

FINAL STATEMENT OF REASONS

SAFER CONSUMER PRODUCTS REGULATIONS – LISTING SPRAY POLYURETHANE FOAM SYSTEMS WITH UNREACTED METHYLENE DIPHENYL ISOCYANATES AS A PRIORITY PRODUCT

FEBRUARY 2018

Department Reference Number: R-2014-04

Office of Administrative Law Notice File Number: Z-2017-0307-02

UPDATE OF INITIAL STATEMENT OF REASONS

As authorized by Government Code section 11346.9, subsection (d), the Department of Toxic Substances Control (DTSC) incorporates by reference the Initial Statement of Reasons prepared for this rulemaking.

This regulation was noticed one time for public review and comment:

75-day Public Review and Comment Period:

The public notice and comment period for this rulemaking proposal began on March 24, 2017, and ended on June 6, 2017. The public hearing on the proposed regulations was held on May 16, 2017. This public review and comment period was originally scheduled to conclude on May 16, 2017, but was extended an additional 21 days to accommodate requests made by stakeholders for additional time to review the regulatory documents.

The regulatory text, first proposed in May of 2017, has undergone neither substantive nor non-substantive changes.

LOCAL MANDATE DETERMINATION

The proposed regulations do not impose any mandate on local agencies or school districts.

ALTERNATIVES DETERMINATION

DTSC determined that no reasonable alternative considered would be more effective in meeting the purpose for which the action is proposed, nor would be as effective and less burdensome to affected private persons. Equally, none of the alternatives considered would be more cost-effective to affected private persons or as effective in implementing the statutory policy or other provision of law. DTSC did not receive any proposed alternatives that would lessen the impact on small businesses.

Chosen Alternative: DTSC determined that listing spray polyurethane systems containing unreacted MDI as a Priority Product is the most effective and least

burdensome approach to meeting the mandates specified in Health and Safety Code sections 25252, 25253 and 58012. This option was selected because it allows DTSC to effectively achieve the goal of reducing the potential for workers and consumers to be exposed to levels of unreacted MDI that could be harmful to their health during normal use of high- or low-pressure SPF systems. These exposures have the potential to contribute to or cause significant adverse impacts to human health. DTSC estimates there are 17 manufacturers of SPF systems who make or sell their products in California and may be affected by this proposed regulation. DTSC estimates that it would cost a total of \$1,067,600 to \$3,107,600 for all SPF systems manufacturers to comply with notification and reporting requirements.

Considered and Rejected Alternatives:

Alternative 1: DTSC considered listing two-component SPF systems with unreacted MDI used for insulation, filling voids and gaps, and roofing materials and roof coatings containing toluene diisocyanate (TDI) as a Priority Product. In this option, the Chemicals of Concern included both unreacted MDI and TDI. DTSC rejected this option after SPF systems manufacturers explained that TDI-containing coatings are a separate product that serves a different function. DTSC did not quantify costs or benefits associated with this alternative, although it would have affected a greater number of manufacturers and costs would have exceeded those associated with the proposed regulation.

Alternative 2: DTSC also considered listing two-component SPF systems with unreacted MDI used for insulation, filling voids and gaps, and roofing materials and one-component pre-mixed cans of SPF products for insulation and filling of gaps and voids.

This product is not included in the product-chemical description because the chemicals, including unreacted MDI, are pre-mixed in the one-component can and most of the MDI has been reacted. While there may be small amounts of unreacted MDI released when consumers apply the foam, exposures are not well characterized so are assumed to be low. DTSC did not quantify costs or benefits associated with this alternative.

Alternative 3: In lieu of DTSC adopting SPF systems with unreacted MDI as a Priority Product in regulation, industry representatives proposed to undertake voluntary actions to educate key stakeholders on workplace safety regulations, SPF product stewardship, and general health and safety. After discussing this proposal with industry representatives, 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. Additionally, voluntary initiatives are not enforceable.

ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES

DTSC did not receive any proposed alternatives during the public comment period that would lessen any adverse economic impacts on small businesses.

SUMMARY AND RESPONSE TO COMMENTS

This section summarizes and responds to public comments submitted to DTSC about the proposed rulemaking, *Listing Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Isocyanates as a Priority Product*. DTSC appreciates the numerous comments provided by a variety of interested stakeholders, including manufacturers, businesses that use the proposed Priority Product, non-governmental organizations, and individuals. This proposed regulation would formally list spray polyurethane foam systems (SPF) containing unreacted methylene diphenyl isocyanates (MDI) as a Priority Product. Completing this listing supports our mission to promote the development of safer products through the evaluation of potential alternatives.

