June 6, 2017

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Barbara A. Lee
Director
Department of Toxic Substances Control
P.O. Box 806
Sacramento, California 95812-0806

Re: Listing Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product (R-2016-04)

Dear Ms. Lee:

On March 22, 2017, the California Environmental Protection Agency's Department of Toxic Substances Control (DTSC) issued its proposed *Listing Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product* rulemaking under the Safer Consumer Products (SCP) program. The American Chemistry Council Diisocyanates Panel, and the Center for the Polyurethanes Industry's (CPI) Spray Foam Coalition, (hereinafter collectively "ACC") submit these comments to DTSC in response to the proposed listing.[1]

ACC strongly opposes the proposed listing because it is unwarranted and misdirected. It is based on inaccurate characterizations of spray foam products, ignores safety practices, and fails to consider exposure profiles associated with their use. DTSC has failed to satisfy regulatory requirements for listing under the SCP program. The proposal raises a variety of legal concerns associated with both the proposed listing and implementation.

[1] The Diisocyanates Panel represents the U.S. companies that manufacture or import methylene diphenyl diisocyanate (MDI) and/or toluene diisocyanate (TDI). The Panel is comprised of BASF Corporation, Covestro LLC, Dow, Huntsman Corporation and Wanhua Chemical (America) Co., Ltd. CPI's global membership includes raw material producers, systems suppliers, processing machinery and equipment manufacturers, as well as users of polyurethane materials that manufacture products made of or from polyurethanes. The Spray Foam Coalition represents 31 spray polyurethane foam systems houses and their suppliers in the U.S. and Canada.

We urge the Department to rescind the proposed listing immediately. We stand ready to continue discussions regarding stewardship alternatives. If you have any questions or need additional information, please contact Lee Salamone at (202) 249-6604, Lee_Salamone@americanchemistry.com.

Sincerely,

Lee Salamone
Senior Director
Center for the Polyurethanes Industry

Sahar Osman-Sypher
Director
Diisocyanates Panel

cc: Meredith Williams, Deputy Director, Safer Products and Workplaces Program
Karl Palmer, Chief, Safer Products and Workplaces Program

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I. Introduction

On March 22, 2017, the California Department of Toxic Substances Control ("DTSC" or "the Department") announced its proposed rulemaking to list *Spray Polyurethane Foam* ("SPF") *Systems Containing Unreacted Diisocyanates* ("Proposed Regulations") as a Priority Product under the Safer Consumer Products Regulations ("SCP Regulations"). Since March 2014, the American Chemistry Council Diisocyanates ("DII") Panel, and the Center for the Polyurethanes Industry's ("CPI") Spray Foam Coalition ("SFC"), (hereinafter collectively referred to as "ACC") have engaged with DTSC regarding the proposed listing. ACC appreciates DTSC's willingness to address some of the concerns associated with the release of the original Priority Product Profile, but we remain concerned about the mischaracterization of the products and the lack of reliable evidence for the proposed listing of the product.

These comments are provided by the SFC and the DII Panel. The SFC was established in 2010 to champion the use of spray polyurethane foam in U.S. and Canadian building and construction applications. The 32 members of the SFC promote the products' economic, environmental and societal benefits while supporting the safe manufacture, transport, and application of spray polyurethane foam. Systems house members of SFC would be considered "regulated entities" under the proposed listing.[2]

The DII Panel includes the U.S. companies that manufacture or import methylene diphenyl diisocyanate (MDI) and/or toluene diisocyanate (TDI). The Panel is comprised of BASF Corporation, Covestro LLC, Dow, Huntsman Corporation and Wanhua Chemical (America) Co., Ltd. Members of the ACC DII Panel manufacture and sell MDI to SPF systems houses.

II. Executive Summary

An insurmountable shortcoming of the proposal stems from the fact that the proposed regulations combine multiple unique products into an oversimplified product category – referred to as Spray Polyurethane Foam Systems. This overgeneralization ignores how the products are used and undermines the technical accuracy of the proposal. The proposal overlooks that each type of SPF product exhibits a different exposure profile given the specific use, chemical concentration, and application method. DTSC does not consider these different products and has not demonstrated that each separate SPF product meets the prioritization criteria for listing. The economic analysis anticipates just one abridged Alternative Analysis (AA), when it may not be possible to conduct an AA for a product category that has products with different performance attributes and exposure profiles.

The Initial Statement of Reasons (ISOR) for listing SPF Systems as a Priority Product under the regulations does not adequately justify how SPF Systems present the potential for "public and/or

[2] Initial Statement of Reasons (ISOR), pg. 13

aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product;" and "one or more exposures to contribute to or cause significant or widespread adverse impacts."[3] Even one of the Department's own peer reviewers called this determination into question. As this important regulatory standard is not met, there is no defensible rationale for regulating SPF Systems as a final Priority Product under the SCP regulations.

In making a decision to prioritize SPF Systems under the SCP regulations, DTSC has mischaracterized several studies and ignored significant product stewardship, safety recommendations, and industry practices that curtail potential exposure to MDI during the use of SPF Systems. In addition, DTSC has not provided reliable evidence that SPF Systems present the potential for significant or widespread adverse impacts. While the Department alleges that expanded use of SPF is resulting in increasing rates of work-related asthma from unreacted MDI in SPF Systems, this is not borne out by workplace asthma data provided by the National Institute for Occupational Safety and Health ("NIOSH") data nor by data presented by the California Department of Public Health. In fact, recent data show a decline in asthma rates associated with isocyanates and no cases attributable to unreacted MDI in SPF in California.[4]

The Department's suggestion of a prioritization scheme used to identify SPF systems and the conclusions regarding potential for exposure and adverse impacts appear to be the result of an arbitrary and capricious approach lacking an objective, scientific systematic process.

Due to the lack of accurate and reliable information supporting DTSC's conclusion that SPF Systems present "a potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product" *or* "a potential for significant or widespread adverse impacts," the Department must immediately remove SPF Systems from its proposed list of initial Priority Products.

The following comments provide additional information on SPF products, including but not limited to information on the product chemistry, product types and uses, health and safety data, and a detailed account of the industry-led research, product stewardship and training programs. The comments also provide information to correct the record on several of the inaccuracies appearing in the technical information and economic analysis provided by DTSC.

Finally, we point out that in several places (ISOR at 22; Economic Impact Statement), DTSC indicates its belief that the AA which will be submitted will be an Abridged AA. By this statement, DTSC concedes it believes there are no currently available alternatives to MDI in the manufacture of SPF now available on the market. Therefore, the AA process is simply an exercise, and is not anticipated to change the manufacture or use of SPF; the requirement to do an AA appears to be an unabashed attempt to garner an unspecified amount of research funding for "green chemistry alternatives" from the regulated entities and thus assumes that no other

[3] Cal. Code Regs. Title. 22 §69503.2(a)(2): § 69503.2.
[4] Work-Related Lung Disease Surveillance System (eWoRLD). 2015-851 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Respiratory Health Division, Morgantown, WV. Available at: https://wwwn.cdc.gov/eworld/Data/851. May 25, 2017.

research has already occurred or is occurring. Conducting an AA for a product with no alternative provides no justifiable benefit to public health, the State or regulated entities. DTSC can directly improve public health by reconsidering ACC's offer to partner with the State on increased education and training and other exposure reduction efforts.

III. Background on Product and the Industry

A. Description of the Products

The ISOR and Summary of Technical Information do not provide an accurate description of the major types of SPF Systems. Contrary to the proposal's outlook, there are different product categories for SPF – high-pressure (insulation and roofing), and low-pressure SPF Systems. Each of these constitutes a different product; they vary in their intended purpose, delivery system, applicator profile, and exposure potential. It is essential to recognize the differences among SPF products because their properties, uses, safety measures and potential exposure scenarios vary. We believe DTSC's failure to differentiate between SPF products results in a misdirected prioritization outcome, undermines the accuracy of the proposal, and has led to an underestimation of the compliance costs.

SPF is formed via an exothermic chemical reaction between approximately equal amounts of MDI and MDI-based isocyanates with a polyol blend, referred to as the A-side and B-side, respectively. The A-side is typically a mixture of 50% monomeric MDI and 50% polymeric (pMDI). The B-side, or resin, is a proprietary mixture of polyols and other chemicals that have specific roles in the reaction process or impart important characteristics to the finished foam insulation.

A detailed description of the multiple SPF products covered by this proposed regulation is included in Appendix A – Product Descriptions: SPF Systems.

B. Product Benefits and Performance Attributes

SPF insulation, sealant, and roofing products provide cost-effective energy efficiency to the citizens of California and provide performance attributes that cannot be met using traditional insulation, sealing, and roofing products. California's Title 24 requirements, effective January 1, 2017, call for increased building energy efficiency. California builders and building owners need tools like spray foam insulation for the State to meet these new requirements and move toward zero net energy homes and buildings.

The ISOR and Summary of Technical Information do not fully consider the benefits of SPF insulation, air sealing, and roofing products. The potential loss of the SFP products would have serious consequences to California consumers – due to decreased energy efficiency – and may hinder the State's efforts to achieve its energy efficiency and climate goals. Each SPF product type is used for different purposes and offers unique performance attributes that are valued

across industries and applications. There are currently no commercially available alternative chemistries that offer the same all-in-one product attributes.

Building Science Attributes

Fully cured SPF insulation, sealant and roofing products do not contain unreacted MDI. Cured SPF products are high-performance, multi-attribute products that provide unique benefits. The SPF flows into cavity spaces and gaps quickly filling these voids with material that cures to both insulate and be "air impermeable."[5] Because they adhere to the substrates, they enhance air sealing where applied thereby avoiding air leakage and heat loss around the insulation. The physical properties of some types of SPF also limit moisture movement through the SPF. The control of air leakage and moisture enhances the durability of the building. In addition, many closed cell foams have moisture-resisting characteristics that allow for them to qualify as code-compliant water resistant barriers when applied towards the exterior of sheathing on the building.

The fact that SPF is inherently air impermeable allows it to be used as the primary air barrier, a key feature of energy efficient construction. This characteristic allows builders to test and inspect air leakage characteristics of buildings at an earlier stage of construction (i.e., pre-drywall application) and helps ensure consumers get the required performance from the finished product.

Construction innovations pioneered by the SPF industry have important non-energy efficiency benefits that are important to California. The product works in sealed attics to create a structure that can provide important defense against the spread of wildfires by eliminating eave vents and air sealing the upper attic vents at ridges to significantly decrease the entry paths for embers into homes, and in sealed basements and crawlspaces to help reduce the ingress of soil gases such as methane and radon. Also, SPF sealing of walls and floors over utility spaces like garages can help avoid the ingress of carbon monoxide and other pollutants.

SPF roofing is one of the most energy efficient cool roofing system available for low slope applications. SPF roofing is uniquely sustainable, with a life expectancy up to 50 years. Its ultra-low weight allows encapsulation of an underlying roof, avoiding costly tear offs and less landfill. With an aged R-value of 6.7 per inch, and an unparalleled ability to insulate and waterproof holes, seams and gaps, SPF roofing is an integral part of California's Green House Gas Reduction Program (AB32) and the Governor Brown's 2020 energy efficiency and conservation goals**.**

A Life Cycle Assessment (LCA) is available for open and closed-cell SPF insulation in buildings.[6] The LCA results show that SPF products can save more energy and reduce environmental impacts during the life cycle of the building insulation products compared to the relatively minor energy and environmental impacts associated with making the insulation. The LCA was conducted using hydrofluorocarbon (HFC) blowing agents. As the industry transitions

[5] Defined by the California Code as a material having an air permeability of less than 0.02L/s/m^2 @ 75 pa.
[6] A copy of the SPF Life Cycle Assessment is *available at*: http://www.sprayfoam.org/technical/energy-the-environment.

to hydrofluoroolefin (HFO) blowing agents, we expect to see a further reduction in environmental impacts.

A description of the multiple attributes of SPF products is included in Appendix B – Product Attributes.

Benefits to California's Climate and Energy Goals

The unique properties of SPF provide energy savings and help reduce greenhouse gas emissions. In 2006, California passed the California Global Warming Solutions Act of 2006 (AB 32) which sought to reduce greenhouse gas emission to 1990 levels by 2020. This was followed by Governor Brown signing Executive Order B-30-15 in August 2015, which seeks to reduce greenhouse gas emissions 40% below 1990 levels by 2030. California's landmark SB 350 requires that the State double its energy efficiency, and building code, Title 24, requires that all new residential construction in the State be zero net energy-ready. SPF Systems can help provide the needed energy efficiency and reduction in greenhouse emissions to aid the State in meeting its climate and energy goals.

As California considers itself a climate change and energy efficiency leader, the State should be promoting the use of SPF systems, as opposed to attempting to limit their use or requiring investigation into unproven and undeveloped alternatives. This proposed listing is at odds with the efforts of the California Energy Commission, the State Legislature and the intentions of Governor Brown when he set the State's climate goals. We urge the State to acknowledge that SPF products help in the fight against climate change, and that subjecting them to unnecessary regulation or even discouraging their legitimate use will further impair this important overarching policy objective.

C. Health and Safety Information: Two-Component SPF Products

The SPF industry takes product stewardship seriously and decades of health and safety programs have reduced exposure to unreacted MDI in SPF systems. SPF insulation and roofing products are made available in varying package sizes and delivery systems. DTSC has failed to make any distinctions among the multiple SPF products despite the well-understood and documented differences in application rates and practices, and potential exposure. This section clarifies the health and safety information for SPF systems that limit the frequency, extent, level and duration of potential exposure associated with different SPF products.

The Department has indicated, through comments and presentations at the public workshops, that it is concerned with potential exposure to unreacted MDI during the application process. While airborne concentrations of the A-side containing unreacted MDI exist during application, potential exposure to applicators can be eliminated through use of Personal Protection Equipment ("PPE"). It is worth noting that when selecting Priority Products, DTSC must consider a variety of factors including a) how a product is used, b) the frequency, extent and duration of the exposure, and c) engineering controls that reduce exposure concerns associated with the product. For this reason, there is concern that the Department has failed to take the SPF

industry's existing stewardship programs into sufficient account during the selection process.[7] In contradiction to the regulations, in the supporting documentation, DTSC repeatedly dismisses the decades of successful product stewardship that have been put in place and resulted in declining MDI-induced asthma rates, as noted in section IV. A. of these comments.

The exposure to unreacted MDI would typically occur through breathing (inhalation) or direct skin or eye contact. Therefore, protective equipment is used to minimize exposure to vapors and aerosols during spray application and subsequent operations.

In that context, DTSC incorrectly notes "any person involved in or near the application risks inhalation exposure to unreacted MDI, even when protective measures are used".[8] On the contrary, people are protected when protective measures are properly used. To overlook this fact ignores realistic conditions of use and available safety controls, as required the regulations.

In addition to the use of required PPE, manufacturer recommended times for re-entry and re-occupancy are provided so applicators, other trade workers, and building occupants know when it is considered safe to return. Re-entry times refer to the time elapsed after installation of SPF when it is deemed safe for applicators, helpers or other trade workers to enter and resume operations without the need for PPE. Re-occupancy times refer to the time elapsed after installation of SPF when it is deemed safe for building occupants or residents to resume normal building operations and activities. Re-entry and re-occupancy times may differ depending on several factors including ventilation rates, the use of engineering controls, the amount of product sprayed, and the formulation. Manufacturers' recommendations should always be followed and Evaluation Service Reports can be consulted.[9] An industry study specifically conducted to evaluate re-entry times for trade workers following application of three generic SPF formulations concluded, "MDI vapor does not present a significant airborne health risk to unprotected trade workers beginning 1 hour after application even when using minimal exhaust ventilation."[10]

A summary of the recommendations for PPE and engineering controls can be found in Appendix C – PPE and Engineering Controls.

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[7] California Code of Regulations. Title. 22 §69503.3 Adverse Impact and Exposure Factors.
[8] ISOR. Pg. 18.
[9] Evaluation Service Reports (ESRs) are a resource used by code officials to verify that new and innovative building products comply with code requirements. The evaluation reports provide information about what code requirements or acceptance criteria were used to evaluate the product, how the product should be installed to meet the requirements, how to identify the product, etc. Information on ESRs is available at http://www.icc-es.org/Evaluation_Reports/read.shtml
[8]Wood, R. (2014). CPI Ventilation Research Project for Estimating Re-Entry Times for Trade Workers Following Application of Three Generic Spray Polyurethane Foam Formulations. Paper presented at the 2014 Polyurethanes Technical Conference.

