

Comment on the Proposal to List Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product

We respectfully ask that DTSC reconsider its prioritization of Spray Polyurethane Foam Roofing (SPFr).

There is minimal scientific evidence to prioritize SPF and no evidence to prioritize SPFr

In our previously submitted comment dated 11.11.15, hereby incorporated by reference, each case as well as every argument DTSC proffered for the prioritization of SPF and SPFr was addressed. In DTSC's Revised Technical Report of February 2017 (TR 2017), DTSC included "APPENDIX B. Summary of Revisions" and an additional 14 new references, none of which, in our opinion, provide any further scientific basis for SPFr's prioritization per the requirements of 69501ff.

Although DTSC had over 2 years to revise and supplement its arguments, commenters have only been provided a short window to respond. Due to this limited time frame, the focus of this Comment is on information DTSC appears to be relying upon in TR 2017 to prioritize SPFr.

External Peer Reviews

Rather than addressing each new reference and revision set forth in TR 2017, we instead reference the comments and conclusions of External Peer Reviewer, Benoit Nemery, MD, Ph.D:

I am not sure these terms ["significant and widespread"] are entirely appropriate in the absence of a clear definition of what is to be considered "significant"... (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? ESPR

...it should be recognized that none of these studies deal with MDI-based SPF.ESPR

An aspect worth mentioning with regard to exposure is the fact that SPF is often applied in "confined spaces", such as attics or crawling spaces, hence in environments with poor ventilation leading to potentially high exposures to MDI (and other harmful agents).ESPR

It would be appropriate to indicate that no systematic review on MDI-related occupational asthma has been published in the biomedical literature. ESPR

The choice of sources quoted to provide evidence for the existence of MDI-induced occupational asthma is somewhat strange and unbalanced... the three cases described by Bonauto and Lofgren (2004) (presumably non-peer-reviewed) appear anecdotal. ESPR

Again this section is important [Non-occupational exposure potential], but one should acknowledge that the "evidence" reported in c, d and e is weak with regard to a causal role of MDI. The language used in e (anecdotal, physiological reactions, alleged) does suggest that the evidence is poor (or even non-

existent), but I recommend that our ignorance (or skepticism) about these effects among occupants of insulated buildings be acknowledged more candidly. ESPR

Again, I generally agree with the content of this section [Conclusions], although, as argued above, I would query the use of “significant and widespread” in the last sentence. ESPR

[Final Conclusions]...as indicated above, I have some reservations about the use of the (poorly defined terms) “significant” and “widespread.” I also suggest to be more explicit (providing actual data) about our knowledge regarding the exposure scenarios in SPF operations. ESPR

The term “significant or widespread” is a *sine qua non* of prioritization. Without a finding that a product –chemical has this potential, there can be no lawful prioritization.

§ 69503.2. Product-Chemical Identification and Prioritization Factors. (a) Key Prioritization Principles:

(2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

The word “Potential” is defined and requires reasonable foreseeability based on reliable information.

(51)(A) “Potential” means that the phenomenon described is reasonably foreseeable based on reliable information.

In order for DTSC to properly evaluate this “potential,” we ask that as a condition precedent to prioritization, DTSC take note of External Peer Reviewer Dr. Lockey’s comments:

There is a paucity of data that documents whether or not MDI SPF systems can be safely utilized under current commercial and consumer work practice situations. ESPR

Would comment on the lack of data on potential exposed populations and how this lack of data supports this proposal to adopt SPF systems with MDI as a Priority Product. ESPR

These conclusions by Drs. Nemery and Lockey, with respect to the paucity and lack of reliable information, provide clear and convincing evidence that there is insufficient scientific support for the prioritization of SPF.

(57) “Reliable information” means a scientific study or other scientific information that meets the criteria in subparagraphs (A) and (B):

(B) With respect to a scientific study, the study design was appropriate to the hypothesis being tested, and sufficient to support the proposition(s) for which the study is presented to the Department.