The proposed regulations are part of the Safer Consumer Products program, which has created a new approach to accelerate the quest for safer consumer products. To implement this program DTSC adopted framework regulations in 2013 that establish a structure for identifying, listing, and analyzing products that contain harmful chemicals. The framework regulations rely on a series of basic tenets that inform the approach for developing safer products. They specify that the process should be precautionary in nature and that in many instances DTSC will make decisions even though there may be gaps in the available data. As a result, the criteria in the framework regulations for listing a product-chemical combination as a Priority Product focus on potential exposure to the Candidate Chemical in the product and the potential for such exposures to contribute to or cause adverse impacts, observed as health effects or environmental impacts.

Because the precautionary aspect of the framework regulations allows DTSC to consider potential exposure and impacts, we are able to use available data to establish the rationale for the Priority Product listing. In the specific case of these proposed regulations, considerable research documents the health effects associated with exposure to MDI – providing evidence of the potential for adverse impacts associated with the Candidate Chemical. Next, DTSC gathered monitoring data to show unreacted MDI was observed in the breathing zone of applicators during SPF spraying activities – these data provide the potential for exposure to the Candidate Chemical in the product. Within the intentionally precautionary framework of the regulations, DTSC met the criteria for listing the Priority Product without necessarily showing that SPF spraying caused observed cases of asthma. Such an observation would be particularly difficult in this instance because one of the potential health effects associated with MDI is respiratory sensitization, which requires subsequent exposure to trigger asthma. Because the time frame and methods for developing asthma can be lengthy and varied, establishing causation is demonstrably challenging for this Priority Product and effectively illustrates the power of the precautionary approach.

DTSC understands that SCP is a novel process, and has not been undertaken to this extent by other chemical policy programs. To verify our rationale, we specifically asked our independent peer reviewers whether DTSC had adequately supported the conclusion that there is potential for exposure to MDI during use of SPF systems, and

whether these exposures could potentially contribute to or cause significant or widespread adverse impacts to people, especially workers and consumers. All three peer reviewers confirmed that DTSC had supported its conclusion.¹

In addition to the peer review, DTSC conducted over three years of active engagement with our interested stakeholders to further bolster our confidence in the criteria in the framework regulations, and in the methods we used to analyze and apply the available data. Over the years DTSC held workshops, issued draft documents, and met with individuals who wished to confer directly with DTSC. The in-depth engagement of stakeholders over this time-period culminated in the extensive and detailed comments we received for this proposed rulemaking.

During our review and evaluation of the submitted public comments, DTSC carefully considered all suggestions, reasons, contentions, and statements offered by commenters to improve or change the proposed regulations. After completing the review, DTSC concluded that none of the comments provided compelling reasons to change or withdraw our proposed regulations. Notably, none of the comments suggested specific language changes to the proposed regulations. DTSC made no changes to the proposed regulation as a result of the public comments.

However, DTSC recognizes that the variety and extent of the comments, as well as the common themes we observed among the comments, reflect stakeholders' discomfort with the underlying tenets of the framework regulations. Many of the common themes of the comments address various issues associated with making the Priority Product listing determination in the face of uncertainty or definitive causal data. For example, these are the general comment themes:

I. Provisions in the framework regulations – This group of comments focused on the criteria and definitions in the framework regulations and how DTSC applies them. Many of these comments, in particular, address the precautionary approach.

- *Definition of the Priority Product* – comments generally expressed questions about DTSC's decisions to include or exclude certain product subcategories based on the available data.
- *Exposure and personal protective equipment (PPE)* – comments generally questioned the exposure data and criteria, challenging DTSC's determination of potential exposure, and advocating for protection using PPE.
- *Significant or widespread adverse impacts* – comments typically challenged DTSC's determination of potential impacts.

¹ The External Scientific Peer Review (*External Peer Review for the Proposed Adoption of Spray Polyurethane Foam Systems with Methylene Diphenyl Diisocyanates as a Priority Product*, September 9, 2016) is required by Health and Safety Code section 57004(b). DTSC incorporated responses to recommendations made by the peer reviewers in Appendix 1 of the Technical Summary.

II. Technical and global topics – This group of comments addressed specific technical topics in the background information for the proposed regulations, and subjects that apply in general to the proposed regulations.

- *Use of cited information in the Technical Summary* – comments generally challenged the quality, and our use, of studies cited in the background document.
- *External Scientific Peer Review* – comments questioned the independence of the peer reviewers and some of their findings.
- *Economic impact* – comments questioned the methodology and data used in the economic impact studies.
- *Energy efficiency* – comments described impacts of the proposed regulations on efforts to achieve energy efficiency goals.
- *Duplication with existing law* – comments asserted the proposed rule is duplicative of existing requirements.
- *Comments in support of the proposed regulation* – commenters agreed with the goals and language of the proposed regulations.
- *General disagreement with the proposed regulation* – commenters disagreed with the proposed regulations for various reasons.