D. Stewardship Practices, Training Programs and Existing Controls Have Already Reduced Exposures to Applicators

The SPF industry has developed numerous professional development courses and training programs available throughout the SPF value chain. The SPF industry recognizes that a professional, well-trained workforce is key to the continued overall success of the SPF industry and has made a concerted effort to promote safe use of SPF products. Given the success of these efforts and associated occupational asthma data on the subject, ACC believes that existing product stewardship practices combined with existing regulatory controls provide appropriate protection.

SPF worker training and outreach programs are outlined in Appendix D – SPF Stewardship Practices and Training Programs.

E. Cooperation with Regulatory Authorities

Industry has been participating in information exchanges and collaborating with various federal agencies to study, understand, and manage SPF products. Due to the extensive and meaningful work completed and ongoing in these cooperative relationships, we believe the regulatory scheme contemplated by DTSC will provide no meaningful or measurable increase in protection to workers or the public and might reduce the amount of resources available to continue in voluntary programs supported by federal agencies.

Information describing industry's cooperation with regulatory authorities is outlined in more detail in Appendix E – Cooperation with Regulatory Authorities.

F. Voluntary Research Initiatives Demonstrate and Reinforce Industry's Commitment to Responsible Practices

Extensive research and training are available so that all SPF users can understand and effectively manage the products. The SCP regulations require DTSC to analyze both the hazard and exposure to the Candidate Chemical as part of the product-chemical combination before determining whether to list a product-chemical combination as a Priority Product. While all products contain chemicals and ingredients that carry inherent levels of hazard, the risks regarding SPF Systems are being managed at appropriate levels.

In many cases, Environmental Protection Agency ("EPA"), Occupational Safety and Health Organization ("OSHA"), NIOSH and the Consumer Product Safety Commission ("CPSC") are offered the opportunity to consult on the methodology and receive in-depth briefings on the results. CPI scientists and Spray Polyurethane Foam Alliance ("SPFA") member contractors have provided educational opportunities and extensive briefings on industry safety and product stewardship efforts. The research programs led by industry organizations are in addition to the

millions of dollars invested annually through research and development budgets of product suppliers and manufacturers.

CPI continues development of data on SPF raw materials, engineering practices, and analytical methods. Most relevant for these comments is a ventilation research project.

Ventilation Research Project

CPI's Ventilation Research Project studied the impact of changes in ventilation rates on the concentration of SPF chemical vapors and particulates emitted during SPF application. CPI's Ventilation Research Project has completed Phase I (testing for spray equipment and development of three generic SPF formulations) and Phase II (monitoring chemical emissions during SPF application under controlled environmental conditions and evaluating re-entry times for trade workers following application). This is a worker safety focused project and was used to inform industry reference practices.

Based on the results of this study, it is apparent that emissions of MDI during SPF application will vary depending on the type of foam (open cell vs. closed cell) and high-pressure versus low-pressure and the work site (interior vs. exterior). This protocol has been submitted to ASTM D22.05 as a framework for developing a Standard Method for Measuring Chemical Emissions from Spray Polyurethane Foam (SPF) in a Large-Scale Spray Booth (WK51588). Papers presented at the annual Polyurethanes Technical Conference on this project are available online.[11]

In conclusion, sufficient research has been conducted and the necessary training is available so that SPF users can understand and effectively handle the products safely. Existing product stewardship programs, health and safety recommendations, and industry practices limit the exposure to the Candidate Chemical in the proposed Priority Product. Requiring a mature and responsible industry, with a robust product stewardship program, to conduct an AA on a chemistry with no currently available alternative is misdirected and does not provide the State of California with any measurable benefit to human health or the environment.

IV. DTSC has Impermissibly Interpreted its Authority to List SPF

The ISOR and Supporting Technical Information do not provide adequate grounds for the proposed listing of SPF as a Priority Product. DTSC has not been transparent in its process for prioritizing SPF Systems. DTSC has ignored exposure data, engineering controls and safety procedures to improperly conclude that SPF Systems meet the criteria for listing, as required by the regulations. Finally, DTSC has failed to distinguish the different product types and the different potential exposures for different product types which has led the Department to greatly underestimate the compliance burden on industry and themselves.

[11] Papers presented at the annual Polyurethanes Technical Conference on this project are available online at: http://polyurethane.americanchemistry.com/Resources-and-Document-Library#CPI.

The proposal seemly reflects an approach whereby DTSC selects Priority Products based on the mere presence of a chemical in a product that is sold within the State. In contrast, the SCP requires DTSC to follow a structured, systematic, scientific approach for determining Priority Products. These products must demonstrate present "potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product" and "potential for significant or widespread adverse impacts" with the consideration of product use information, frequency, and engineering controls. For DTSC to properly explain its selection process, the Department should define "significant or widespread adverse impacts." In that definition, DTSC must prioritize chemical products that cause exposures that are statistically meaningful.

A. SPF Systems do not Present the "Potential for Public and/or Aquatic, Avian, or Terrestrial Animal or Plant Organism Exposure to the Candidate Chemical(s) in the Product" or the "Potential for Widespread or Significant Adverse Impacts" and DTSC Improperly Characterizes the Hazard Profile of SPF Systems

DTSC has failed to demonstrate that SPF Systems present "potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product" *and* "potential for significant or widespread adverse impacts."[12] Importantly, the increasing availability of a product in California and the presence of a chemical in the product cannot, alone, serve as DTSC's rationale for determining a product's potential exposure in the environment or a measure of the potential impacts. Under the SCP program, DTSC is required to consider several control factors when determining if a product has the potential for exposure.[13] While DTSC provides anecdotal information, the Department fails to provide sufficient information to justify listing SPF systems as priority product.

Potential for Public and/or Aquatic, Avian, or Terrestrial Animal or Plant Organism Exposure to the Candidate Chemical(s) in the Product

DTSC is required, among other factors, to consider: a) how a product is used, b) the frequency, extent and duration of the exposure, and c) engineering controls. In determining that SPF Systems present the potential for exposure, DTSC has dismissed realistic engineering controls, application methods and other safety practices described in the appendices that curtail exposure to MDI. If a non-professional user applies a low-pressure SPF systems without hiring a professional, it is likely to be a one-time event. DTSC has not shown, nor could it be reasonably envisioned, that consumers would have any need to continually apply spray foam insulation in their residences and the data for the type and method of application show a very low potential for exposure.

[12] Cal. Code Regs. Title. 22 § 69503.2(a)(1) and (2).
[13] Cal. Code Regs. Title. 22 § 69503.3 Adverse Impact and Exposure Control

DTSC proposes to regulate multiple distinct SPF products as one generic product – SPF systems. Low-pressure SPF products (insulation and sealants) and high-pressure SPF products (open-cell insulation, closed-cell insulation, and roofing) each have distinct physical properties, application procedures and exposure considerations. They should be considered different products for purposes of this proposed regulation. The Department must consider them independently to determine if there is "potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product" and "potential for significant or widespread adverse impacts." DTSC has failed to individually consider the frequency, extent, level and duration of potential exposure associated with different Spray Polyurethane Foam products.

The Department's proposal is inconsistent with the scientific literature and health-based information regarding SPF systems and unreacted MDI. The potential toxicity and the potential for health-based effects are overstated and in places incorrect, portraying SPF systems in a biased manner that is prejudicial to the industry and which may steer consumers away from a product with many benefits. These technical inaccuracies and mischaracterizations are covered in more detail in Appendix F – Technical Inaccuracies and Mischaracterizations.

Potential for Significant or Widespread Adverse Impacts

The regulations specify that, when identifying a chemical, there must be the "potential for one or more exposures to contribute to or cause significant or widespread adverse impacts." What must be demonstrated to meet that standard, however, fails to be defined, making it impossible for responsible entities and the public to understand what requirements must be fulfilled to meet this ambiguous threshold. This lack of information represents a significant shortcoming in adequacy of DTSC's decision-making process and severely undermines stakeholders' ability to fully comment in an informed manner. Furthermore, absent defined threshold exposure limits, the selection of the SPF Systems appears to be without a principled basis.

The Department identifies unreacted MDI in SPF Systems as having the potential to cause significant or widespread adverse impacts. Yet the Department fails to articulate, or reference, what would constitute permissible threshold limits for exposure to the Candidate Chemical in the proposed regulations. DTSC has declined to issue a threshold value, under which MDI in unreacted SPF would no longer be considered a Priority Product.

Without this threshold, it is impossible for interested parties to determine what would be appropriate for an alternative without a wholesale change of the product. It is difficult to imagine how the Department will determine if an alternative is suitable under the regulations or contains "regrettable substitutions" without defined threshold limits for exposure to the candidate chemical.

DTSC cites the fact that the SPF market is growing both globally and in California as an indication of the potential for a wide spread significant impact on the consumers of California. However, a growing presence in the marketplace does not equate to exposure and certainly does not prove that consumer health will be adversely impacted. Quite the contrary, this growing market presence, combined with the lack of recent occupational asthma cases specifically

attributed to MDI exposure in SPF applications, indicates that industry product stewardship efforts with users are successful. Merely listing statistics showing the growth of a product in the market does nothing to support DTSC's mandate to show a potential for significant or widespread adverse impacts.

DTSC implies that worker deaths from exposure to polyurethane paints, MDI-induced worker fatalities, and MDI-induced worker asthma are justification for listing SPF Systems.[14] The SCP program requires a specific chemical be addressed under a specific product, and paints are not the same as spray foam insulation or sealants regardless of any potential chemistry similarities. It is important to clarify for the record that polyurethane paints may be made of various isocyanates and use various application methods impacting exposure potentials; the actual chemistry and specifics of application must be determined before this conclusion can be made. Even then, exposures to polyurethane paints are not directly comparable to exposures from SPF Systems. DTSC has provided no information or data linking MDI-induced worker fatalities, and MDI-induced worker asthma to SPF Systems. Such unsupported allegations fall short scientifically, do not meet the criteria for reliable information set forth in the regulations, and do not constitute rational decision making to list SPF Systems.

DTSC uses the products' availability to serve as the basis for concluding that SPF Systems have the potential to cause "significant or widespread adverse impacts." In the ISOR, DTSC provides no evidence that exposure to MDI from the application of SPF Systems is either significant *or* widespread. DTSC states that over 15 years the California Department of Public Health determined that eight cases of work-related asthma were caused by MDI, however these cases were not specifically linked to SPF Systems. This statement alone shows the weakness in DTSC's justification which cannot stand.

Moreover, the fact that exposure to MDI from SPF Systems is neither significant nor widespread, is supported by the Department's own peer reviewer. B. Nemery, MD, PhD, recommends that the use of the words "significant and widespread" be removed:

> "[S]ignificant and widespread"; I am not sure these terms are entirely appropriate in the absence of a clear definition of what is to be considered "significant" (serious? – some purists argue that one should restrict the use of "significant" to its statistical meaning, i.e. "unlikely due to chance", and then also specify what degree of significance is accepted, e.g. $p<0.05$) and "widespread" (some could argue that "only" 23 cases of occupational asthma over a period of 15 years in a population of several millions does not represent a widespread occurrence of disease); are these terms really necessary/mandatory?
>
> "However, as indicated above, I have some reservations about the use of the (poorly defined terms) "significant" and "widespread."[15]

[14] Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with Unreacted Methylene Diisocyanates as a Priority Product (Technical Summary document), pg. 20
[15] "Review of documents related to "DTSC's proposal to adopt spray polyurethane foam systems with methylene diphenyl diisocyanates as a priority product" August 25, 2016.

In the proposed regulations, DTSC did not respond to Dr. Nemery's comments outlining its reasons why the Department has determined that the scientific justification for stating SPF Systems present the "potential for one or more exposures to contribute to or cause significant or widespread adverse impacts" are based on sound scientific knowledge, methods, and practices.[16]

DTSC states there is no evidence linking the increased use of SPF Systems in the consumer market place to asthma or sensitization, yet, also concludes that

> "Despite the paucity of data, DTSC remains concerned that consumers who use low-pressure SPF systems have an elevated risk of exposure because they are least likely to understand or take steps to mitigate the hazards posed by MDI."

DTSC continually cites the increasing demand for spray foam insulation as a direct correlation to the potential for widespread exposure, while in reality – as detailed below – public health data shows no evidence adequate to support DTSC's claim. DTSC has not demonstrated that the rates of occupational or consumer exposure due to MDI in SPF are rising or that SPF Systems present "significant or widespread adverse impacts."

Occupational Asthma Rates for MDI are Declining

Contrary to DTSC's claim of rising health concern, reliable and peer-reviewed data demonstrate that occupational asthma rates for MDI are declining. Publicly available information also demonstrates that isocyanates are not a leading cause of occupational asthma in California.

Various national data collection programs on worker exposure and disease incidence present a consistent picture, showing a reduction of diisocyanates-related asthma cases over the last decade in Finland, Ontario, Germany, Belgium, France United Kingdom, and the United States

[16] Cal. Code Regs. Title. 22 § 57004(d)

even as production and use increase around the world.[17],[18],[19],[20],[21],[22],[23],[24] This is primarily due to a variety of product stewardship activities including education and training, enhanced worker awareness, improved work practices, use of less volatile isocyanate forms (e.g., prepolymers), continuing emphasis on compliance with existing exposure standards, and better medical surveillance programs. Data relevant to the U.S. is summarized in an infographic available from the ACC in the link in the footnote below.[25]

According to the NIOSH Work-Related Lung Disease Surveillance System (eWoRLD), work-related asthma statistics indicate that isocyanates have fallen to number 19 in frequency of reported asthma cases.[26] In addition, MDI is only one of the isocyanates that are grouped into this category, which indicates the number of MDI work-related asthma cases is even lower. The data tables accompanying this report show that the MDI-related cases in California are zero. It is noteworthy that the information referenced to support this proposed rulemaking is outdated and that rates of isocyanate asthma have further declined. The data presented by NIOSH are from 2009-2011[27] and show a continued decline from the data that was originally presented in the Department's previous technical documents.

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[17] Piipari, R. & Keskinen, H. (2005). Agents causing occupational asthma in Finland in 1986-2002: cow epithelium bypassed by moulds from moisture-damaged buildings. *Clin.Exp.Allergy*, *35* (12), 1632-7.
[18] Buyantseva, L. V., Liss, G. M., Ribeiro, M., Manno, M., Luce, C. E., & Tarlo, S. M. (2011). Reduction in diisocyanate and non-diisocyanate sensitizer-induced occupational asthma in Ontario. *J.Occup.Environ.Med.*, *53* (4), 420-6.
[19] Vandenplas, O., Lantin, A. C., D'Alpaos, V., Larbanois, A., Hoet, P., Vandeweerdt, M., Thimpont, J., and Speybroeck, N. (2011). Time trends in occupational asthma in Belgium. *Respir.Med.*, *105* (9), 1364-72.
[20] Paris, C., Ngatchou-Wandji, J., Luc, A., McNamee, R., Bensefa-Colas, L., Larabi, L., Telle- Lamberton, M., Herin, F., Bergeret, A., Bonneterre, V., Brochard, P., Choudat, D., Dupas, D., Garnier, R., Pairon, J. C., Agius, R. M., & Ameille, J. (2012). Work-related asthma in France: recent trends for the period 2001-2009. *Occup.Environ.Med.*, 2012 Mar 1. [Epub ahead of print].
[21] Stocks et al. (2015) Isocyanate exposure and asthma in the UK vehicle repair industry. Occ. Med. Preprint 25 July 2015.
[22] Ott MG, Diller WF and Jolly AT. 2003. Respiratory Effects of toluene diisocyanate in the workplace: a discussion of exposure-response relationships. *Crit. Rev. Toxicol., 33*, 1-59.
[23] Ott MG, Diller WF and Jolly AT. 2003. Respiratory Effects of toluene diisocyanate in the workplace: a discussion of exposure-response relationships. *Crit. Rev. Toxicol., 33*, 1-59.
[24] NIOSH 2015. Work-Related Lung Disease Surveillance System (eWoRLD). 2015-851 U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Respiratory Health Division, Morgantown, WV. Available at: https://wwwn.cdc.gov/eworld/Data/851 . May 30, 2017.
[25] Infographic: Decrease in Diisocyanate-Related Occupational Asthma Aided By Enhanced Industry Stewardship. Available at: https://dii.americanchemistry.com/Infographic-on-Declining-Asthma-Cases.pdf.
[26] *Available at* http://www2a.cdc.gov/drds/WorldReportData/FigureTableDetails.asp?FigureTableID=2607&GroupRefNumber=F09-01.
[27] https://wwwn.cdc.gov/eworld/Data/Work-related_asthma_Ten_most_frequently_reported_agent_categories_associated_with_cases_of_work-related_asthma_20092011/851.