Drs. Nemery's and Lockey's comments on the paucity of reliable information are buttressed by the statement of environmental scientist in the indoor environment division of EPA's Office of Air and Radiation- David Price:

I think you have to be careful when you discuss the toxicity of spray foam," says David Price, environmental scientist in the indoor environment division of EPA's Office of Air and Radiation. "I have not seen any information at this point that there is any hazard to occupants." While Price supports EPA's decision to gather data on possible post-occupancy issues with SPF, he doesn't want the public to "find the accused guilty before you hear the case. Price has seen some of the anecdotal evidence as well as some of the scientific findings, and says that no cause-effect relationship has yet been found between SPF installation and post-occupancy illnesses. "It's appropriate for EPA to look at this stuff; that's what we do," Price said. "But I'm very sensitive about tagging a product as 'of concern' or 'may be toxic'" before the data has been gathered and reviewed. <https://www.buildinggreen.com/blog/epa-raises-health-concerns-spray-foam-insulation>

OEHHA

OEHHA's findings as set forth in "Reference Exposure Levels for Methylene Diphenyl Diisocyanate (MDI), adopted on Mar 28, 2016" also contravene the prioritization of SPFr:

Most studies that have collected personal breathing zone samples in the polyurethane foam industry have measured very low (often <1 µg/m³) to nondetectable levels of MDI (Liljelind et al., 2010). In a study of a large body of industry air sampling data (8,134 samples), most (74.6%) of the airborne MDI concentrations measured were below the limit of quantitation (LOQ) (Booth et al., 2009). Depending on the quantitation method, the LOQ was 0.04 to 0.5 µg/sample.

We specifically call to DTSC's attention our incorporated by reference Comment of 11.11.15 relating to OEHHA's use of certain rat studies and other unreliable reports (e.g. Jan, Kullman) to justify a lower REL. Also note that OEHHA's and DTSC's only reference to any adverse impact from SPFr –"JL Long" - should be struck in its entirety from the public record, due to NIOSH's conclusion that there was no scientific basis that SPFr was the source of any adverse impact at the school.

Unclear definition of proposed priority product

There are numerous SPF systems in the California marketplace. Section 69503.5(b)(1)(A) requires a clear description of the proposed Priority Product so responsible entities can determine whether one or more of their products is a Priority Product and subject to regulation. ISOR19

By arbitrarily collapsing multiple products into one, in contravention of industry and USEPA promulgations, DTSC has created the likelihood of ongoing confusion. Even DTSC switches back and forth, sometimes classifying SPF as one system and at other times as various product types. In its ISOR, DTSC in conformance with the USEPA 2013(c) lists SPF Systems as "Various Types of Spray Polyurethane

Foam Products”. See Table 1. *Overview of SPF Systems.5 Information on the Various Types of Spray Polyurethane Foam Products.*

Conversely, in TR 2017, DTSC decided to delete the word “products” and replace it with “Systems”.
Table 1. Overview of SPF systems (USEPA 2013(c) † SPF Systems Overview

This reclassification of multiple product types into one hyperbolic system, while arbitrary, allows DTSC to combine the alleged adverse impacts of multiple products and market share into one.

In this way, DTSC is able to claim that individual product-chemicals with no record of harm and de minimis market share have the potential to cause widespread adverse impact. While this approach enables DTSC to address the regulatory requirement of widespread adverse impact, the reclassification of multiple product chemicals as one raises another issue. By creating one hyperbolic SPF system, DTSC subjected the majority of all polyurethane foam products to prioritization, which would require their subsequent exemption.

Toward this end, DTSC appears to have constructed a three part strategy to differentiate polyurethane paint (PP) and factory produced SPF (FSPF) from SPFi and SPFr, so that all PP and FSPF products could be exempted.

First, and antithetical to the 3rd principal of green chemistry, DTSC stated that the situ of production, a controlled factory environment, was dispositive.

Pre-fabricated flexible or rigid polyurethane foam and assembled products containing polyurethane foam. Although these foam products may be made from chemicals similar to those used in SPF systems, they are manufactured in factories under controlled conditions ISOR p 13

Second, DTSC employed the term “spray” in an attempt to further differentiate factory products from those applied in the field. The term “spray” however is not specific to any polyurethane product-chemical but rather to the atomization of a liquid. “SPF with unreacted MDI” is equally applicable to both field and factory applied polyurethanes and is descriptive of a nozzle design.

https://en.wikipedia.org/wiki/Spray_nozzle

Third, DTSC proposed that documented fatalities from polyurethane spray paint had “not been well characterized”:

Polyurethane products[containing unreacted MDI that are applied by methods other than spraying] that are poured, rolled, or brushed may present a potential for exposure to unreacted MDI, but the incidence of such exposures has not been well characterized ISOR p13

This is somewhat perplexing, since death per SCP § 69502.1 would seem to be a well characterized toxic end point.

