other applicable patents and the rationale for excluding these patents for further consideration.

Response: In the original Report, we noted that members were queried about patents and other research that had been conducted in the past. This questioning of REs led to many of the patents identified in the original Report. In the revised Report, we have expanded the patent search section to include the patent search criteria we used in the Abridged AA. Additionally, the revised report contains a new section, section 4.4.2, which discusses products and patents focused on lower MDI exposure.

14. *“In addition, information on the timing of commercial availability would be useful. Commercial availability is dynamic, and is often determined by market demand. If the formulation can or will be available within weeks, months, a year, or more, for example, this information should be included.”*

DTSC notes that the commercial availability of patented products should be discussed further to support the statement that these products are not suitable alternatives for assessment.

Response: Inquiries with the relevant REs did not provide any information concerning the timing for commercialization of these products .

15. *“The responding entities have noted limitations due to Safety Data Sheets (SDSs) not being available. It is not clear to us why a full SDS would be subject to CBI protections. We would expect that if necessary, the SDS could be redacted to remove customer information, for example, and could be reviewed. In order to complete a valid hazard assessment as part of a broader alternatives assessment, it is necessary to obtain and take account of any available hazard and constituent information.”*

DTSC requests the REs review California Code of Regulations, §69507(a) and §69509 regarding trade secret claims and submit the required information.

Response: It is not clear which SDSs are being referred to in the comment. For the non-commercial patent-related formulations, compositions are not fixed and SDSs would not be available; SDSs are only required for commercial products. We inquired with the REs who hold the patents and they confirmed no SDSs are available for the Canary, Dow, and DuPont patents. This detail was added to the revised Report. For existing products (i.e., those subject to the regulation), in some cases SDSs may reveal confidential business information (supplier-customer information), but the technical information on the SDSs (i.e., chemical identities) can be disclosed. The manufacturer(s) who did not submit SDSs due to CBI concerns will resubmit SDSs according to the SCP regulations.

16. *“While we recognize the challenge of summarizing toxicity information in a summary table, noting whether a hazard endpoint was “discussed” or “not discussed” in the Hazardous Substances Data Bank (HSDB) is not informative. If the toxicity of a given endpoint is described in HSDB, it should be characterized in the assessment. Simply mentioning that a database “discusses” an endpoint is not sufficient and would not, in general, be considered a good faith effort to assess hazard.”*

DTSC requests “toxicity endpoint information” from HSDB that was used to assess the relevant hazard endpoints.

Response: We note that the commenter and DTSC appear to be making different requests. The commenter is apparently requesting a full discussion (i.e., a toxicological profile) for each of the 20 plus health hazard endpoints required by the SCP regulation. Doing so is incompatible with the “easily understood matrix” concept of the SCP regulations. Moreover, it makes little sense to devote the effort to evaluating the hazards of alternative ingredients that will not be carried forward. DTSC is requesting the information that forms the basis for the discussed/non-discussed evaluation. In the revised Report, we replaced HSDB as a data source with ECHA dossiers, US EPA or Australia IMAP framework reports for the Group B endpoints. We also included a qualitative description of the effects (or lack thereof) observed.

17. *“The responding entities also state there are “data gaps” in cases in which information is readily available. For example, a google search of “aquatic toxicity and MDI” shows multiple citations/sources for this information.[1] We have not fact checked all of the entries, but on a first pass, they do appear to be incomplete.”*

DTSC notes that aquatic toxicity has to be evaluated for relevance under the SCP regulations.

Response: The commenter appears to be requesting an exhaustive literature review, which as noted above, may not be relevant for all alternatives. It is also important to evaluate all alternatives using the same approach/methods. The first hazard table using Pharos only (Table 5.2) does list “data-gap” for aquatic toxicity under MDI, however, the supplemental hazard table using ECHA dossier (Table 5.3) reports “Not classified” for

MDI due to the available data suggesting no hazard. The updated Table 5.2 also shows more information regarding the Group B endpoints, as noted above.