Data collected by the State of California demonstrate that the number of occupational asthma cases associated with MDI are very low and, again, do not provide a reasonable basis for concluding that SPF presents the "potential for significant or widespread adverse impacts."

- The California Department of Public Health indicates that in the period of 1993-2008, 0.5% of work-related asthma cases reported DII exposure at work.
- The California Department of Public Health's surveillance of work-related asthma indicates that since 1993, there have been only eight cases reported associated with MDI and it is unclear how many, if any, were associated with SPF.
- The 2014 communication below with Jason Wilken of the United State Public Health Service (USPHS) confirms there were zero MDI cases reported for the most recent 8 years (2006-2014).

California is one of several states to receive funding from NIOSH to conduct surveillance of work-related asthma. The California Department of Health Services' Sentinel Event Notification System for Occupational Risks (SENSOR) program was developed to identify primary and secondary cases of work-related asthma, characterize exposures and disease, and devise prevention strategies. The CA Department of Public Health's publication from May 2013, Asthma in California, A Surveillance Report,[28] contains data on work-related asthma associated with isocyanates. From the report, during 1993-2008, isocyanates do not make the top 17 list of agents causing work-related asthma (page 102).

Number and Percent of WRA Cases Reporting Exposures at Work, California 1993–2008

Exposure	N	%
Dust	775	19.1
Chemicals, NOS	681	16.8
Cleaning Chemicals	507	12.5
Smoke, NOS	408	10.0
Mold, NOS	321	7.9
Indoor Air Pollutants	313	7.7
Paint, NOS	254	6.3
Air Pollutants from Construction	170	4.2
Stress	158	3.9
Perfume	152	3.7
Pesticides, NOS	133	3.3
Glues	96	2.4
Cigarette Smoke	83	2.0
Asphalt	83	2.0
Diesel Exhaust	78	1.9
Bleach	77	1.9
Fiberglass	76	1.9

Note: Up to three exposures reported for each case; NOS=Not Otherwise Specified

Data Source: California WRAPP Surveillance Data, 1993–2008 (N=4,677)

In the same report, exposure to isocyanates (of which MDI is only a portion and SPF is not specifically mentioned), comprises only 0.5% of cases reported from 1993-2008 (page 104).

[28] Asthma in California, a Surveillance Report, *available at*: https://archive.cdph.ca.gov/programs/ohsep/Documents/AsthmaInCA_WRA.pdf

Number and Percent of WRA Cases Reporting Asthmagen Exposures at Work, California 1993–2008

Asthmagen Exposure	N	%
Bleach	77	1.6
Chlorine	59	1.3
Latex	50	1.1
Ammonia	43	0.9
Formaldehyde	37	0.8
Glutaraldehyde	28	0.6
Sulfuric Acid	27	0.6
Diisocyanates	23	0.5
Rat Antigens	22	0.5
Epoxies	19	0.4
California Redwood Dust	17	0.4
Quaternary Ammonium Compounds	16	0.3
X-ray Chemicals	13	0.3
Flour	12	0.3

Note: Up to 3 exposures reported for each case; asthmagens are known asthma inducers as defined by the Association of Occupational and Environmental Clinics, www.aoec.org.

Data Source: California WRAPP Surveillance Data, 1993–2008 (N=4,677)

In addition, a (27 May 2014) personal communication with Jason Wilken, Ph.D., LT, USPHS, states that there have only been a total of 10 reported cases of asthma related to MDI in California from 1993-2014.

> *"Of these ten, three were associated with plastics molding and two were associated with exterior wall molding; therefore, 5 of the 10 known cases were associated with molding. Of the remaining 5 cases, two were associated with packing/packaging. Of the remaining three, one was a carpenter, one a janitor, and we do not have an occupation identifiable for the final case. The industries associated with these cases (i.e., NAICS coding) are "All Other Plastics Product Manufacturing" (3), "Other Concrete Product Manufacturing" (2), "Machinery Manufacturing" (1), "Other Computer Peripheral Equipment Manufacturing" (1), Repair and Maintenance (1), and "Specialty Trade Contractors" (1); one record does not have an associated industry listed.*
>
> *"We have not identified any cases of work-related asthma attributed to MDIs from after 2006."*

The Department has also failed to include reference to the most recent available NIOSH data which shows that for the period 2009-2011, isocyanates are no longer listed as a top 10 leading cause of workplace asthma.[29] This NIOSH data provides further evidence that SPF systems do

[29] The National Institute for Occupational Safety and Health (NIOSH). Work-Related Lung Disease Surveillance System (eWoRLD). 2012. Work-related asthma: ten most frequently reported agent categories associated with cases of work-related asthma, 2009-2011, available at: https://wwwn.cdc.gov/eworld/Data/Work-related_asthma_Ten_most_frequently_reported_agent_categories_associated_with_cases_of_work-related_asthma_20092011/851
1993-2008, *available at*:
http://www2a.cdc.gov/drds/worldreportdata/FigureTableDetails.asp?FigureTableID=2607&GroupRefNumber=F09-01.

not present "potential for significant or widespread adverse impacts" and the Department should not proceed with regulating SPF systems under the SCP program.

The NIOSH surveillance data cited by DTSC do not indicate that MDI exposure from SPF is a leading cause of occupational asthma nationally or locally in California. Given that the Department only cites eight cases of worker related asthma over a 15-year period, without attributing any specifically to SPF Systems, and no other health effect data, we submit that this proposed regulation is not supported by the record, does not fulfill the prioritization criteria, and will not provide a measurable benefit to public health.

Non-Occupational Exposure Potential

The Department has provided no substantive evidence that non-occupational exposure to SPF Systems causes significant or widespread adverse impacts. DTSC concedes that "although consumer use appears to be rising, it is difficult to attribute specific cases of non-occupational illness, such as asthma or allergic sensitization, to the use of SPF products that contain MDI."[30] Despite the paucity of data, however, DTSC remains concerned that consumers who use low-pressure SPF systems have an elevated risk of exposure because they are least likely to understand or take steps to mitigate the hazards posed by MDI.[31] DTSC provides no support for this assertion.

To support its allegation of consumer exposure, DTSC cites general population statistics on asthma in the U.S. and California, but provides no context on how many are related to isocyanates in general, or more importantly, to MDI in SPF, in particular. Further, DTSC concedes that "incidence of asthma from chemical exposures, such as MDI, in the non-occupational setting is difficult to determine."[32] This statement is in direct conflict with the regulations, which require DTSC to demonstrate the potential significant or widespread adverse impacts on the health or the environment.

DTSC's assumption that sole proprietors and individual consumers will not use ventilation or PPE as specified in the guidance documents is not supported in the record.[33] To the contrary, industry's PPE recommendations for low-pressure SPF Systems are included in the Health and Safety sections of many documents with such audiences, including supplier user manuals found in product packaging and online resources including manufacturer and U.S. EPA resources, safe handling videos, and other documentation.

DTSC once again does not provide any objective data to support its claim that "the number of people who are sensitized to MDI, and who are at risk of life-threatening asthma attacks from subsequent exposures is unknown, but may grow as the popularity of SPF insulation grows."[34]

[30] Technical Summary document pg. 21.
[31] Technical Summary document, pg. 21.
[32] Technical Summary document, pg. 21.
[33] ISOR, pg. 17
[34] Technical Summary document, pg. 25.

B. DTSC Has Improperly Prioritized SPF Pursuant to the SCP Regulations

Pursuant to the SCP regulations, identification and prioritization of chemical-product combinations for listing as Priority Products includes evaluating the potential for exposures to a Candidate Chemical in a product, and the potential for the Candidate Chemical to contribute to, or cause, significant or widespread adverse impacts due to exposure to that Candidate Chemical in the consumer product.[35] These criteria serve to help the agency identify and prioritize Priority Products "to ensure that the limited resources of DTSC, responsible entities, and other interested parties are focused" on high priority products.[36] Needless to say, for this regulatory provision to have meaning, it must be the case that some product-chemical combinations meet the criteria and some do not. If DTSC continues to apply the regulation in such a manner that every chemical-product combination meets the prioritization criteria, then the criteria are meaningless and wholly arbitrary.

The Department apparently views the first criteria – evaluating the potential for exposures – as merely a process step. Under it attempted approach, DTSC could readily find, for virtually any consumer product sold in California, that there is at least an articulable case that there is "potential" for exposure to some person under some circumstance to a chemical in a chemical-product combination. This is no threshold at all; this construction is arbitrary because it applies to everything.

The second criteria has also been applied in a manner that make it a meaningless limitation. DTSC's attempted construction of "widespread or significant adverse impacts" sweeps so broadly that it fails to function as a prioritization tool at all, and that virtually any consumer product sold in California would likewise be viewed to have triggered the "widespread or significant" criteria. This of course is an arbitrary and capricious application of the regulations, and it cannot stand.

Based on any reasonable construction of "significant or widespread adverse impacts," the record evinces no reliable evidence that SPF contributes to or causes (either) significant or widespread adverse impacts due to exposure.

The Administrative Record Lacks Evidence that Adverse Human Health Effects from Application or use of SPF in California are "Widespread"

The Statement of Reasons accompanying the SCP regulations explains that "widespread" impacts are those that could cause severe adverse effects to public health:

Section 69502.2(b)(1)(C) specifies that DTSC will give special consideration to the potential for the chemical to contribute to or cause widespread adverse public health and/or environmental impacts. Impacts of this magnitude could cause severe pollution or public health impacts, and it is necessary to control the chemical before widespread impact has occurred rather than after the

[35] California Code of Regulations. Title. 22 §69503.2
[36] Safer Consumer Product Regulations Final Statement of Reasons, p. 171.

chemical has done its damage. By allowing special consideration of the chemical's potential to contribute to or cause these widespread adverse public health and environmental impacts such impacts may be prevented. Some examples of the types of information that might indicate potential widespread impacts include:

- data that indicates that the chemical or its degradation products are present in the California solid waste, waste water, or storm water streams that pose potential public health or environmental threats;
- chemical clean up or corrective action information from facilities that require permits to operate and handle chemicals; chemical clean up or corrective action information from facilities that require permits to operate and handle chemicals;
- significant public funds are required to clean up or mitigate chemical threats to public health and/or the environment; chemical presence in consumer products that increases the cost of reusing or recycling the consumer product's materials; and widespread usage of chemicals or consumer products containing the chemical.

While widespread usage of chemicals or consumer products containing a chemical is evidence to be considered as the Department evaluates potential adverse health effects, it is not a proxy for demonstration of adverse health effects. If the Department wants to point to current widespread use and availability of a consumer product (based on whatever objective measure - sales volume, TRI data, etc.), it must then demonstrate not just that actual exposure to the chemical at issue is occurring or has occurred at some level in some duration, but -- that based on the toxicology of the chemical -- that adverse health effects have presented. SPF is applied with the use of PPE and other control measures, including ventilation, to reduce or eliminate exposure during application. Actual exposure reflects actual use of these control measures. The State has data available with respect to incidences of worker injury and illness, but has not shown data – despite alleging ongoing use of SPF in the state – of adverse health effects in workers – whether widespread, significant, or otherwise.

There is No Reliable Evidence in the Record that Adverse Human Health Effects from Application or use of SPF in California Are "Significant"

Exposure to a chemical – or the mere possibility of exposure to a chemical, under actual conditions of use or assumed conditions – is not itself an adverse health effect, nor is it a proxy for an adverse health effect. Incidental or isolated occurrences of fleeting or minor exposure, whether speculative, anecdotal, or documented, cannot be assumed or projected to cause health effects. Mere theoretical possibility of sensitization based on speculative exposure (or product misuse) does not support an assumption of adverse human health effect. Likewise, a theoretical possibility of sensitization under such circumstances would not support an agency finding of "significant" health effects.

Reasonable constructions of the term "significant" in the regulations could mean (1) statistically significant health effects observed in a population; or (2) something other than "insignificant" adverse health effects – serious effects, permanent effects, etc. Neither construction of the term is satisfied on this record. DTSC cannot point to any documented occurrence of adverse health

effects from application of SPF in California, and therefore there is no statistically significant incidence upon which to justify this proposal. With respect to "serious" or "substantial" health effects, there are none shown. With respect to whether health effects are "more than insignificant," there are none provided. This construction of "significant" is consistent with U.S. statutory interpretations of the term. For example, under the federal Clean Water Act (CWA), statutory text uses the term "significant nexus" to describe the type of connection required between waterbodies sufficient for the EPA to assert jurisdiction over them. A "significant nexus" means that one water "significantly affects" the chemical, physical, or biological integrity of the connected water, and a "significant effect" is defined as one that is "more than insignificant or substantial."[37] The federal Clean Air Act (CAA) defines "hazardous air pollutants" to tie "significant or widespread" with "adverse effect," providing that "[t]he term 'adverse environmental effect' means any significant or widespread adverse effect, which may reasonably be anticipated, to wildlife, aquatic life, or other natural resources, including adverse impacts on populations of endangered or threatened species or significant degradation of environmental quality over broad areas."

Professionally Installed SPF (SPF with Unreacted MDI) is Not a "Consumer Product" Pursuant to Statute, and DTSC has Improperly Conflated Potential Exposures to Workers with Consumers

Section 25253(a)(1) of California's Health and Safety Code requires DTSC to adopt regulations "that establish a process for evaluating chemicals of concern in consumer products." DTSC has no statutory authority to designate a product that is not a consumer product to be a Priority Product. The legislature was fundamentally concerned with consumer exposures and adverse health effects; worker exposures are already regulated in California by the Division of Occupational Safety and Health and the federal level by the Occupational Safety and Health Administration.

The Priority Product at issue here, however – professionally installed, SPF systems and large volume low-pressure SPF containing unreacted MDI – is not "used" by most consumers at all. Consumers "use" the installed, fully reacted product that no longer contain MDIs and are considered inert by EPA.[38] Similarly, consumers may not be said to "buy" unreacted, high pressure SPF and large volume low-pressure SPF at all; professional installers purchase the unreacted systems and consumers hire installers to provide a service and contract for a particular quality of installed (fully reacted) product.

This is highly relevant for purposes of considering whether there are "widespread or significant" effects. DTSC's proposal does not consider the different SPF systems as part of the calculation of "widespread or significant" effects; the evaluation is thus substantially flawed and the prioritization decision is likewise impaired.

[37] 40 CFR §122.2(3)(v).
[38] https://www.epa.gov/saferchoice/potential-chemical-exposures-spray-polyurethane-foam

The Prioritization Process was Deficient

The process employed by the Department to select the initial list of Priority Products is not clearly articulated in documents published by the Department and appears arbitrary and capricious in nature. While the Department has alluded to conversations between DTSC and other agencies or stakeholders in which the topic of "isocyanates" was raised, it is unclear how SPF Systems were selected as the product-chemical combination for the initial list of Priority Products. The Department should articulate who provided the information that led to selection of isocyanates as the Candidate Chemical and SPF Systems as the Priority Product, as well as the process it undertook to verify that the suggestions or nominations it received from outside groups were balanced and based in reliable science and actual conditions of use. The Department should describe which criteria SPF Systems met for selection as a Priority Product and how the Department weighted those factors against selection criteria SPF Systems do not meet.

The Department's lack of transparency on the prioritization process DTSC employed is concerning. Without a clear articulation of the actual process used, impacted stakeholders are prevented from ensuring that the process has been conducted in a defensible manner consistent with the regulations. The lack of transparency also denies the public of assurances that the Department is making the appropriate selections for prioritization, using public resources effectively, and has not targeted products in an arbitrary and capricious manner.

C. Existing Laws Provide "Adequate Protection with Respect to Potential Adverse Impacts and Exposure Pathways"

Listing SPF Systems as a priority product is not necessary because existing laws already provide adequate protection against potential adverse impacts and exposure pathways. Efforts to address SPF under the SCP program would be duplicative of existing requirements. Recognizing that many chemicals and products are already regulated by the state of California and the federal government, DTSC's regulations state that they will not be applied to consumer products that are already regulated by state or federal programs that address the same potential adverse impacts and exposure pathways and provide the same protection of public health and environmental health that regulation under the SCP program would provide.[39] SPF products are subject to multiple regulations by both state and federal regulators and clearly meet this standard. Considering these existing regulations, it would be contrary to DTSC's regulations to list SPF Systems as a priority product.