MDI-induced fatalities have been documented for workers using spray polyurethane paints (NIOSH 1996a; NIOSH 2006) and resins containing MDI (Carino et al. 1997). TR 2017

DTSC’s priority product description and its reasoning for exemptions remain unclear. DTSC has exempted every polyurethane product that has ever caused harm or death but retained SPFr with no documented harm. Given this, DTSC’s prioritization of SPFr can only be seen as arbitrary and capricious.

If DTSC exempts FSPF solely on the basis of engineering controls, why does it deny California installers of SPFr this same consideration?

Of the two categories of SPF systems, workers who operate high-pressure systems are more likely to complete industry-recommended training and certification programs, follow safety procedures, and to be provided with PPE. ISOR12/29

If FSPF is exempted based on engineering controls, why is DTSC unwilling to consider any hierarchical hazard control less than elimination for SPFr?

DTSC has determined that industry recommended engineering and administrative controls and use of PPE reduces the likelihood of exposure, but cannot eliminate worker exposure to MDI during spraying of high-pressure systems... DTSC/ TR

For these reasons, inter alia, DTSC's prioritization process is without rational basis and discriminates against small California SPFr businesses. Should DTSC prioritize SPFr, DTSC's actions will constitute violations of Article 5 of the California Administrative Procedure Act ("APA") as well as a violation of due process under ARTICLE I, §3 and §7 of the California Constitution.

Under the California Constitution, "due process safeguards required for protection of an individual's statutory interest must be analyzed applying the principle that freedom from arbitrary adjudicative procedures is a substantive element of one's liberty." Saleeby v. State Bar of California, 39 Cal.3d 547, 563-64 (1985).

This due process violation is further manifested by DTSC documents which unequivocally attribute fatalities, worker injuries and chemical spills to both factory controlled conditions and to polyurethane spray paint, which DTSC dismisses as safe and/or "not well characterized".

Fatalities from exposure to unreacted MDI have been documented for workers using spray polyurethane paints. Although those affected workers were applying polyurethane paint and not polyurethane foam, their deaths were caused by inhalation of unreacted MDI from the spray polyurethane product. This common exposure pathway illustrates the severity of potential adverse health effects from inhalation of unreacted MDI during application of SPF. 16/29

It is also well established per CDPH that the majority of WRA documented by the multi-state surveillance program occur in factories under controlled conditions.

"Please note that Michigan accounts for 73% of the isocyanate exposures for the time period of 1993-2008. Michigan data are clearly driving the fact that isocyanates were in the top 10 exposure categories during that time period. Nearly half of Michigan's total WRA cases identified during that time period were identified in the auto manufacturing industry" CDPH JFlattery
<http://www.oem.msu.edu/userfiles/file/Annual%20Reports/asthma/00asthma.pdf>

Throughout its TR, and at every public meeting on SPF, DTSC represented that only elimination and substitution were acceptable methodologies, per green chemistry, for hazard control. No descent down the pyramid was permissible. Yet, DTSC's exemption of the majority of SPF products is based squarely on engineering controls rather than on the elimination or substitution of a Chemical of Concern in a specific product-chemical, as mandated by green chemistry.

...compared with hazard elimination, administrative controls and PPE, which are the recommended controls by the industry, are considered to be the least desirable approaches to control potential occupational exposure (CDC 2015). This is largely because the original hazard is still present in the workplace. TR 2017

Is it DTSC's position that factory produced foam does not present a hazard of unreacted MDI in the workplace?

As a consequence of its arbitrary exemptions by means of descending down the hazard control pyramid, DTSC's defense of green chemistry principles has been compromised. If DTSC continues to ignore its proffered scientific studies, as well as CDPH's epidemiologic data and moves forward with prioritization of SPF as defined, will it not have created an off-ramp for all future priority products, based on the "least desirable approaches to control potential occupational exposure"?