18. *"In addition, it is surprising that the consortium did not conduct a supplemental literature review (beyond noting that HSDB "discussed" an endpoint of interest). In TURI's experience, additional literature reviews are especially necessary when evaluating novel materials, such as those that may be relevant when developing innovative formulations."*

DTSC notes that "supplemental literature reviews regarding novel materials" may assist the REs in recommending possible Regulatory Responses.

Response: See comment above. The REs believe that a full literature review of all health effects for chemicals in all candidates would be a misallocation of efforts. Such an in-depth review would be appropriate in a Stage 2 AA, if the identified possible alternatives had data to support a Stage 2 analysis. As noted earlier, this is not the case. However, in the revised Report, we replaced HSDB as a data source with ECHA dossiers, US EPA hazard characterization reports, or Australia IMAP framework reports for the Group B endpoints. We also included a qualitative description of the effects (or lack thereof) observed.

19. *"More generally, the hazard assessment is organized by information source, not endpoint. It would be more useful to understand a summary of the hazard assessment by endpoint."*

DTSC requests that the REs ensure that the referenced section is consistent with the requirements of the SCP regulations.

Response: As DTSC requested, the REs have reviewed the relevant section of the SCP regulations and have confirmed that the organization of the hazard information is consistent with what is required by the regulations.

20. *"In some cases, use of some color coding, rather than simple listing of the classifications, might also be helpful to support comparisons."*

DTSC requests that the REs ensure that the referenced section is consistent with the requirements of the SCP regulations.

Response: As DTSC requested, the REs have reviewed the relevant section of the SCP regulations and have confirmed that the organization of the hazard information is consistent with what is required. We did, however, add color-coding to Table 5.3 in the revised Report.

Commenter – Consumer Product Safety Commission

21. *"Through the Consumer Product Safety Risk Management System, CPSC has received reports of approximately 58 incidents regarding SPF installation in consumers' homes. The incidents reportedly occurred between January 2011 and January 2020."*

Residents have reported health effects, including severe respiratory irritation, breathing difficulties, dizziness, and nausea, occurring days to months after SPF installation in homes. In some cases, consumers reported that they were present during SPF application; and in other cases, consumers reported that they could no longer live in their homes.

Because many of these reported health effects persisted up to 2 years after the SPF was applied, we suspect that those diisocyanates, which react quickly, are not the sole cause of the reported health effects. As you know, emissions of other chemicals (amines, blowing agents, surfactants, flame retardants, or by-products of the reactions) from the SPF have been measured (NIST 2017). Because other chemicals besides MDI may be associated with toxicity following exposure to SPF, California may wish to expand the scope of priority product replacement for SPF to other chemicals, as well as MDI."

DTSC requests that the REs evaluate potential public health impacts to the general public of the various alternatives in relation to the CPSC comment.

Response: We note that the CPSC comment was filed only in connection with the Rhino Holdings AA, which was submitted to DTSC after the submittal by other REs. DTSC provided us with the original public comments on December 12, 2019 and provided this additional comment on March 17, 2020. The chief concern expressed by CPSC is that other chemicals in the products (i.e., chemicals other than the MDI which is the basis for the Priority Product listing) could be a health concern even after possible MDI exposure ceases when the foam is fully cured. Consistent with statements made above, the REs believe it would be a misallocation of resources to devote the time to creating full health hazard profiles of B side ingredients where products do not have sufficient data to evaluate them further as alternatives. This would not change the outcome of the AA, and the B-side of the product was not the basis for the listing.

The priority product listing is for unreacted MDI, which is only present in the A-side of the product and not the B-side of the product. That being said, in order to be responsive to the CPSC comment, we have created a new table, Table 5.1, which compares the A- and B-side composition of the various alternative formulations and reduced exposure products. As noted in the text discussing this table, all of the alternatives contain reactive chemistries and similar catalysts, flame retardants and blowing agents. All of the reduced exposure products contain the same chemistries as the current priority products. Most also contain at least one California Candidate Chemical. Thus all of the possible alternatives contain chemicals that will present similar concerns.