Exposure to MDI is regulated by the California Occupational Health and Safety Administration ("California OSHA") and by the federal OSHA. Specifically, the California OSHA has established a permissible exposure limit ("PEL") for MDI of 5 parts per billion ("ppb") and the federal OSHA has established a PEL at 20 ppb.[40] Under both state and federal regulations, employers must adopt engineering and administrative controls to ensure proper ventilation when SPF is applied, develop worker training programs regarding the safe installation of SPF, and

[39] Cal. Code Regs. Title 22 § 69501(b)(3)(A).
[40] 20 C.F.R. § 1910.1000.

provide workers with PPE to limit exposure. These measures protect workers subject to OSHA standards and can be adopted by other individuals who install SPF to ensure adequate protection against exposure to MDI.

The fact that existing laws provide adequate protection is reinforced by results from the detailed three-year National Emphasis Program ("NEP") for isocyanates, including MDI used in SPF products, that federal OSHA recently conducted. The purpose of the NEP was to "identify and reduce or eliminate the incidence of adverse health effects associated with occupational exposure to isocyanates.[41] The NEP included a detailed analysis of workplaces where isocyanates are used, including SPF installation. After the 3-year NEP program concluded, OSHA elected to take no further action, indicating that existing standards and programs were sufficient to protect workers from isocyanate exposure.

D. Listing SPF Systems as a Priority Product Will Not Meaningfully Enhance Public Health

Listing SPF Systems as a Priority Product would not serve the SCP program's goal of reducing human health and environmental health exposures because doing so would not meaningfully reduce exposure to MDI. Potential MDI exposures due to SPF installation are already very low and are controlled effectively by existing regulatory requirements, combined with the voluntary actions taken by the SPF industry. As a result, proceeding with listing SPF as a Priority Product and requiring manufacturers to complete an AA will constitute a waste of time and limited resources.

As detailed above and in prior comments to DTSC, the SPF industry continues to be committed to reducing potential exposure to MDI during the installation of SPF products. The SPF industry has developed and actively promotes extensive product stewardship programs to maximize worker safety and identify superior practices for the handling of chemical products. In addition, product manufacturers provide programs that include a focus on training their distributors and end-users, give guidance on proper PPE, contain online modules for health and safety training, provide application and ventilation guidelines, provide instruction on product labeling practices, and make critical chemical health and safety information available to the end-users. A partial list of publicly available resources provided by the SPF industry can be found in ACC's prior submissions to DTSC.[42] When coupled with existing regulations applicable to SPF manufacturers and SPF users, these product stewardship programs effectively reduce exposure to MDI during the installation of SPF products. This position is reinforced through data provided through the Michigan State University Sentinel Event Notification System for Occupational Risks (SENSOR) and the CDC Work-Related Lung Disease Surveillance System (eWoRLD) which show that as production volumes for several diisocyanates including MDI have increased between 1998 and 2014, the incidents of occupational asthma cases have decreased.

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[41] OSHA, National Emphasis Program – Occupational Exposures to Isocyanates, Directive No. CPL 03-00-017 (June 20, 2013).

[42] See Supplemental Comments. June 2014. ACC Supplemental Comments pg. 18-19.

Moreover, as ACC has previously explained and as DTSC has recognized, there are no viable alternatives to SPF products currently on the market. As explained more fully in the Appendices, SPF products offer a suite of benefits that cannot be matched by competing products. These multiple attributes are conferred on the final product in one step, making SPF a unique, multi-attribute, single application product, which saves time and labor associated with construction.

Listing SPF Systems as a priority product will simply result in a significant expenditure of resources on the part of SPF producers, and confirm to DTSC that there is no currently known alternative chemistry available, that matches the key performance attributes, in the marketplace to the use of MDI in SPF Systems – a conclusion DTSC and industry have agreed upon. As DTSC offers no rational basis upon which to order industry to undertake an AA and has no information to indicate that such a substantial undertaking might be productive. The Department is sending industry on the proverbial wild goose chase--a speculative exercise to find an unknown, undefined, and perhaps unknowable alternative. Imposing a regulatory burden with no prospect of obtaining meaningful benefits in return is poor policy and a waste of state resources.

V. DTSC has Failed to Fulfill its Procedural Obligations

A. Economic Analysis

DTSC has not fully estimated the cost of compliance with the proposed listing, nor appropriately estimated the cost of the ultimate outcome of the regulation. Without a full understanding of how DTSC defines the chemical/product combination it has listed or how it will evaluate AAs--including how the Department will define key criteria (e.g., "regrettable substitution," "green chemistry")-- it is impossible to fully quantify the impact of the listing regulation. DTSC has also presented mismatched costs and benefits because it omits certain items on the cost side while including them on the benefits side.

DTSC has presented costs for an abridged AA only. Given the Department's belief that the end result of an abridged AA requires the vague "green chemistry research" funding requirement, affected industries face many unanswered questions.[43] While this is one potential outcome of a regulatory listing, the Department has not presented the potential full costs of compliance with this proposed regulation. DTSC should also have engaged in the analysis of the extended time and resources that could be required for production of a full two-staged AA. As described in Section III, and in great detail in Appendix A, SPF Systems comprise multiple distinct products (professionally installed insulation products, roofing products, gap sealers, air barriers, etc.). Each product may vary in formulation and each product may present different exposure potential. As DTSC has proposed to regulate multiple SPF products under one regulation, it is likely that <u>each product</u> would necessitate a separate AA. The projected cost estimates are thus grossly underestimated and could reach the level of a major regulation in California.

[43] ISOR. Pg. 8.

The costs that DTSC estimated to complete the abridged AA reflect a relatively narrow range based on information from several sources not fully referenced in the economic analysis document. It appears that most of the referenced documents do not provide details about the time to conduct AA activities or the costs associated with an AA and thus we question how the estimates were derived. In addition to estimating the cost of conducting the abridged or full AA itself, DTSC should have included an estimate of the time it would take for parties (managers, analysts, legal counsel and others) to familiarize themselves with the regulatory requirements and the complex, still vaguely defined requirements to produce a compliant AA.

At the time of the issuance of this listing proposal, DTSC has not yet completed its guidance for how to appropriately conduct an AA (either abridged or two-stage). While the Department has repeatedly said that it will work with the regulated entities to blaze the trail for these initial priority products, it remains unclear how the Department will judge an AA is complete or satisfactory.

- How will DTSC judge whether the AA is complete?
- How does DTSC intend to judge whether an alternative substance has the appropriate functional properties to create an equally appealing and attractive product that fulfills the multiple end use benefits of SPF (thermal insulation, air sealing and vapor retarder all in one product)?
- How does DTSC intend to measure what research efforts undertaken by an individual company or industry have been rigorous enough to accept or eliminate a candidate from consideration as an alternative?
- How does DTSC determine if research and development (R&D) would be required? Or, if more R&D by a company is required after that company has already spent millions of dollars and years of company time on research?
- How will DTSC determine if a substitution is "regrettable?" On a health basis only? Hazard basis only? What if a proposed substitute is inferior in terms of performance?
- What risk assessment studies would be required to prove the substitute is not "regrettable"? Who would oversee the human health studies on an unknown compound?
- To which experts would DTSC suggest regulated entities turn for the appropriate expertise to conduct an abridged or full AA?
- With such uncertainty in the process, it is unlikely that <u>all</u> costs that must be analyzed under CA's regulatory mandates have been appropriately considered.

The analysis estimates a high and low cost which are in a relatively narrow range and appear to be linked to the hours spent with no variability on the cost per hour to perform those tasks. In addition, DTSC concedes that costs could be much higher. The references that DTSC provided on the economic analysis do not discuss the cost to conduct an AA. On page 3 of the Economic Analysis, DTSC includes the caveat that "actual costs may be higher depending on the number of alternatives assessed; availability of data for each alternative considered; the need to hire external consultants; and the effort needed to respond to the public's comments and DTSC's reviews." The Department failed to also consider the number of actual products that may need to be assessed. Given the tremendous uncertainty regarding the cost of AA's and the level of

collaboration that may be required, some scenarios of additional costs would give policy makers a truer picture of the degree of uncertainty and potential cost impacts.

It is important to note that when estimating costs for the completion of a consortium-based AA, the costs of administering a consortium should also be considered. As noted in ACC's May 9, 2016, letter on the topic of estimated costs to complete an AA, the feasibility of using a consortium approach is not yet known.

Mismatched Costs and Benefits

DTSC's economic impact statement falls short of its intended function because it omits certain items on the cost side while including them on the benefits side. In the economic impact analysis, DTSC provides only the cost data to prepare a Priority Product Notification and an abridged AA report. However, in the discussion of the (unquantified) benefits, DTSC cites "potential job expansion in business consulting; worker safety training education and certification; manufacturing and distributing personal protective equipment; research and development of safer chemicals and products."[44] If the rule is expected to generate these benefits, there are costs to industry associated with them that should be included, such as:

- the higher cost of using business consultants - if DTSC is expecting manufacturers to use consultants, the hourly costs are likely several multiples of the $50/hour rate assumed in the preparation of the Priority Product Notification;
- the cost of new worker safety requirements (i.e., purchase of PPE equipment and training and certification of workers where it doesn't already exist); and
- research and development costs to develop "safer chemicals and products"

DTSC cannot conclude that reduced worker health and safety costs will be a benefit of this regulation when no data has been presented that indicates an alternative to unreacted MDI in SPF would have a different hazard or exposure characterization.

The ISOR asserts that responsible entities who choose to take the abridged AA approach are required to initiate research and development projects or fund challenge grants. However, the regulation only suggests that the Department may require these as outcomes from the abridged AA process. The ISOR should not presume the outcome where there is clearly latitude for the Department to not require the responsible entity to initiate R&D projects nor fund a challenge grant. In estimating the uncertain benefits of this regulation, DTSC is leaping to the conclusion that an alternative will be found and implemented. This is not supported by the current state of the market.

We believe the estimation of benefits of compliance with this regulation should not appropriately include an increase in employment opportunities for consultants, researchers and safety educators or increased sales or production of PPE. It is our understanding that the SCP regulation is not a job creation tool.

[44] Economic and Fiscal Impact Statement (STD 399), pages 8 and 9.

Consideration of Alternatives to the Regulation

While DTSC described three possible alternatives to the current proposal, including industry's proposed alternative to the regulation,[45] we disagree with DTSC's conclusion. Throughout the supporting information for the proposed listing, DTSC has variously described the goal of the regulation as improving public health, reducing exposure to users, and driving SPF manufacturers to safer alternatives while avoiding regrettable substitutions. While these goals are not mutually exclusive, the fact remains that DTSC, in many places in the documents accompanying the proposed listing, has indicated a preference for reformulation away from current SPF ingredients while not fully considering an alternative regulatory approach to the listing that costs significantly less and is readily available to be implemented.

The alternative to the listing regulation proposed by industry in 2015 could address concerns expressed by the DTSC (albeit without any documented evidence) that potential exposure to MDI in SPF is increasing while allowing the marketplace to rightfully determine when alternatives are developed and considered as equal to or superior to the products they may displace. In this section of the economic analysis (page 12), DTSC indicates its preference to secure funding for development of what the Department determines will be safer alternatives to current materials. In rejecting the industry proposal, the Department was willing to forgo the benefits of immediate collective industry action to continue existing mature product stewardship programs to force market transformation where none is yet occurring and cannot be assumed to will develop.

As discussed in more detail in Section V. B. of these comments, ACC disagrees with the Department's assertion that such an agreement would not be enforceable or binding. The Department could have executed enforceable agreements with each of the regulated entities to engage in activities to further enhance work place safety, training, labeling, outreach and other activities. Each potentially regulated entity indicated its willingness to do so at the time and this interest was conveyed to Director. In lieu of agreeing to an effective alternative approach to inclusion of SPF Systems in this program that would be demonstrably less burdensome to industry and the government of California, the Department has instead proposed a burdensome and unjustified listing.

DTSC Has Not Estimated the Cost to the State of the Potential Loss of SPF as an Insulation, Sealant and Roofing Products

As described in detail in our June 2014 comments to the Department and above, the unique, multi-attribute performance qualities of SPF insulation and sealant make the product a valuable tool in reducing energy consumption. According to industry estimates, ten percent (10%) of the 35,000 new single-family homes constructed in California in 2013 were insulated with SPF. The resulting energy savings from these homes can add up to $3.3 million each year or approximately $900 in savings for each California household. The annual energy savings are equal to removing 800,000 tons of greenhouse gas equivalents from the environment of the 60-year life span of the homes. The environmental and economic benefits of SPF rise significantly for California when

[45] Economic and Fiscal Impact Statement (STD 399), pg. 12.

the savings from existing home construction or renovation projects, commercial construction projects (new and existing buildings), and industrial applications are factored in.

According to industry estimates in 2014, there are approximately 1,500 jobs in California related to the application of high-pressure SPF and it is generally acknowledged that users of high-pressure SPF also handle low-pressure SPF. The California high-pressure SPF market is a $63 million annual market, according to industry estimates. Similar information for low-pressure SPF products is not available at an industry level. There are three systems houses which operate manufacturing facilities related to high-pressure SPF in California, two of which are headquartered in California. A third systems house is headquartered in the State, but does not manufacture in California. ACC is unaware of any manufacturing facilities located in California for low-pressure SPF products.

The potential loss of market, or reputational harm from the product being subject to inaccurate claims that it harms workers, users and the public, could cause fewer builders to specify the product and fewer building owners to desire it globally. Since it is a product with multiple attributes, a diminished desire to specify the product will make it more resource-intensive for Californians to meet the State's energy requirements and address the climate change goals outlined by the Governor in 2015 and various federal requirements. Further, reluctance to use a product, based on damage to its reputation in the global market, could raise the cost of construction labor as multiple products could be required for insulation, roofing, air sealing and other attributes achievable with a single product. DTSC has failed to account for the potential loss of benefits to the state and globally.

B. DTSC's Consideration of An Alternative to A Regulation was Insufficient

As there is currently no technically and economically feasible alternative to the use of unreacted MDI in SPF Systems currently available on the market, ACC offered DTSC an alternative to the regulatory listing. The pathway was developed because conducting an abridged AA would not provide the Department with meaningful information. ACC's alternative pathway proposed that the SPF industry undertake a multi-year, California-focused product stewardship and safety campaign to further educate key stakeholders on existing workplace safety regulations, the availability of SPF product stewardship materials, training programs, and general health and safety information.

This California Spray Polyurethane Foam Campaign would have created a mutually beneficial cooperative agreement that would have furthered ACC's and DTSC's shared goals of safe use of products, continuous improvement in workplace safety, and addressing stakeholder concerns.

Upon considering the alternative regulatory pathway, DTSC concluded "all of the solutions proposed can be accomplished within the framework of the regulations" and that regulating SPF Systems under the SCP program ensures that DTSC is able to enforce any regulatory response.[46]

[46] Lee, Barbara to Salamone, Lee; November 17, 2015

In contrast, in the Economic analysis, DTSC states:

> "DTSC rejected this option because it does not advance the goals of the SCP regulations in general and of this proposed regulation in specific: to drive SPF systems manufacturers to find safer alternatives to MDI in SPF while avoiding regrettable substitutions."

Outside of the formal regulatory package, DTSC previously stated that ACC's alternative regulatory pathway could accomplish the same goals of the SCP program, however it appears the Department simply wants an AA for a product that the agency has already concluded does not have an alternative. DTSC has essentially predetermined the outcome of any AA by concluding that DTSC expects an abridged assessment. Based on DTSC's potential confusion on the issue, we reaffirm our continuing interest and request that DTSC reconsider a voluntary stewardship program as opposed to listing.

VI. The Proposed listing of SPF as a Priority Product is Not Authorized Under and Conflicts with Federal and State Law

A. DTSC's Role is to Protect Human and Environmental Health; Not to Pick Market Winners and Losers

By arbitrarily selecting SPF Systems for potential listing as a priority product and potentially requiring SFP manufacturers to fund third-party research into the development of alternatives, DTSC's proposal reflects that inadequate consideration has been given to the fact that SPF is already well controlled and represents an important product that provides significant benefits to Californians. As noted previously, given DTSC's core role is to protect human health and the environment, the decision to focus on SPF Systems as a priority is unjustified and serves little purpose.

DTSC's proposal also has the effect of inappropriately picking market winners and losers by targeting one specific industry and product while ignoring other industries and products that may offer greater potential to reduce exposure to toxic chemicals. Listing SPF Systems as a Priority Product will produce a significant and direct economic impact on SPF manufacturers that will reduce their ability to complete in the marketplace and diminish the benefits that SPF products provide. DTSC's potential path forward demonstrates a continued reliance on California's prior approach focused on "single product bans," even though the SCP regulations were intended to change this orientation. Implementing the SCP program in this manner is inconsistent with the legislature's intent and contrary to DTSC's mission.