Additionally, DTSC's allowance for exemptions based on engineering controls will open up a Pandora's Box of unintended alternatives, such as the substitution of field spray guns with internal impingement guns, thereby removing field applied polyurethane foam from DTSCs definitional framework.

Duplicative Regulations

*The SCP regulations established a **unique approach** to regulating Chemicals of Concern in consumer products that grants DTSC authority to take actions to protect people and the environment when such actions are outside the scope of other regulatory programs. There are **no equivalent federal regulations** that require product manufacturers to determine if the chemical in their product is necessary, if there is a safer alternative, and to take steps to protect human health and the environment. ISOR 28*

It's curious that the drafters of the regulation added the proscription that DTSC's prioritization could not be duplicative.

§ 69501(b)(3)(A) This chapter does not apply to a consumer product that the Department determines is regulated by one or more federal and/or California State regulatory programs:

If we accept DTSC's position that § 69501 established "a unique approach" without equivalent, no duplication would ever be possible, therefore why would the regulation contain this surplus language?

It is a settled rule of statutory interpretation that courts must avoid rendering particular terms meaningless or mere surplusage. See, e.g., City of San Jose v. Superior Court, 5 Cal. 4th 47, 55 (1993)

The *Rule against Surplusage* is settled law in California:

Where one reading of a statute would make one or more parts of the statute redundant and another reading would avoid the redundancy, the other reading is preferred.^[9]

<https://www.law.georgetown.edu/academics/academic-programs/legal-writing-scholarship/writing-center/upload/statutoryinterpretation.pdf>

If it were the position of the drafters that regulatory scope of *Safer Consumer Products* was unique and without equivalent, it would have made no sense for them to have included language barring duplicative regulation, since none would have been possible. Therefore the drafters must not have intended for *Safer Consumer Products* to be unique, and thus DTSC is required to apply the *Rule against Surplusage* and substantively address this limiting language.

Case Studies distinguishing SPFi from SPFr

The scientific evidence presented strongly supports the proposition that DTSC should distinguish exterior grade SPFr from SPFi used in interior spaces. This distinction is supported by the findings of both Marlow and Crespo and Galan et al.

As a condition precedent to DTSC prioritizing SPFr, we ask at minimum that DTSC address its own case studies as presented in TR 2017.

Crespo and Galan

Thirteen of the applications sampled were indoors (sprayed on the inside of the exterior wall) and five were outdoors (two facades and three roofs). One block of flats received both an indoor and a roof application...The values recorded show that the most unfavourable conditions occur indoors, as could be expected, because these partially closed spaces favour the accumulation of contaminants. During open-air spraying (roofs and facades), natural dilution by wind obviously reduces the presence of contaminants in the work area...In exterior applications, the reference limit was surpassed in exceptional cases in the sprayer's position...The helper always receives less exposure than the sprayer because he is not always in the area where the work is going on, and he stands further away from the spray-gun.

The exculpatory findings of Crespo and Galan for Exterior SPFr are further supported by Marlow:

Marlow

Air sampling was conducted to characterize the chemical exposures to compounds present during SPF installation during three work shifts. Personal breathing zone air samples were collected for MDI, NCO monomer, and NCO oligomer. The mean MDI concentration for the sprayer was 10.1 µg/m³ ranging from 4.85 to 18.7 µg/m³. The helpers' mean MDI concentration was 2.86 µg/m³, ranging from 0.18 to 7.89 µg/m³. None of these measurements exceeded the NIOSH TWA REL of 50 µg/m³.

Per Marlow, elevated levels of MDI were only observed in interior spaces where "...spraying was conducted in an area with little air movement..." and even then "None of the PBZ sample results exceeded the NIOSH TWA REL to MDI monomer of 50 µg/m³." Marlow -P.8

Given the greater air exchange on a rooftop (open air exchange being equivalent to engineered ventilation), what information is DTSC relying upon to conclude that SPFr has the potential to cause or contribute to widespread or significant adverse impact?

The only case that DTSC and OEHHA cite for the proposition that SPFr has the potential for adverse impact is JL Long Middle School. Please see our Comment 11.11.15 for a detailed chronology in which it was determined by two independent industrial hygienists that SPFr was not the cause of any respiratory illness at the school. Even NIOSH, which cut, sawed, poured and sampled every corner of the school and its roof, concluded there was no evidence from which it could attribute fault to SPFr.