B. Listing SPF Systems as a Priority Product May Result in a Violation of the Commerce Clause

DTSC's proposed listing of SPF Systems as a Priority Product may result in a violation of the Commerce Clause of the United States Constitution because such a listing will compel DTSC to take certain regulatory responses pursuant to Article 6 at the conclusion of the AA process. As

DTSC notes, 14 of the 17 manufacturers that will be affected by the proposed listing are headquartered outside of California.[47] To the extent that DTSC's regulatory responses include the regulation of commerce outside of California or impose excessive burdens on interstate commerce, those regulations would violate the Commerce Clause.

The dormant Commerce Clause Limits State Regulation of Interstate Commerce

The Commerce Clause provides that "Congress shall have power … [t]o regulate Commerce with foreign nations and among the several States."[48] Although a literal reading of the Commerce Clause "evinces a grant of power to Congress, the Commerce Clause also directly limits the power of the States to discriminate against interstate commerce."[49] Under the "negative" or "dormant" aspect of the Commerce Clause, "State and local governments may not use their regulatory powers to favor local enterprises by prohibiting patronage of out-of-state competitors at their facilities."[50]

The bar on extraterritorial regulation applies regardless of whether the state law or regulation discriminates against interstate commerce or involves economic protectionism.[51] In this respect, the Commerce Clause not only ensures the free flow of goods and services across state lines, but also enforces the territorial limitations on state power inherent in a federal system composed of 50 separate sovereigns, by preventing any one state from "project[ing] its legislation" onto other states.[52]

Further, even if a statute or regulation regulates in an even-handed manner and does not attempt to regulate commerce extraterritorially, it may nevertheless violate the Commerce Clause when "the burden imposed on [interstate] commerce" by the law or regulation "is clearly excessive in relation to the putative local benefits."[53] While "a State's power to regulate commerce is never greater concern than in matters of local concern… the incantation of a purpose to promote the public health and safety does not insulate a state law from Commerce Clause attack."[54] Further, "[l]ess deference is to the legislative judgment is due … where the local regulation bears disproportionately on out-of-state residents and businesses."[55]

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[47] ISOR at 22.
[48] U.S. Const. Art. I, § 8, cl. 3.
[49] *Wyoming v. Oklahoma*, 502 U.S. 437, 454 (1992).
[50] *C. & A. Carbone, Inc. v. Clarkstown*, 511 U.S. 383, 394 (1994).
[51] *Miller*, 10 F.3d at 638 ("discrimination and economic protectionism are not the sole tests); *accord Midwest Title Loans, Inc. v. Mills*, 593 F.3d 660, 665 (7th Cir.).
[52] *Baldwin*, 294 U.S. at 221.
[53] *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970); *Quill Corp. v. North Dakota*, 504 U.S. 298, 312 (1992) (Commerce Clause "bars state regulations that unduly burden interstate commerce"); *see also Kassel v. Consolidated Freightways Corp. of Del.*, 450 U.S. 662 (1981); *Raymond Motor Transp., Inc. v. Rice*, 434 U.S. 429 (1978); *Bibb v. Navajo Freight Lines*, 359 U.S. 520 (1959).
[54] *Kassel*, 450 U.S. at 670.
[55] *Id.* at 675-76.

DTSC's Regulatory Response to Listing SPF May Constitute Extraterritorial Regulation

If SPF Systems are listed as a Priority Product, the regulatory response imposed by DTSC at the conclusion of the AA has the potential to be an unlawful extraterritorial regulation because the vast majority of the SPF manufacturers are located outside of California. As part of the AA, each regulated entity must prepare a final assessment that requires a comparison and selection among possible alternatives based on the "relevant exposure pathways and life cycle segments."[56] This means that, in selecting between alternatives, a regulated entity must consider "the sum of all activities in the course of a consumer product's entire life span, including raw material extraction, resources inputs and other resource consumption, intermediate materials processes, manufacture, packaging, transportation, distribution, use, operation and maintenance, waste generation and management, reuse and recycling, and end-of-life disposal."[57] Thus, because of this assessment, the regulated entity may ultimately be required to alter, redesign, or reformulate its product depending on whether factors in the life cycle of the product (or its alternatives) are deemed to contribute to adverse impacts or create a demonstrable difference between alternatives.[58]

The result of this process is that DTSC asserts authority to condition importation of SPF Systems (or an alternative Priority Product) on DTSC's determination that certain out-of-state practices result in safer consumer products. By viewing the adverse effects associated with various alternative products and processes through the lens of a life cycle analysis, DTSC asserts the authority under the regulations to condition the importation of SPF Systems on changes made wholly within another state, including changes to the "raw materials used," the "intermediate material processes," or the "manufactur[ing]," "packaging," and "transportation" of the product out of state.[59] If DTSC were to act in such a manner when selecting a regulatory response, its actions may "extend the [State's] police power beyond its jurisdictional bounds" by attaching "restrictions to exports or imports in order to control commerce in other States."[60] If California were to "project its legislation" into other States in this manner, the SCP regulations, as implemented for SPF Systems may violate the dormant Commerce Clause.[61] To avoid such an outcome, DTSC's remaining regulatory response options may be so limited that listing SPF as a priority product would not result in any meaningful change to current operations under existing laws and regulations.

DTSC's Regulatory Action May Unduly Burden Interstate Commerce

Even if DTSC's regulatory responses were not deemed to constitute extraterritorial regulation, they may nevertheless violate the Commerce Clause if "the burden imposed on [interstate] commerce is clearly excessive in relation to the putative local benefits."[62] The SCP regulations

[56] Cal. Code Regs. Title 22 § 69505.6(a)(3)(A).
[57] *Id.* § 69501.1(a)(42).
[58] *Id.* § 69506.5(a)(b).
[59] *Id.* § 69501(a)(42).
[60] *C. & A. Carbone*, 511 U.S. at 393.
[61] *Baldwin*, 294 U.S. at 521.
[62] *Pike*, 397 U.S. at 142.

are designed to protect health and welfare of California consumers, which is a strong local benefit for which DTSC would normally have considerable regulatory power.[63] However, DTSC's regulatory response could conceivably require an out-of-state SPF manufacturer to overhaul its out-of-state operations to produce an alternative product that meets DTSC's requirements while producing little if any real benefit to public health. There is a substantial likelihood that such an outcome could occur because, as described above, existing state and federal regulations, along with voluntary efforts taken by ACC and the SPF industry, have already significantly addressed any risks to public health associated with SPF Systems. Again, in light of the limited public health benefits that listing SPF Systems will have DTSC's regulatory response options would have to be extremely limited in order to avoid imposing an undue burden on interstate commerce.

C. Listing SPF as a Priority Product May Result in a Violation of the Takings Clause

If DTSC lists SPF Systems as a Priority Product, there is also a risk that its ultimate regulatory response may constitute an unconstitutional taking under the Fifth Amendment. As explained above, there are no current viable alternatives to unreacted MDI in SPF Systems, meaning that DTSC's regulatory response may focus on the advancement of green chemistry and green engineering.[64] Under the regulations, DTSC would be authorized to require regulated entities to fund challenge grants whereby they would fund third-party research to develop alternatives to the SPF Systems that they produce. While critical details on DTSC's future actions, if any, remain unclear at the time of this listing proposal, there is concern that such a regulatory response constitutes an unconstitutional taking.

The Takings Clause of the Fifth Amendment prohibits the taking of "private property for public use without just compensation."[65] A paradigmatic taking occurs when the government causes a "permanent physical occupation" of an individual's property.[66] However, a government regulation also can effect a taking when it affects or limits the use of private property to a sufficient degree.[67] A regulatory taking claim is evaluated under the three-part *Penn Central* test where a court must consider (1) "[t]he economic impact of the regulation on the claimant," (2) "the extent to which the regulation has interfered with distinct investment-backed expectations," and (3) "the character of the government action."[68]

Requiring SPF manufacturers to fund a challenge grant could constitute a regulatory taking under the Fifth Amendment. First, while the size of a challenge grant is unknown, the economic impact on SPF manufacturers could be significant. There are no viable alternatives to unreacted

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[63] *See, e.g.*, *Kassel*, 450 U.S. at 670 (plurality op.).
[64] Cal. Code Regs. Title 22 § 69505.6(a)(3)(A).
[65] U.S. Const., amend V.
[66] *See, e.g.*, *Lingle v. Chevron U.S.A.*, 544 U.S. 528, 537 (2005).
[67] *Id.* at 537-3; *see also Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393 (1922) ("a strong public desire to improve the public condition is not enough to warrant achieving the desire by a shorter cut than the constitutional way of paying for the change").
[68] *Penn Central Transp. Co. v. New York City*, 438 U.S. 104, 124 (1978).

MDI in SPF Systems currently on the market, and the resources needed to develop such an alternative (if one could be developed at all) could be substantial, necessitating a large challenge grant. Second, requiring SPF manufacturers to fund a challenge grant would conflict with their investment-backed expectations. Not only would funding a challenge grant increase the cost of producing SPF products for sale in California, it would directly undermine the investment-backed expectations of the regulated entities by promoting the development and increased market penetration of competing "safer" alternative products. Third, it would be fundamentally unfair to impose on SPF manufacturers the obligation to fund the development of alternative products that they do not produce and for which they have no ownership. To the extent that California seeks to promote the development of alternatives, the expense of that obligation should be borne by the public, not by a limited group of companies, the majority of which are located in other states.

Finally, imposing a challenge grant obligation on SPF manufacturers may constitute an unconstitutional condition. Under the unconstitutional conditions doctrine, a government cannot condition certain actions on the relinquishment of a party's rights under the Takings Clause absent a showing of a sufficient "nexus" and "rough proportionality."[69] More recently, the Supreme Court has explained that this doctrine also applies when the condition imposed by the government includes the payment of money.[70] In this case, requiring SPF manufacturers to fund a challenge grant as a condition of marketing their products in California may violate the unconstitutional conditions doctrine. First, as discussed above while details on DTSC's potential future actions, if any, remain unclear, the requirement to fund the development of an alternative product may qualify as the taking of property under Fifth Amendment. Second, the legal requirement to fund a challenge grant may not bear a sufficient nexus or rough proportionality to the regulatory benefit at issue, which is the ability to sell SPF Systems in California.

D. DTSC's Proposed Notice of Exemption is Unlawful Under CEQA

DTSC's actions under the SCP program are subject to the California Environmental Quality Act ("CEQA"). DTSC has proposed to issue a Notice of Exemption ("NOE") under CEQA on the basis that "it can be seen with certainty that there is no possibility that the activity in question may have a significant effect on the environment."[71] Such a determination is premature and unlawful because the potential environmental effects of listing SPF Systems as a priority product cannot be known until an alternatives analysis is complete and DTSC has determined the regulatory response that will be required.[72]

Making changes to the manufacturing process for SPF or selecting an alternative product that cannot provide the full suite of benefits that SPF provides could have significant environmental

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[69] *Nollan v. California Coastal Commission*, 483 U.S. 825 (1987); *Dolan v. City of Tigard*, 512 U.S. 374 (1994).
[70] *Koontz v. St. Johns River Water Management District*, 133 S. Ct. 2586, 2599-600 (2013).
[71] Cal. Code Regs. Title 14 § 15061(b)(3); *see also* DTSC, Proposed NOE, *available at* http://www.dtsc.ca.gov/SCP/upload/SPF_CEQA_NOE.pdf.
[72] For the same reasons, DTSC's assertion in the Notice of Proposed Action ("NOPA") that the proposed listing of SPF will not impact housing costs is premature. SPF is a critical product for new housing and the selection of a more costly regulatory response by DTSC would impact housing costs. NOPA at 7.

effects that differ from the alleged effects associated with SPF Systems. For example, selecting an alternative the lacks the durability of SPF could require more frequent replacement with increased environmental impacts. Likewise, less effective alternatives may result in increased energy use to heat and cool homes. Given the compelling absence of any human health or environmental concern, there is material risk that the Department will order a "regrettable substitution." It is incumbent under CEQA for the Department to consider that potential outcome now, before it takes any further steps to list the product.

DTSC cannot short circuit the CEQA process by issuing an NOE before potential environmental effects of alternatives can be identified and evaluated. Thus, DTSC must comply with CEQA's requirements and conduct a full environmental review of potential impacts that could arise from listing SPF as a priority product. Moreover, DTSC must ensure that the CEQA process remains open until any alternatives analysis is complete so that DTSC can fully evaluate potential environmental impacts before selecting a regulatory response. Failing to do so would unlawfully undermine the purpose and intent of CEQA to promote informed agency decision making.

VII. Conclusion

ACC strongly opposes the proposed listing because it is unwarranted and misdirected. The proposal is based on inaccurate characterizations of the spray foam products, as well as the safety practices and trends associated with their use. Moreover, DTSC has not met the requirements for listing under the SCP program and the proposal raises a variety of legal concerns associated with implementation.

VIII. Appendix A – Product Descriptions: SPF Systems

High-Pressure Two-Component SPF Insulation and Roofing

High-Pressure Two-Component SPF Insulation is available as an open cell (half-pound) foam or a closed cell (2-pound) and roofing (3-pound) foam. High-pressure SPF products (open-cell insulation, closed-cell insulation, and roofing) have distinct physical properties, different potential exposure profiles, and should be considered different products.

High pressure SPF insulation and roofing systems use 55-gallon drums or 250 gallon totes and truck-based spray rigs to apply foam in buildings or on roofs. They are more often used when insulating larger areas on new construction or major renovations on walls and roofs. These systems are heated to approximately 120^{o} F and pressured to approximately 1000-1300 psi. These SPF products and the equipment used to apply them are intended for professional use. Manufacturers typically require installers to have special training in the handling and the safe use of the products and equipment that is used. Installers are typically outfitted in specialized PPE, including coveralls, skin protection and gloves. SPF insulation for interior applications typically involves supplied air respirators; exterior applications, such as roofing and exterior tank or building insulation, where natural ventilation exists typically involve applied air respirators with appropriate air filter cartridges. The differences in these worksite considerations support the conclusion that cavity insulation SPF and roofing or exterior applications of SPF be considered different products.

For SPF wall cavity insulation, installers typically contain work areas with tarps and partitioning as appropriate, restrict access to the spray area during and for a period after spray, ventilate the work area during and after spray, and wear appropriate PPE during and after spray for a certain amount of time.

For typical high pressure SPF insulation and roofing applications, a spray rig (truck) which houses the SPF ingredients, air supply and other items is parked near the home or building to be sprayed. Hoses (up to about 300 ft. in length) are carried to the application area. A professional high-pressure SPF installer company has a high capital investment for these systems, engages in specialized training to use the equipment, as well as industry training and manufacturer training in the safe handling of materials.

Low-Pressure Two-Component SPF Insulation

Low-pressure two component SPF products are both open- and closed-cell and have a slower delivery rate and expel a smaller volume of foam compared to high-pressure two-component SPF products.

Typically, they are used to cover smaller surface areas and are applied as a froth without heating and under low-pressure (less than 250 psi). The material is applied at an initial rate of 5-7 lbs/minute reducing to less than 2 lbs/minute during the application. Low-pressure two-component SPF products are insulation and/or sealant products.

Single Use Kits:

Low-pressure systems can be sold as a one-time use kit. Generally, two 3 or 5 gallon containers are sold in a ready-to-use system. The kits are typically emptied in 15-30 minutes. Low-pressure foams kits do not aerosolize the two primary chemicals, but instead the chemicals are combined in a static mixer and begin to polymerize before release. This significantly reduces the exposure to unreacted MDI during the application process.

Refillable Drums and Tanks:

Low-pressure systems are also available in a refillable drum or tank system. These systems are larger than the single-use kits and are typically a 17-250 gallon size depending on the customers' need. They use either a refillable nitrogen tank or air to apply the foam as a froth. This type of equipment is for professional use, requiring a larger investment than low-pressure kit foam, but a smaller investment than typical high pressure equipment. This equipment is likely to be used for smaller jobs, but because of the ability work from standard 55-gal drums or 250 gal tanks, it can also be used for larger jobs. Regardless of size, these low pressure systems still use static mixing to polymerize the foam before release and do not aerosolize the two primary chemicals; the nitrogen or air is only used to get the product out of the container and the pressure of the "propellant tank" is not the same as the pressure seen at the static mixing gun. This significantly reduces the exposure to unreacted MDI during the application process.

Low-pressure SPF products (insulation and sealants) and high-pressure SPF products (open-cell insulation, closed-cell insulation, and roofing) each have distinct physical properties, application procedures and exposure considerations. They should be considered different products for purposes of this regulation. The Department should have considered them independently and recognized that an AA must be different for each thus driving up the potential cost of compliance with this proposed listing. We do not believe these factors have been considered adequately.

IX. Appendix B – Product Attributes

Thermal Insulation: SPF provides exceptional thermal insulation performance under a wide range of operating temperatures. Thermal insulation performance, measured as an R-value, depends on maintaining a still layer of air or gas within the insulation. R-value is a term used to rate an insulation's ability to resist conductive heat transfer. The higher the R-value, the more effective the insulation's ability is to reduce conductive heat flow.

SPF is especially valued for its ability to resist heat transfer. Air-impermeable SPF insulation results in a consistent thermal performance over a wide range of operating temperatures.

SPF insulation is installed at various thicknesses, depending on the application, and R-value is expressed per inch. Closed cell SPF provides an R-value in the range of 6 - 7 per inch. Like double-pane glass windows, the closed-cell foam structure entraps an insulating gas that enables it to achieve this range of R-values in limited spaces. Open cell SPF provides an R-value in the range of 3.5 – 4.5 per inch.

Air Barrier: All SPF insulation, sealants (open and closed cell), and SPF roofing products are inherently air-impermeable at typically-installed thicknesses, qualifying it as an approved air-barrier material. Model and adopted energy codes, including California Title 24, require air-impermeable materials to be installed in direct contact with all sides of air-permeable fibrous insulations to provide similar performance.

SPF is mixed on the jobsite, expanding in place to fill nooks and crannies in the building envelope, providing consistent air seal for all cracks, gaps and penetrations in the surface where it is applied. The use of SPF for the building envelope, in combination with low-pressure SPF sealants around window and door penetrations, with minimal sealing in other others, will create an air-barrier assembly for walls, roofs, ceilings or floors. Without SPF, extensive caulking and sealing at seams and joints is needed to create a complete air barrier system for the building enclosure. For this reason, the performance of SPF assemblies is hard to match.

Vapor Retarder: Building enclosures constructed in colder climates require some type of vapor retarder to control moisture and reduce the occurrence of water condensation. Regardless of what insulation type is used, without proper application of a vapor control layer, water condensation can develop leading to mold, mildew, rot and corrosion of building materials. Traditional fibrous insulations require separate air sealing in addition to the vapor retarder layer to avoid moisture problems thus requiring additional steps and time for installation.

Closed-cell foams provide a Class II vapor retarder at a thickness of 1.5 to 2.0 inches, without the addition of any facing, paint or film. This vapor retardant classification means one product can provide insulation, air barrier and vapor barrier all in one. When open-cell foams are used in colder climates, a vapor barrier is required. The needed vapor control layer can be obtained more easily with the addition of retarding paints versus conventional paint primers.

Flood Resistance: The cell structure of closed-cell SPF insulation provides water resistance in the event of a flood. Closed-cell foams are the only insulation recognized as flood resistant by the Federal Emergency Management Agency (FEMA). For this reason, FEMA recommends the use of closed-cell insulation in applications where water contact is likely – such as on basement or crawlspace walls – to mitigate losses in a flood event and help prevent mold growth.

Structural Enhancement: The closed-cell SPF expands in place to create a rigid foam material. When mixed and applied in the field, closed-cell SPF adheres to almost any clean, dry substrate material, such as wood, steel or concrete. Several independent studies have shown that closed-cell SPF provides structural enhancement to walls and roofs, increasing resistance to racking and wind uplift loads.[73]

Durability: The adhesion properties of SPF make it an excellent choice in many overhead applications because it does not require labor-intensive wire supports, netting, or fasteners to remain in-place. In addition, the stable cellular structure of SPF does not sag or settle over time, maintaining its performance over the life of the building.

[73] Test results are reported in "Testing and Adoption of Spray Polyurethane Foam for Wood Frame Building Construction" (May 25, 1992) prepared by NAHB Research Center for The Society of the Plastics Industry/Polyurethane Foam Contractors Division. Test results are reported in a letter from Bob Dewey, Mechanical Engineer, NAHB Research Center to Mason Knowles, Society of the Plastics Industry/Spray Polyurethane Foam Division (November 18, 1996).

X. Appendix C – PPE and Engineering Controls

PPE is required for applicators, helpers, and other adjacent workers who may enter a SPF application work area during and for a specified time after the application process. PPE requirements vary between indoor and outdoor applications and between high-pressure and low-pressure SPF systems. PPE recommendations are contained within company safety programs and manuals as well as the Safety Data Sheet ("SDS") for the product. Industry level information is also made available on trade association websites.

The use of appropriate protective clothing is necessary whenever there is the possibility of direct contact with SPF chemicals. A PPE evaluation prior to beginning work is used to determine the appropriate PPE for the job task. The following factors help in the selection of the right PPE for a job task:

- The type of product selected; not all types of SPF require the same level of PPE.
- Location of the job tasks, such as outdoors versus indoors, whether the work will take place in an enclosed space, the type of ventilation available, the ambient temperature and relative humidity, wind speed and direction, as applicable.
- Potential for inhalation exposure or eye or skin contact with SPF chemicals based on the job tasks.
- The quantity of SPF chemicals applied and the delivery method (aerosolized versus froth application).

The OSHA Respiratory Protection Standard (29 CFR 1910.134) requires employers to have a written respiratory protection program for employees required to use respiratory protection. The Standard outlines requirements for respirator selection, respirator maintenance, annual fit testing, medical evaluation, and annual training. Respirator user requirements are clearly outlined on the materials accompanying the product at the time of purchase.

OSHA requires employers to provide medical evaluations administered by a physician or licensed healthcare professional for all employees required to wear respirators. Employees must receive approval prior to fit testing and subsequent issuance of the respirator. OSHA also requires that employees complete a successful fit test using a respirator of the same make, model and size as the respirator issued. Fit testing must be repeated annually thereafter. In addition, annual training is required under the OSHA standard for all personnel required to wear respiratory protection.

PPE care and maintenance are critical considerations for proper PPE. These topics are addressed in industry programs and manufacturer recommendations. Single-use PPE must be disposed of in accordance with local or state environmental regulations. Reusable PPE is decontaminated after exiting the work area. Manufacturer recommendations cover the regular cleaning and disinfection requirements for reusable PPE.

Periodic inspection of PPE is conducted to identify equipment or components that need to be replaced, repaired, or refilled. Respirators are inspected per OSHA Respiratory Protection Standard. Generally, air purifying respirator (APR) inspection includes inspecting the mask and cartridges for damage and adhering to the end-of-service life indicator or the respirator filter/cartridge/canister change-out schedule. For powered air purifying respirators (PAPR), the inspection includes the elements of the APR inspection as well as the blow unit and battery.

For all SPF products, restricting access to the work area during these tasks helps prevent exposure. For example, employers can restrict access to personnel whose job responsibilities require them to be in the work area, are trained in the hazards of exposure to the chemicals, and use appropriate PPE properly.

SPF industry practices for SPF systems are designed to curtail potential MDI exposures to occupants and bystanders. The guidance below applies only to SPF application inside the building envelope. Requirements for outdoor application of SPF, including roofing, may vary significantly.

1. The building should be vacated during SPF application
2. Where the building cannot be vacated, the spray application area should be contained/isolated and ventilated
3. The spray area should be ventilated for a period following SPF installation;
4. Building occupants should not return until after the manufacturer's recommended re-occupancy time has elapsed

Additional considerations for the application of SPF would include marking the job site with signs to warn non-workers to stay away, utilizing windscreens to avoid overspray, protecting surfaces from overspray, and considering wind speed and direction during the application process.

The potential risk from exposure to a chemical is dependent on several factors, including the route of entry, the dose, and the frequency and duration of exposure. To prevent potential exposure to unreacted MDI above the applicable occupational exposure limits (OEL) during the SPF application process, some industry practices include, but are not limited to, the following steps to control and reduce exposure to acceptable levels.

Consideration for High-Pressure SPF Insulation Systems (Interior)

Engineering Controls: Proper containment and ventilation techniques can help prevent workers and building occupants from potential chemical exposure during and after SPF application. Containment creates a contained workspace while the ventilation system removes SPF chemicals from the work area by drawing the air out of the workspace though the use of a fan. Active ventilation is achieved by using one or more fans to draw air to or from the workspace to create pressure differential to ensure the flow of air into or out of the workspace. The exhaust from the workspace is routed to an appropriate location outside and away from the building and occupied places. Guidance for engineering controls for outdoor applications may differ to reflect the conditions.

Site Preparation: Careful consideration of many factors goes into planning an SPF installation. For example, site preparation may include consideration of: design of containment and ventilation methods; ordering HVAC systems to be shut down during application; establishing a controlled work zone at the site to notify and protect other trade workers; designation of an area for putting on and removing PPE.

Occupant Outreach: In some instances, it may be impossible to completely vacate a building during SPF application. SPF applicators develop containment and ventilation methods to help prevent migration and communicate necessary information about potential health hazards associated with SPF to building owners and other occupants. Administrative controls, such as work schedules and work practices, are used concurrently to minimize exposure.

PPE: Applicators and helpers wear disposable coveralls to keep spray and mist from contacting skin and clothing. When not wearing a hood respirator, PPE can be selected that includes an attached hood or spray head cover. For tasks where there is a potential for splash, a suit coated with an impermeable coating such as PVC can be used.

Gloves made of nitrile, neoprene, butyl or PVC are used to protect against A-side materials.

Appropriate eye protection helps prevent eye contact from splashes of liquid chemicals, accidental sprays of reacting foam, aerosols and vapors that are likely to be present during spraying, and airborne particulate associated with sanding and grinding. The type of eye protection needed depends on the nature of the activity. Persons handling liquid SPF chemicals in open containers can protect their eyes by wearing safety goggles or safety goggles in combination with face shields. During application of SPF, eye protection may be provided by wearing a full-face or hood respirator.

Respirators are used when air concentrations exceed occupational exposure limits when engineering and administrative controls are implemented.

APRs and PAPRs are generally appropriate when spraying high-pressure spray polyurethane foam in exterior applications. Supplied air respirators (SAR) are typically used in interior applications for high-pressure SPF applications.

High-Pressure Two-Component SPF Roofing (Exterior)

Because SPF roofing is applied outside, the manufacturer's health and safety recommendations are often different as compared to high-pressure two-component SPF insulation products applied to an interior space. As mentioned for interior high-pressure two-component insulation, occupant outreach, site preparation and PPE are still required for exterior SFP roofing application. APR's and PAPR's are generally appropriate for exterior applications and may be used when spraying polyurethane foam in exterior applications.

Low-Pressure SPF Kits

Product Engineering Controls: The amount of product and method used in an application and the application process are important factors to consider when analyzing potential user exposure. As discussed in the May 13, 2015 presentation to the DTSC (and submitted in detailed comments in June of 2014), low-pressure two-component SPF single-use kits are sold in 3-5 gallon kits.

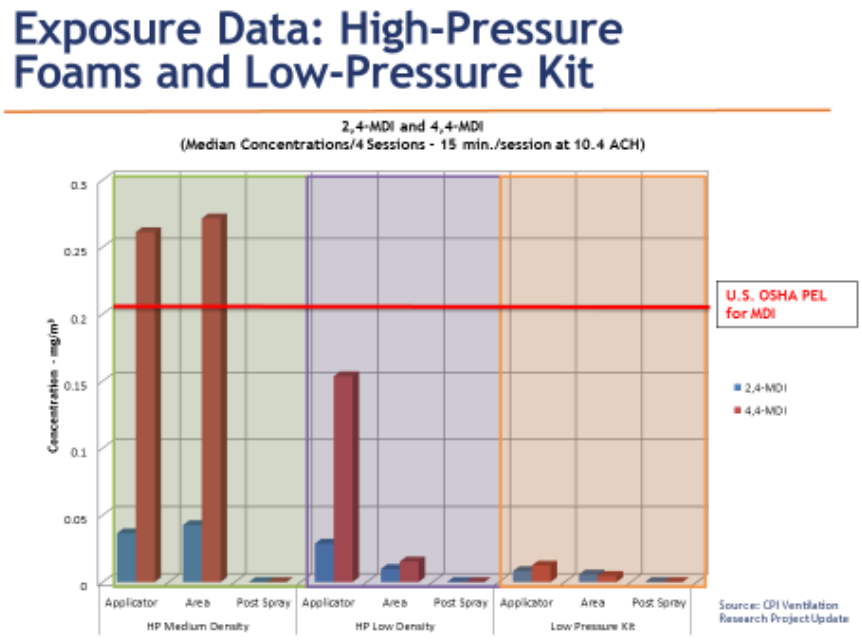
Applicators use low-pressure SPF systems for sealing cracks and gaps around doors and windows, sealing/insulating attic floors and rim joists, and insulating small areas or repairing larger insulation jobs. Less product is applied and the time to use it is brief in comparison to whole building insulation applications of high-pressure systems; these factors result in low potential exposure for users. For example, when air sealing with a kit, one foam kit would be needed for sealing around a typical basement wall. The product would be applied in a discontinuous manner with the user moving from one location to another. When insulating with a kit, the material is spray applied to a limited area like rim joists or ceiling areas or used in repairing other spray foamed areas (after a renovation, for example). It would not be cost effective to use kits to fully insulate large areas (about 14 kits would be needed to fully insulate the basement of an 1800 ft^2 house with 2 inches of foam). Therefore, kits are generally used for short periods, in small jobs.

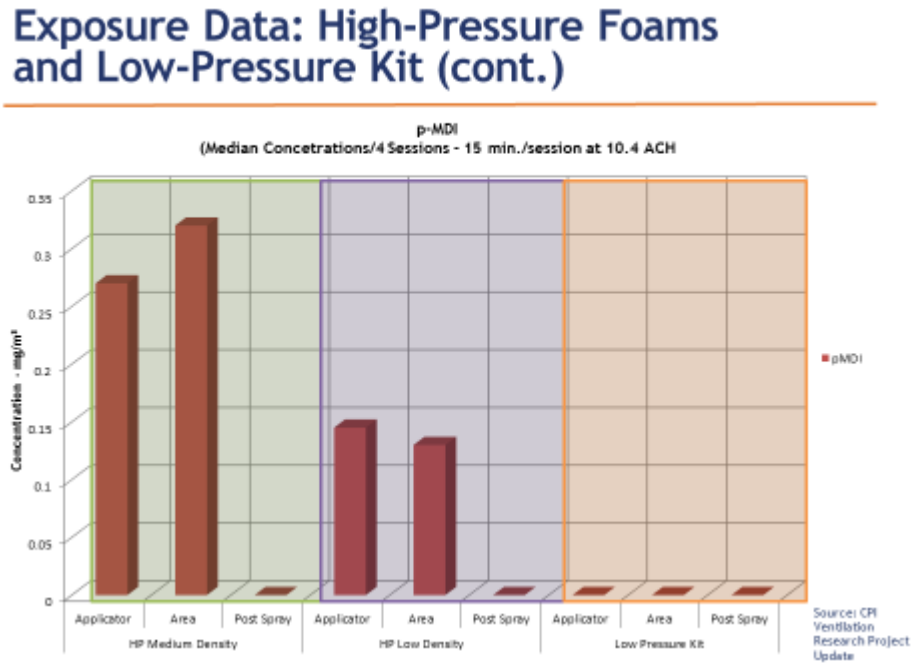
Further, low-pressure spray foam is applied without heating and is applied in the form of a froth which further reduces the potential for exposure to airborne unreacted MDI. Applicators are not exposed to the aerosolized particles typical in high pressure application methods. The kits are typically emptied in 15-30 minutes due to the low volume of material used. These application factors combine to reduce significantly the already low inhalation exposure potential. Again, building occupants should not return until after the manufacturer's recommended re-occupancy time (some manufacturers recommend 1 hour for low-pressure) has elapsed.

While low-pressure systems can use larger refillable containers (17-250 gallons), these are for professional use and are sold only to specific companies with trained employees as stated in the product reports showing building code compliance evaluated in accordance with AC377.[74] These professional users would be expected to follow all of the product, engineer, and PPE controls outlined and have the same exposure potential as the kit systems due to use of the same low-pressure froth application.

Extensive company-specific data was submitted to DTSC in ACC's June 2014 comments. Industry data comparing interior applications of high-pressure foams and low-pressure kits was submitted to DTSC multiple times and is reproduced below:

[74] Acceptance Criteria for Spray-Applied Foam Plastic Insulation (AC 377), ICC Evaluation Service. Approved May 2015.





Use of low-pressure kits results in low potential exposures to MDI to applicators during spray of froth foam (well below the OSHA PEL). Use of kits results in non-detectable area concentrations within approximately 30 minutes of spraying.[75]

[75]Wood, R. (2012). CPI Ventilation Project Phase 1 and Phase 2 Update. Paper presented at the 2012 Polyurethanes Technical Conference. Table 5.