There is also a Canadian study of SPFi installations on exterior vertical surfaces from enclosed spaces on raised platforms. This installation methodology is not representative of SPFr which is sprayed at a greater distance from the applicator's personal breathing zone (PBZ) in an open air environment onto a

horizontal substrate. We ask that DTSC consider these differences prior to attributing any potential exposure risks from these Canadian cases to SPFr.

Also consider Wood's research, complementing Marlow's, which demonstrates that the force of high pressure SPFr material serves to remove any unreacted MDI from the applicator's PBZ.

Area sample concentrations were significantly higher than applicator sample concentrations. These unanticipated findings were likely caused by the force of the overspray, the location of the air sampling devices, elevated foam temperature during initial cure, and air flow pattern in the booth. RICHARD WOOD, CIH, CPI Ventilation Research Project Update

SPFr fully utilizes effective Hazard Control Technologies per § 69503.3. (b) (G)

§ 69503.3. (b) Exposures.

In evaluating a product-chemical combination for possible listing as a Priority Product, the Department shall evaluate the potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure(s) to the Candidate Chemical(s) in the product, by considering one or more of the following factors for which information is reasonably available:

(G) Engineering and administrative controls that reduce exposure concerns associated with the product;

Administrative:

OSHA's NEP outreach program to the SPFr industry has resulted in administrative controls to enhance safe work practices with the goal of reducing worker exposure to hazardous chemicals or situations.

Just a few examples of SPFr NEP enhanced administrative controls include written safety policies and supervision instructing applicators and helpers not to remove PPE in the spray zone, when without PPE to remain out of spray zone and to increase the frequency of respirator cartridge change- outs.

Engineering

Engineering controls can be effective, especially when their use is combined with the use of administrative controls and PPE. ISOR p17

Professionally trained [SPFr] applicators represent a category of workers most likely to properly use PPE
TR 2017

It is well established that dilution on a roof top reduces applicator exposure potential by means of natural mechanisms rather than by engineered air exchanges required within enclosed spaces. (See Addendum A , Under General Coatings Letterhead)

During open-air spraying (roofs and facades), natural dilution by wind obviously reduces the presence of contaminants in the work area. Crespo and Galan

Although I understand the meaning of this claim [“administrative controls and PPE are considered to be the least desirable approaches”], it would be prudent to qualify this statement by adding “if they are the only measures taken. BNemery ESPR

Large commercial operations may be willing and able to invest in training, and purchasing of equipment for engineering controls and personal protection for their workers...There is little evidence that applicators who are exempt from state and federal worker protection standards, such as sole proprietors and individual consumers, receive industry recommended training or certification, invest in engineering controls, or hire industrial hygienists. TR 2017

Based on these clear and concise statements, distinguishing SPFR professional operations from exempt workers, sole proprietors and individuals, who do not install SPFR, we ask that DTSC be consistent in its application of § 69503.3(b)(G) and not prioritize SPFR.

Finally, in reference to Lockey et al. below, it should be noted that all cases (identified by DTSC) of adverse impact arising out from accidental spills, leaks, cleaning and maintenance of equipment are unrelated to SPFR [See Addendum B, Under General Coatings Letterhead].

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 (Lockey et al. 2015)

No functional substitute

We ask that DTSC take into consideration that all substitutes for SPF proffered in the PPPs are specific to SPFI not SPFR. Unlike SPFI, SPFR is a high density material that not only insulates but waterproofs. Neither fiberglass nor any product mentioned in the PPP are functional alternatives to SPFR.

Additionally, the new NIPU chemistry, even when perfected, is specific for interior insulation; it has no waterproofing ability or structural integrity, and is therefore in no way a functional alternative to SPFR. The use of rigid isocyanate board underneath a built up roof or single ply system does not provide a true air barrier and thus has minimal insulating capabilities. Most critically, SPFR is a sustainable system with up to a 50 year life expectancy. This translates into far less roof tear offs and less material being dumped into California landfills.

Plus, SPFR’s performance capabilities reduces the likelihood of mold growth and enhances indoor air quality, which reduces the incidence of both occupational and non-occupational asthma.

We call upon DTSC to recognize that as a direct result of its prioritization of SPFR, Californian’s will substitute asphalt based (bitumen) systems for SPFR. These include hot tar, which is an extreme fire and burn hazard and contains a plethora of toxic air contaminants. Alternatively, they will avail themselves to roofing sheets impregnated with asphalt (single ply and mod bit), which typically require hot torches (fire hazard) or formaldehyde and/or high VOC based glues to apply. Once applied, per the Manual of

Low-Slope Roof Systems: Fourth Edition, many of these “alternatives” degrade over a relatively short lifetime, while outgassing an unending stream of toxic bitumen.

“...particulate fractions of asphalt fumes collected in the personal breathing zone (PBZ) of workers during paving operations were mutagenic...laboratory-generated roofing asphalt fumes have been tested in genotoxicity studies. These fumes have been shown to be mutagenic, to cause increased micronuclei formation, and to inhibit intercellular communication in Chinese hamster lung fibroblasts (V79 cells) and in human epidermal keratinocytes.” Concise International Chemical Assessment Document 59 ASPHALT (BITUMEN), World Health Organization Geneva, 2004.

Compare this to SPFR with its limited potential exposure during application that, once cured, is inert and non-toxic for up to 50 years.

SPFR exposure potential mitigating factors

We ask that DTSC take into consideration all the factors which mitigate applicator exposure potential during the short installation window. These include the fact that SPFR is installed by highly trained applicators who according to DTSC are those most likely to use PPE, Administrative and Engineering controls. Also, unlike exempted one component foam, SPFR is not installed by sensitive subpopulations, which per DTSC is a category of persons deserving special protection.

Compare this to alternative asphalt products, where roofers receive little if any hazard training, and it's extremely rare to find an installer utilizing respiratory protection. This in part can be attributed to the effectiveness of ACC's ongoing informational campaign targeted to SPFR companies to upgrade their hazard controls when applying or handling MDI. It is also the result of the good work of the NEP program along with the focus on isocyanates by OEHHA, HESIS, CAL EPA, US EPA and NIOSH. We in the SPFR industry take this information extremely seriously and are keenly aware of our responsibility to protect our workers, the public, and the natural resources of California.

Marketing Data

§ 69503.3 (1) In evaluating a product-chemical combination for possible listing as a Priority Product, the Department shall evaluate the potential for the Candidate Chemical(s) to contribute to or cause adverse impacts, by considering Market presence of the product, including: (A) Statewide sales by volume; (B) Statewide sales by number of units:

Per the Freedonia Group, market share is quantified for the category Residential Roofing Demand by Product and Application 2002-2022 info@freedoniagroup.com.

All plastic roofing (TPO, PVC and SPFR) constitutes less than 1% of the total residential roofing market. SPFR's market share represents so little of the total plastic residential roofing market, its exact share is only broken out for the commercial market, where it represents 3.5% of that subset. In other words, assuming SPFR's share of the residential market were equal to its share of the commercial market (which it is not, it is less), SPFR would have a total market share of .07%.

This overestimate is further distorted by Freedomia's expectation that SPFr's market share would remain fairly constant through 2022. With the damage done by this prioritization process however, it is now reasonably foreseeable that SPFr's market share will decrease substantially. Thus, with a current market share of less than .07%, SPFr does not have the market presence to justify a finding that the mere presence of monomeric MDI, as a portion of one part of its constitution, represents a 69503.2(a)(2) potential for widespread or significant adverse impact.

Conflict of Interest

The criteria specified in section 69503.2(b)(1)(C) provide a practical and valid approach to evaluation of information quality in the prioritization process. For example, the issue of conflicts of interest that may be germane to the findings in any given report or study that is conducted and/or published can be addressed if the report or study is reviewed by a qualified disinterested reviewer with suitable education and experience.

But what assurance is there that 69503.2(b)(1)(C) criteria was adhered to, given the below identified potential conflicts?