Low-Pressure SPF Product Stewardship: Product stewardship efforts for low-pressure SPF Systems promote safe installation practices, and health and safety information on the proper handling and disposal of products. Among these practices are appropriate design, packaging and labeling of products including the provision of detailed product information, operating instructions, and health and safety precautions on the packaging or easily accessible on line. Outreach on responsible practices, PPE, product information and customer / technical support is made available by the manufacturers and free online health and safety training (in English and in Spanish) is advertised. Detailed use and safety instructions are provided with the products. The combination of manufacturer and industry-wide product stewardship programs combine to provide a comprehensive network of readily available sources of information and training to users.

PPE: Recommended PPE is indicated on packaging and is sometimes sold alongside the product itself. The use of appropriate protective clothing is necessary whenever there is the possibility of direct contact with SPF chemicals. The appropriate protective clothing varies depending upon the potential for exposure and the type of product in use. Applicators and helpers typically wear disposable coveralls to keep spray and mist from contacting skin and clothing. To protect skin, it is recommended that PPE be worn.

Gloves made of nitrile, neoprene, butyl or PVC protect against A-side materials.

Appropriate eye protection helps prevent eye contact from splashes of liquid chemicals, accidental sprays of reacting foam, aerosols and vapors that are likely to be present during spraying, and airborne particulate associated with sanding and grinding.

APRs are generally appropriate when spraying low pressure spray polyurethane foam.

Engineering Controls: Ventilate work area through open windows and doors as suggested by the manufacturer to help provide ventilation. This may include the use of fans and containment measures.

Risk associated with exposure to unreacted MDI for all SPF systems is well researched and extensive information is provided through multiple channels to users through existing industry reference practices, manufacturer guidelines, packaging, instructions and recommendations, and workplace safety standards and regulations. Users have access to reference practices through several resources offered by the industry. Training and certification programs offer initial and continual education on the proper methods for handling and installing SPF insulation. As a result of the promotion and dissemination of these industry reference practices, manufacturer recommendations, and workplace safety standards and regulations, SPF roofing, sealing, and insulation products are well-understood and the risk of exposure to chemicals can be managed to acceptable levels. For DTSC to assert that SPF systems products present the potential for widespread or significant adverse impacts ignores realistic conditions of use and is not supported by the data, as previously stated.

XI. Appendix D – SPF Stewardship Practices and Training Programs

Spray Foam Coalition Code of Conduct

ACC's SFC requires each systems house member to sign and adhere to a Code of Conduct. The Code demonstrates an important and continuous commitment to product stewardship that benefits the entire SPF value chain as well as everyone in the built environment. The signatories, SFC members that manufacture SPF systems, promote worker and public health and safety with respect to their SPF products, which include the chemicals that react to make SPF and the final SPF materials.

The SFC Code of Conduct includes commitments to leadership, communication, applicator training, education, and research. Agreement and adherence to this code of conduct is a requirement for membership in the SFC for members that manufacture SPF systems.

Professional Development & Certification

CPI supports professional development courses and certification programs for SPF professionals, including applicators, helpers, site managers and weatherization contractors. An example is the SPFA Professional Certification Program (PCP).[76]

The SPFA PCP multi-level certification is a rigorous and extensive program for professionals who install SPF insulation and roofing. The program is developed, designed and operated in compliance with internationally recognized ISO-17024 standards. The program includes the following requirements:

- Complete CPI's High-Pressure SPF training program (described below);
- Pass the PCP exams related to the levels of certification being pursued, which for higher levels of certification require demonstration of knowledge and testing inclusion of content for all lower level exams.[77]
- Document spraying experience, and complete CPR, first aid and OSHA safety courses (OSHA 10- or 30-hour card) for higher levels of certification by SPFA; and
- Maintain certified status annually and recertify every five years with SPFA.

The PCP enables individuals who complete the program to demonstrate knowledge, skills and professional accomplishment. The program also enables homeowners, architects and builders to identify and employ SPF professionals who have learned the highest installation and safety standards by identification cards issued by SPFA upon successful completion of the PCP.

[76] Additional information on the SPFA PCP is available at: http://www.sprayfoam.org/certification.
[77] Certification levels include: SPF Assistant; SPF Insulation Installer; SPF Roofing Installer; SPF Insulation Master Installer; SPF Roofing Master Installer; SPF Insulation Project Manager; and SPF Roofing Project Manager.

CPI Online Training Courses

CPI has two online chemical health and safety training programs which provide information about the use, handling and disposal of SPF, potential health hazards and control measures, including engineering controls and PPE. Since its release in 2010, more than 16,800 individuals have accessed the High-Pressure SPF Chemical Health and Safety Training either online or in an instructor-led setting in either English or Spanish. The launch of the Low-Pressure SPF Chemical Health and Safety training program in late 2012 - in English and Spanish - provides a national level, free basic chemical health and safety training program for professional SPF contractors and helpers, and weatherization professionals. Materials developed for the low-pressure training were produced with funds from an OSHA Susan Harwood Grant. Since its release in December 2012, more than 3,300 individuals have accessed the low-pressure training. In addition, the CPI training programs were approved for the Building Performance Institute's (BPI) continuing education units (CEU) and RCI, Inc. for Continuing Education Hours (CEHs).[78]

CPI has also created a low-pressure training video "Working Safely with Low-Pressure Spray Polyurethane Foam Insulation." The video provides general guidance for professionals on how to apply low-pressure spray polyurethane foam. It is intended as a supplement to other job safety information already available such as specialized training, Safety Data Sheets (SDS), product label information and other materials. It can be viewed on CPI's website or downloaded for user to keep. Since 2011 there have 3,300 recorded downloads.

Manufacturer Training

All manufacturers of high and low pressure spray polyurethane who have a report showing building code compliance evaluated in accordance with AC377 must provide user training to their customers. As noted in the ACC377 document, these "evaluation reports (typically) issued by ICC Evaluation Service, LLC (ICC-ES), are based upon performance features of the International family of codes." "This acceptance criteria has been issued to provide interested parties with guidelines for demonstrating compliance with performance features of the codes referenced in the criteria. The criteria was developed through a transparent process involving public hearings….. and/or on-line postings where public comment was solicited." Under section 5.2 on installer credentialing "the evaluation report shall state that the installation shall be by professional contractors certified, accredited, authorized or approved by the report holder, or by SPFA."[79]

Product suppliers help promote applicator safety by through regular training, the completion of which is documented in company certification databases. Certified contractors are required to re-certify every two years. Manufacturer certification requirements typically include: reading the operating manual, completing on-line safe handling and product handling training, completing a certification quiz, and finally receiving validation from the manufacturer that they have passed the certification quiz

[78] Both training courses are accessible to the public at www.spraypolyurethane.org.
[79] AC 377.

XII. Appendix E – Cooperation with Regulatory Authorities

U.S. EPA

In 2009, the polyurethane industry, working together through CPI and the SPFA, launched an enhanced product stewardship program to support further understanding of the benefits of SPF, safe use and handling, hazard communication, and marketing claims. This voluntary program focuses on the following practices and communications that can help to minimize potential for exposure of workers and building occupants to SPF chemicals.

- Worker Performance and Training. Develop and deploy health and safety training programs for professional SPF applicators;
- Outreach. Educate applicators and the building/construction sector about responsible practices on key issues including the selection of a contractor; different types of SPF products; health and safety considerations for applicators during and after SPF product installation; and
- Research. Develop research and support testing programs to improve understanding of potential exposure to chemical components for workers applying SPF and potential occupant exposure to SPF emissions.

As a result of this collaborative approach, CPI has developed a plethora of resources on product stewardship and safe handling information, including videos, regulatory compliance information, as well as training modules to address questions about raw materials related to environmental, health and safety, distribution, use, emissions, and waste issues.[80] Progress relating to these efforts is detailed in annual or semi-annual updates provided to EPA leadership. Progress in training programs is reported monthly to EPA and industry stakeholders as both a metric for success and an impetus for continued progress.

In addition, EPA has made extensive information available on its website that complements other product stewardship information. This information has been made available at industry conferences for several years.

U.S. OSHA

CPI promotes opportunities to provide guidance on safe use and handling of polyurethane products, and has developed extensive programs to educate and provide information and safety precautions to workers, including information about compliance with U.S. EPA and OSHA regulations. CPI works with the value chain and provides these extensive resources, including training opportunities, guidance documents, tools and videos, as well as professional development courses that can help manufacturers and facilities learn about important OSHA requirements (e.g., 29 CFR 1910), such as workplace exposure limits that are established and enforced by OSHA. This industry will continue to lead worker safety and product stewardship efforts and coordinate with OSHA on worker safety initiatives.

[80] Resources *available at*: www.spraypolyurethane.org.

Further, ACC is currently working with the OSHA Office of Outreach Services and Alliance on establishing a national alliance between OSHA and ACC to develop a collaborative relationship. At this time, the Alliance is being developed to provide additional training resources to protect the health and safety of workers, particularly by reducing and preventing exposures to diisocyanates and understanding the rights of workers and the responsibilities of employees under the Occupational Safety and Health Act – similar to OSHA alliances with other industries. These goals will be accomplished through continued effective training programs on health and safety procedures relative to diisocyanates regarding responsible practices, effective approaches and guidance through workshops, seminars and lectures. The Alliance is intended to include labor organizations as well.

Consumer Product Safety Commission (CPSC)

In 2014, CPI provided research samples of freshly spayed cured foam to the CPSC for its work with the National Institute of Standards and Technology (NIST) to support work to develop ASTM International standard methods for measuring emissions from cured SPF. This work is ongoing.

XIII. Appendix F – Technical Inaccuracies and Mischaracterizations

This Appendix outlines technical inaccuracies and mischaracterizations in the ISOR and Summary of Technical Information. This provides further evidence that DTSC has failed to demonstrate that SPF systems present "a potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product" *or* "a potential for significant or widespread adverse impacts."

Inaccurate Worker Exposure Routes, Monitoring Studies, MDI-induced Worker Fatalities and MDI-induced Occupational Asthma:

- DTSC users reference *US EPA 2013c* to show the various exposure routes for isocyanates. This is a secondary reference that links to a CPI document entitled "Polyurethanes and Thermal Degradation." The CPI document is product stewardship information designed to explain the concerns with thermal degradation of polyurethanes due to hot work. It is not specific to MDI or SPF systems and does not discuss exposure to MDI in SPF applications. However, the reference is presented in such a way as to lead the casual reader to believe that it is EPA showing that heat-generating processes in SPF applications cause worker exposure to MDI. This reference does not support the allegation that DTSC has made in the text and should be removed.

- DTSC implies that there are occasions where the use of PPE may not be recommended or mandated thus leading to exposure to MDI.[81] As stated early, SPF systems are accompanied by extensive recommendations for PPE selection. PPE is always recommended when using high-pressure or low-pressure SPF systems. This vague statement does not support the proposed listing and should be removed.

- DTSC states that "there have not been many monitoring studies conducted to measure airborne concentrations of MDI during SPF applications."[82] "Many" is a highly subjective term, but by any reasonable definition, industry has conducted extensive monitoring of SPF applications, both outdoor and indoor. By ACC's count, over 100 monitoring studies have been conducted to measure airborne concentrations of SPF emissions during or immediately following application. Exposure to MDI used in SPF applications is a topic that is very well researched and understood, and has been used to help industry establish recommended return times for other trades and building occupants and safe zones during application. To imply otherwise is highly misleading. Further, a lack of data cannot serve as justification for DTSC's prioritization decision.

- DTSC's statement that monitoring data suggests workers may be exposed to MDI during spraying, especially when applicators do not use protective measures does not support a prioritization decision under the SCP regulations. DTSC must be able to demonstrate a product meets the prioritization criteria.

[81] Technical Summary document, pg. 18.
[82] Technical Summary document, pg. 19.

- DTSC provides exposure sampling data without context. The monitoring studies referenced are for a mix of professional high pressure applications and low pressure applications. Exposure potential for these two types of applications is much different (i.e., aerosol versus vapor) and data for these two types of applications should be clearly differentiated within the documents.

- DTSC states "other studies also included detected measurable levels of airborne MDI up to 20 feet from the applicators breathing zones for a considerable amount of time after spraying."[83] The use of "measurable" and "considerable" are misleading and open to interpretation. The Department references the Lesage et al, 2007 study to support this assertion. Lesage 2007 reports that by the time 60 minutes has passed post-application, airborne concentrations of MDI are below the analytical detection limit. Lesage 2007 also monitored the foam surface with isocyanate-indicating colorimetric wipes at various times after application. Their results showed that the presence of removable isocyanate on the foam immediately after spraying, but in all cases (20 samples) no removable isocyanate was detectable on the foam surface 15 minutes after application. When evaluating exposure potential, these results to do not support the proposed listing.

- DTSC's reference to Environment Canada (2014b) mischaracterizes the results.[84] Environment Canada found airborne MDI concentrations ranging from 0.1 to 1,320 $\mu g/m^3$, it must be noted that these appear to be stack emission concentrations and not ambient workplace air concentrations. The 1,320 $\mu g/m^3$ value, representing the high end of the range, comes from a 1996 European survey of stack gases associated with various stages of particle board manufacturing, where no control technology was in place. The Environment Canada report shows that most (more recent) stack gas findings fell below 380 $\mu g/m^3$ and were representing total NCO analysis. In addition, the report table from this report gives specific values/studies of SPF application monitoring. Environment Canada detected MDI ranged from non-detected to 23.9 $\mu g/m^3$. DTSC does not mention these study values specifically, but instead cites values from the particle board manufacturing industry which are irrelevant to SPF. DTSC should only reference studies directly associated with the SPF industry, and should remove references to other products.

- DTSC states not all workers will be protected from adverse health effects even though their exposures are maintained below the PEL. However, OSHA expresses PELs as a time-weighted average when the concentration of a substance to which most workers can be exposed without adverse effect averaged over a normal 8-h workday or a 40-h workweek and OSHA also states under "Facts about PELs" that "PELs, or Permissible Exposure Limits, are regulations that establish the acceptable amount or concentration of a substance in the air in the workplace. PELs are intended to protect workers from adverse health effects related to hazardous chemical exposure." DTSC should remove this statement.

[83] Technical Summary Document, Pg.19
[84] Technical Summary Document, Pg. 16

- DTSC references the California Office of Environmental Health Hazard Assessment (OEHHA) MDI Reference Exposure Levels (RELs) in air for MDI. The methodology used for deriving the RELs is highly conservative and explicitly considers possible differential effects on the health of infants, children and other sensitive subpopulations. RELs are not designed for, nor should be referenced, in a discussion of MDI monitoring studies focusing on SPF applicators.[85]

- DTSC also states that "These RELs were established to protect susceptible individuals of the general population. According to OEHHA, individuals could develop adverse health effects, particularly respiratory problems, if they are occasionally exposed to MDI at concentrations above 12 μg/m3 for an hour (Acute REL) or 0.16 μg/m3 for 8 hours each day, 5 days a week (8-hour REL) (OEHHA 2016)." DTSC should be aware of a recent study in a residential retrofit project. MDI indoor air concentrations were evaluated during and for a 3-month period after closed-cell SPF application. SPF was installed in all exterior walls of each floor in the home and the underside of the roof. In this field study, an improved limit of quantitation (LOQ) for MDI was achieved by using a more sensitive analytical method (LC/MS/MS), and the results showed the MDI airborne concentrations were well below both the Acute REL and the 8-hour REL within 2 hours after application in all areas measured in the home. In addition, airborne concentrations of MDI were below the LOQ (<0.02 μg/m3) in all areas of the home as soon as 12 hours after SPF application.[86] These results are orders of magnitude below the published RELs, further indicating the proposed listing lacks credible support.

- None of the examples of MDI-induced fatalities or MDI-induced occupational asthma cited by DTSC were for SPF applications, and involved many other factors (e.g., PPE usage, medical diagnosis) beyond the mere use of MDI. In fact, peer reviewer Nemery stated in regard to the cases of occupational asthma cited that "the choice of sources quoted to provide evidence for the existence of MDI-induced occupational asthma is somewhat strange and unbalanced. In view of the very extensive database on the subject it is appropriate to cite reviews and reports from NIOSH or other agencies. However, the three cases described by Bonauto and Lofgren (2004) (presumably non-peer-reviewed) appear anecdotal. This information is not relevant to SPF systems and should be removed.

[85] ACC comments to the California Office of Environmental Health Hazard Assessment (OEHHA) in response to California OEHHA Proposed RELs for TDI and MDI, Sept 16, 2014.

[86] Emissions Evaluation of a Low-GWP ccSPF System with Laboratory and In-Field Application; Spray foam 2017 Annual Convention & Expo, Palm Springs, California Jan 29, 2017 – Feb 1, 2017. Available to DTSC upon request.

Sensitive Subpopulations with Potential for Adverse Impacts from MDI

Very few of the subheadings in this section discuss "sensitive subpopulations." DTSC should clarify the intent of this section.

- The allegation that sole proprietors and individual consumers who purchase SPF system for various do-it-yourself projects generally use little or no protective measures against hazards associated with SPF systems is not supported by any data or facts from DTSC. As noted in previous sections of these comments, and as discussed with DTSC in meeting and in previous detailed submissions of comments, sufficient product labeling, research and training are available so that SPF users can understand and effectively manage the products. Therefore, this statement does not support the proposed listing and should be removed.

- DTSC states that "despite industry's certification program for some applicators of SPF systems (SPFA 2013), accidental spills, leaks, cleaning and maintenance of equipment create situations where exposure to isocyanates can occur." Applicators are trained to handle any spill, leak or cleaning with the same care as done during spraying. Since these non-spray instances do not vaporize or aerosolize the MDI, the potential for exposure is much smaller and considered well controlled under the supported PPE guidelines. DTSC's assertion does not support the prioritization decision, as ample guidance through industry and the manufacturers is provided for these activities through industry generated information and manufacturers' SDSs.

- DTSC selectively cites the OSHA NEP as a justification for its proposal to list SPF as a candidate chemical. It is noteworthy that OSHA concluded the NEP as the Administration determined that it had met the goals of raising awareness of the hazards of isocyanates and making users aware of the OSHA requirements with regard to worker safety. OSHA did not focus this NEP exclusively on SPF; coverage was for all isocyanate-using industries. Most importantly, OSHA has publicly stated that it did not find the overexposures to the extent it was expecting and the violations cited were often the same as ones issued after many other types of OSHA inspections in many types of industries. DTSC must review all references to the OSHA NEP and correctly reference the results of the program.

- DTSC claims that despite multiple attempts, the Department could not find any further information on the NEP implementation or the number of inspections in the State of California. One would have to question why one state agency (DTSC) could not get information on a program from another state agency (Cal OSHA).

Environmental Fate of MDI

Although it does not appear that the references to the Environmental Fate of MDI were used by DTSC to validate the listing, many of DTSC's statements regarding the environmental fate of MDI are insufficient or incomplete. ACC requests that DTSC remove references to

Environmental Fate where it does not support the record and correct any references DTSC believes support the proposed listing. ACC provides additional context below:

- Airborne emissions are not expected in the event of an accidental discharge, as heating and spraying of the substance is necessary to generate vapors and aerosols. Due to the reactive properties of MDI, the substance will tend to remain in the same location and environmental medium to which it is emitted, as it cannot be carried as a dissolved component of moving surface- or ground water.

- MDI can exist in both vapor and particulate (aerosol) phases in the atmosphere, and as indicated by a vapor pressure of 5.0 x 10-6 mmHg at 20^{o}C, not 25^{o}C as stated in error by the Department. This vapor pressure equates to a saturated air vapor concentration of only 12 ppb (0.12 mg/m3); and thus exposure to potentially hazardous concentrations will require significant heating to generate higher vapor concentrations and/or spraying to generate aerosols.

- Airborne MDI vapor does not readily react with water vapors in the atmosphere (Tury et al. 2003). Vapor-phase MDI is degraded in the atmosphere via reaction with photochemically produced hydroxyl radicals, with a reaction half-life estimated to be between 11 (HSDB 2011) and less than 24 hours (Tury et al. 2003) depending on the assumed ambient hydroxyl radical concentration.

- Atmospheric MDI vapor which is generated at elevated temperatures can condense at lower temperatures in the atmosphere to form aerosols. MDI vapor and aerosols can also condense with particles already in the atmosphere (Environment Canada 2014b).

- MDI is not expected to be susceptible to direct photolysis by sunlight to an extent or rate which would influence its lifetime in the atmosphere (European Chemicals Bureau 2005; HSDB 2011). Indirect photolysis, hydrolysis, and wet/dry deposition will govern the environmental fate and lifetime of the substance in the troposphere.

- Although MDI is hydrophobic (Environment Canada 2014b), it reacts with water at the surface of the MDI particle or droplet to form predominantly insoluble polyureas and carbon dioxide. Studies with the related polymeric MDI substance (CAS 9016-87-9) which is a liquid containing approximately 50% 4,4'-MDI suggest that the heterogeneous hydrolysis reaction occurs slowly at the MDI-water interface and can last for a several hours to several days, depending on the ratio of water to MDI, degree of mixing, and temperature (Yakabe et al. 1999). Since the MDI cannot be dissolved into water, it will therefore not migrate through soil into groundwater or bioconcentrate in organisms living in water.

- Based on studies of hydrolysis for analogous mono-functional aromatic isocyanates which can be dissolved (momentarily) in water, the half-life for hydrolysis of MDI under homogeneous reaction conditions is estimated to be in the order of seconds to minutes. The prolonged half-life under heterogeneous reaction conditions is due to the fact that the

major product of such a reaction is polyurea, which tends to form quickly, starting on the outside of the MDI particle or droplet and forming a crust that may restrict ingress of water and egress of amines such as methylene dianiline (MDA) and substituted ureas which are intermediate products of the heterogeneous hydrolysis reaction (Heimbach et al., 1996; Yakabe et al. 1999).

Hazard Traits of MDI

Many of the references used to outline the hazard traits of MDI have been mischaracterized or overstated. DTSC should update the record in accordance with the information provided below:

- The statement "Once sensitized, re-exposure to even low concentrations of MDI (<1ppb) may trigger severe asthma attacks in some people" was not investigated nor determined by OEHHA 2016. DTSC should not use secondary references and remove this reference from the record.

- The statement "Both high acute exposures and lower level exposures may induce sensitization" again was not investigated nor determined by OEHHA 2016. This statement should be removed from the record.

- The two studies used as examples, Pauluhn and Poole 2011 and Pauluhn 2008, showed respiratory changes after repeated exposures to irritating doses (38 mg MDI/m^3 and 1000 mg pMDI/m^3, respectively). DTSC failed to note that these doses are more than 100 to 3,000 times the potential exposures seen during spraying of high pressure medium density, or closed cell, application (0.28-0.38 mg MDI /m^3; 0.21 -0.33 mg pMDI/m^3); more than 180 to 5000 times the exposures seen during spraying high pressure low density, or open cell, application (0.18-0.21 mg MDI /m^3; 0.11 -0.18 mg pMDI/m^3); and more than 950 times the exposures seen with low pressure 2-component application (0.01-0.04 mg MDI/m^3). Research shows that pMDI was non-detected during spraying of 2-component low pressure.[87] These studies also demonstrate that there is a threshold to the induction of sensitization, which DTSC is not taking into consideration – providing further evidence that DTSC has not presented scientific data support the proposed listing.

- The DTSC failed to include the description of the two different protocols that were used for the induction and elicitation phase in the Pauluhn (2008) publication. DTSC should update the record.

- The third study example used by DTSC (Wisnewski et al. 2011) is a topical application followed by an intranasal delivery of MDI-mouse albumin conjugates. DTSC fails to include that the study reported, "The degree of (secondary) respiratory tract inflammation and eosinophilia depended upon the (primary) skin exposure dose, and was maximal in mice exposed to 1% MDI, but paradoxically limited in mice receiving 10-fold higher doses (e.g. 10% MDI)." This shows that there was not a dose response relationship to the

[87] Wood. 2013. CPI Ventilation Project Update. Polyurethanes Technical Conference, American Chemistry Council.)

effects seen; in addition, intranasal instillation cannot be compared to inhalation exposure and the use of a conjugate cannot be equated with exposure to MDI. This reference, therefore, does not support the proposed listing.

- DTSC misinterprets the conclusion of several studies citing MDA as a marker of MDI sensitization. Both MDI and MDA are primary sensitizers and the cited studies do not indicate that MDI is a major contact sensitizer. The text related to these studies, and the references from which they are drawn, do not support the proposed listing.

    - (Aalto-Korte et al 2012) During the study period, 345 patients were tested with the isocyanate series, and 23 (6.7%) of them reacted positively to at least one isocyanate monomer [12 (3.5%) to MDI]. Of the 45 MDA-allergic patients, 25 were tested with isocyanates, and 13 of them reacted positively to at least one isocyanate monomer. Table 1 in the publication shows 13 positive reactions to MDI out of 691 tested (1.9%) 17 cases of occupational sensitization related to MDI products, but only 8 of them reacted positively to MDI, and, in 9 cases, the diagnosis of occupational contact allergy was based on positive "MDA reactions."

    - Aalto-Korte states: "Many previous reports have implied that MDA is a good marker for MDI sensitivity". However, they do not acknowledge, as does Kiec-Świerczyńska et al. (2014), that "although according to some authors, these two chemicals (MDI and MDA) could have been both primary sensitizers [Frick M, Isaksson M, Björkner B, Hindsén M, Pontén A, Bruze M. Occupational allergic contact dermatitis in a company manufacturing boards coated with isocyanate lacquer. Contact Dermatitis. 2003;48 (5):255–60, http://dx.doi. org/10.1034/j.1600-0536.2003.00107.

    - Aalto-Korte et al. diagnosed occupational sensitization related to MDI products in 17 cases, however only 8 reacted positively to MDI, and in 9 cases, similarly to the Kieć- Świerczyńska et al. study, the diagnosis of occupational contact allergy was based on positive MDA reactions.

    - In addition, Kieć- Świerczyńska et al. states "… in our group, almost all workers (6 among 7) sensitized to MDA reacted to PPD." "No positive reactions were found to the remaining substances of isocyanate series, including MDI."

- The DTSC ignored a comment by Peer Review, I. Kimber, "For completeness, MDI has been implicated as a cause of allergic contact dermatitis (ACD) (Hamada et al., 2012). However, it is not a common contact allergen, and ACD is not the major health hazard associated with MDI." Kimber's comments provide additional support to ACC's claim that DTSC has failed to meet either prioritization criteria.

Respiratory Toxicity

DTSC has misrepresented numerous studies associated with the respiratory toxicity of MDI, and should update the ISOR and Summary of Technical Information to reflect the following comments:

- Several comments by the peer reviewer, B. Nemery, MD PhD, were ignored. If DTSC has additional information or disagrees with its own peer reviewers, a response to the comment should have been published in the supporting materials.
    - "...some critical details (exact route and mode, as well as timing of exposure) must be reported."
    - "However, it should be recognized that none of these studies deal with MDI-based SPF."

- MDI is known and acknowledged to be a respiratory irritant (Weyel and Schaffer 1985), but complete recovery from irritation and pulmonary inflammation (Kilgour et al 2002) is not considered as an important aspect in determining hazard. DTSC failed to indicate that the Weyel and Schaffer study determined the RD_{50} of MDI to be 32 mg/m^3.

- Three chronic inhalation studies in rats (Ernst et al. 1998; Hoymann et al. 1998; Reuzel et al.1994) are given as examples of "Respiratory Toxicity: Pathology and Fibrosis" however, no details of exposure duration nor any description of "high concentrations" were provided. DTSC also does not make the comparison of these exposures to actual exposures seen during application of SPF. In the Hoymann study, high dose rats were exposed to $2mg/m^3$(194 ppb)17 hrs /day; the Ernst article is a re-publication of the Hoymann study but also states, "The exposure to MDI resulted … an impairment of lung function which corresponded to dose-dependent interstitial and peribronchiolar fibrosis of a very slight to moderate degree." The Reuzel study exposed rats in the high dose group to 6 mg/m3 (584 ppb) 6 hr/day 24 months and suggested a NOAEC ~4.1mg/m3 (399 ppb). These exposure concentrations causing "very slight to moderate peribronchiolar fibrosis" are extremely high compared to potential exposures during SPF installation. We believe these studies are not relevant to SPF systems and should be removed from consideration.

- The DTSC uses the publication by Petsonk 2000 as an example of respiratory effects in workers; however, DTSC does not include the details that the "cases" were determined by self-reporting questionnaires and not by accepted medical standard protocol (ACOEM). Also, the exposures were determined by a percentage of workers self-reporting if they ever worked with MDI. Such anecdotal evidence is not appropriate for to support a regulation.
    - The DTSC also disregards that 0 of 43 workers with "low exposure" did not report new onset asthma. This statement supports that there is a threshold (a dose determined to be safe) for developing sensitization.

- The Zammit-Tabona et al 1983 reference discusses specific inhalation challenge to confirm MDI –related asthma. The dose required to induce a 20% decrease in forced expiratory flow was 12 ppb for 60 minutes. Although we do not disagree that MDI is a respiratory sensitizer, the dose of 12 ppb is over 50% of the OSHA PEL of 20 ppb and higher than most workplace exposures, which supports that a threshold exists for elicitation symptoms.

- DTSC references Leroyer et al 1998 which describes a case of reactive airways dysfunction syndrome but does not indicate the concentration of the "…acute high-level inhalation exposure to MDI …" which should be compared to the potential exposures seen in SPF application.

- The DTSC discusses various cases of "suspected" hypersensitivity pneumonitis (Baur, 1995 and Vandenplas et al 1993). These studies were conducted over 20 years ago. The DTSC does not consider that technology has provided the opportunity to substantially reduce or eliminate exposures. The DTSC also does not take into consideration the high-level concentrations required to produce hypersensitivity pneumonitis compare to the potential exposures that may be seen during SPF application. These references should be reconsidered in light of newer PPE and SPF technologies.

- The DTSC also does not acknowledge other results in the Kieć- Świerczyńska et al. study: "Some studies suggest that not only inhalatory exposure, but also skin contact with isocyanates may contribute to the development of asthma Nevertheless, in our study, although some workers complained of respiratory tract symptoms, the results of conducted examinations, including skin prick tests, spirometry and MDI sIgE measurement, did not point to occupational and allergic origin of reported disorders." This study does not support the proposed regulatory listing because it indicates that not all symptoms led to disorders and therefore may not be considered significant in every case.

Physicochemical Properties of MDI

All of the physicochemical properties listed for MDI should cite values from the European Chemicals Agency (ECHA) registrations.[88] The ECHA registration is the most recent and critically-reviewed data. It should be particularly noted that MDI reacts rapidly with water and 1-octanol, such that direct measurements of water solubility and octanol-water partition coefficient are not possible. These properties have been estimated using widely-accepted estimation methods to fulfill regulatory information requirements. Since environmental behavior of MDI is governed by its reactivity rather than by equilibrium/partitioning processes, the water solubility and partition coefficient values are notional concepts and have little or no relevance to environmental fate processes affecting the substance.

[88] https://echa.europa.eu/registration-dossier/-/registered-dossier/15384/4/3

ACC offers the following corrections, based on the ECHA registrations, to the physicochemical properties of MDI:

For MDI with CAS # 101-68-8:

- Appearance: White crystalline solid at 25°C (ECHA, 2017[89])
- ~~Color: White to light yellow (NIOSH 2010)~~
- Molecular weight: 250.25 g/mol (Haynes 2010)
- Density: ~~1.197~~ 1.32 ~~g/mL~~ g/cm^3 at ~~70~~ 20 °C (~~Haynes 2010~~ ECHA, 2017[90])
- Specific gravity: 1.23 (solid at 25ºC); 1.19 (Liquid at 50ºC)(NIOSH 1997)
- Melting point: ~~37~~ 39 - 43 °C (~~Haynes 2010~~ ECHA, 2017[91])
- Boiling point: 314 °C (OEHHA 2016)
- Log K_{ow}: ~~5.22~~ 4.51 ~~(est.)~~ (~~U.S. EPA 2011b~~ Yakabe et al., 2000[92])
- Water solubility: ~~1.51~~ 6.7 mg/L at 25°C, estimated (U.S. EPA 2011b)
- Vapor pressure: 5.0 x 10-6 mmHg at ~~25~~ 20 °C (~~NIOSH 1997~~ ECHA, 2017[93])

[89] https://echa.europa.eu/registration-dossier/-/registered-dossier/15384/4/2
[90] https://echa.europa.eu/registration-dossier/-/registered-dossier/15384/4/5
[91] https://echa.europa.eu/registration-dossier/-/registered-dossier/15384/4/3
[92] Yakabe, Y., Hiromatsu, K., Kawahara, K., and Nakahara, M. (2000). Determination of 1-octanol/water partition coefficients of isocyanate compounds by an HPLC method. *Toxicol Environ Chem*, **77**, 199-206.
[93] https://echa.europa.eu/registration-dossier/-/registered-dossier/15384/4/7