Dr. Lockey

Per Dr. Lockey's BIOGRAPHICAL SKETCH Part D., Research Support:

Research Support HTIW Coalition (Lockey, PI) 07/01/2011 - 12/31/2015 2.64 calendar months HTIW (contract) \$312,253 Pulmonary Surveillance of RCF Manufacturing Facilities. This is an ongoing morbidity and mortality study of workers involved with refractory ceramic fiber production (asbestos substitute) as related to pulmonary health. ESPR p.64

The HTIW Coalition represents the North American High Temperature Insulation Wool (HTIW) industry.
<http://www.htiwcoalition.org/>

HTIW member products are essential for the high temperature glass melting of fiberglass. According to HTIW Associate Member Company HarbisonWalker International, their SERV® product is the industry leader for fiberglass furnaces.

<http://thinkhwi.com/wp-content/uploads/2016/12/HarbisonWalker-Refractory-Solutions-Glass.pdf>

DTSC has identified fiberglass as one of the primary substitutes for SPF.

Given Dr. Lockey's apparent financial relationship with commercial interests arrayed against SPF, see NAIMA's 6.6.17 DTSC submission, we are troubled by Dr. Lockey's appointment as an External Peer Reviewer. Also see:

https://www.dtsc.ca.gov/SCP/upload/DTSC-CA-Priority-Prod-Listing-SPF_063014.pdf

Additionally per *Health and Safety Code 57004 (c)* -No person may serve as an external scientific peer reviewer for the scientific portion of a rule if that person participated in the development of the scientific basis or scientific portion of the rule.

Even a cursory glance at TR 2017 will clearly demonstrate the extent that Dr. Lockey participated in the development of the scientific basis and scientific portion of the rule.

Specifically, DTSC states in the Executive Summary of its Technical Report:

Based on the information presented above, DTSC determined that applying SPF through high- and low-pressure systems, including home use SPF kits, has the potential to cause significant or widespread adverse impacts to human health.

For purposes of a 57004 (c) analysis, it should be noted that Dr. Lockey is the most cited author in DTSC's Executive Summary. Additionally, the purpose of Dr. Lockey's paper, *Isocyanates and human health: multistakeholder information needs and research priorities* was:

"To outline the knowledge gaps and research priorities identified by a broad base of stakeholders involved in the planning and participation of an international conference and research agenda workshop on isocyanates and human health held in Potomac, Maryland, in April 2013." J Occup Environ Med. 2015 Mar;57(3):e24.

Given DTSC's multiple cites to Lockey, it is evident that Lockey's investigation and analysis of these "knowledge gaps" were relied upon by DTSC to develop the scientific basis and/or scientific portion for the prioritization of SPF and its potential to cause or contribute to widespread or significant adverse impact.

Kimber

Neither Professor Kimber nor DTSC disclosed in the ESPR that Professor Kimber was on the Board of Directors of SenzaGen.

SenzaGen AB, a diagnostic spin-off company from Lund University, is proud to announce that Prof. Ian Kimber will join the Board of Directors. <http://senzagen.com/2015/04/15/ian-kimber-joins-the-board-of-senzagen-ab/>

SenzaGen AB is the maker of the "Novel *In Vitro* Assay" GARD which per SenzaGen's 2013 patent application is a "Method for identifying agents capable of inducing respiratory sensitization and array and analytical kits for use in the method."

Applicant	Senzagen Ab
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In short, GARD would appear to allow Kimber to financially benefit on a greatly underdeveloped market, with no validated assay to date for certain classes of LMW chemical compounds, such as diisocyanates

which may sensitize the respiratory tract. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4356558/>
<https://www.google.com/patents/WO2013160882A1>

As an External Peer Reviewer, Kimber's assessment that SPF "may induce and elicit respiratory hypersensitivity" has the potential to increase the market value of SenzaGen. If true, DTSC's nondisclosure of Kimber's pecuniary interest in SPF's prioritization, represents a potential material omission.

Conclusion

We ask that DTSC consider the most up- to- date statistics from the CDPH Surveillance Program, which shows the results of an industry that on the whole has listened and made the necessary changes to work safely. While more can and will be done, the epidemiological evidence conclusively demonstrates that the SPFr industry via effective hazard control methodologies, is successfully mitigating the MDI exposure potential. Therefore, on behalf of all California SPFr professionals, we petition DTSC to work with us, not prioritize us, so that together we can continue our progress. While we applaud the principles of green chemistry, the prioritization of SPFr does not advance those principles.

Respectfully Submitted,

Mitch Fine

Will Lorenz

6.6.17