III. Administrative and procedural issues – This group of comments applied to procedural requests, and topics that did not apply to the proposed regulations.

- *Extension of the comment period* – commenters requested an extension of the comment period.
- *California Environmental Quality Act (CEQA)* – commenters requested that DTSC post the CEQA documents online.
- *Safer Consumer Products framework regulations* – comments that did not apply specifically to the proposed regulations, but that were addressed by the proceedings associated with the framework regulations.
- *Regulatory responses* – comments that did not apply to the proposed regulations, but, rather, addressed the regulatory responses.
- *Obsolete Priority Product Profile* – comments that did not apply to the Technical Summary, but applied to an earlier version of the background document.

DTSC received thirty-nine written letters during the comment period from March 24, 2017, through June 6, 2017, and eight oral comments at the public hearing held on May 16, 2017. We recorded the hearing and uploaded a transcript of the proceedings and testimony to the CalSAFER website. Table 1 provides a complete list of commenters, their affiliations, and the number DTSC assigned to their correspondence or oral comment. Most of the comment letters and testimony covered more than one of these themes. To organize the comments, DTSC numbered individual letters and public hearing comments, as shown in Table 1, then assigned a number to each individual comment. For example, the number “13-3” refers to the third comment in the letter numbered 13, and “PH2-2” refers to the second oral comment made by the second speaker at the public hearing. Finally, DTSC grouped and summarized the comments according to the listed themes, presenting the summaries and responses in this section.

Table 1. List of Commenters

#	Commenter Name	Affiliation
1	Lee Salamone	American Chemistry Council (ACC)
2	Andrew Harris	Accella
3	Rebecca Bernstein	Arkema
4	Erika Peterman	BASF
5	Shawn Hunter	Dow Chemical Company
6	Mojee Cline	ICP
7	Howard Deck	Icynene
8	Jim Perkins	SWD Urethane
9	Lee Salamone	ACC
10	Clarence Tolbert	NCFI Polyurethanes
11	Robert Skoglund	Covestro
12	Steve Burns	Huntsman
13	Will Lorenz	General Coatings
14	Joe Stockdale	Accella
15	Will Lorenz	General Coatings Manufacturing Corp.
16	Will Lorenz	General Coatings Manufacturing Corp.
17	Ted Waugh	American Chemistry Council
18	Teri Hitt	No affiliation provided
19	Bob Mars	BEST Contracting Services
20	Robert Raymer, Jamie Khan, Rex Hime, Debra Carlton	California Building Industry Association (CBIA), Associated General Contractors (AGC), California Business Properties Association (CBPA), California Apartment Association (CAA)
21	Jose Vasquez	No affiliation provided
22	Frank Morsink	MeldpuntPURslachtoffers
23	Tony Brasil	BRS Roofing, Inc.
24	Will Lorenz	General Coatings Manufacturing Corp.
25	Dr. Michael Lax, Greg Siwinski, Dorothy Wigmore	Occupational Health Clinical Centers
26	Blair Cunnings	Barrier Specialty Roofing and Coatings, Inc.
27	Angus Crane	NAIMA
28	Jim Patterson	Assemblyman, 23 rd District
29	Lisa Massaro	The Dow Chemical Company
30	Stephen Wieroniey	American Chemistry Council
31	Paul Warren	SWD Urethane
32	Mark Rossi	BizNGO
33	Howard C. Deck	Icynene
34	Tom Lent	Healthy Building Network
35	Veena Singla	Natural Resources Council, Communication

#	Commenter Name	Affiliation
		Workers of America, Californians for a Healthy and Green Economy, Center for Environmental Health, Environmental Working Group, Worksafe
36	Ferrell Drum	ICAA
37	Kurt Riesenberg	Spray Polyurethane Foam Alliance (SPFA)
38	Will Lorenz	General Coatings Manufacturing Corp.
39	Stephen R. Bowen	Tip Top Roofing, Inc.
PH1	Stephen Wieroniey	American Chemistry Council Center for the Polyurethanes Industry (CPI)
PH2	Randy Fischback	Dow Chemical Company
PH3	Paul Coleman	Huntsman Corporation
PH4	Will Lorenz	General Coatings Manufacturing Corp.
PH5	Gary Talbott	5 Star Performance Insulation
PH6	Mitch Fine	Armstrong
PH7	Alyssa Stinson	California Building Industry Association
PH8	Veena Singla	Natural Resources Defense Council

Comments Regarding the Definition of the Priority Product

Comments: 15-9, 15-25, 15-43, 15-44, 37-10, 38-3, 38-4, PH1-5, PH4-2

Comment Summary:

The definition of the Priority Product is too broad and encompasses more than one product. DTSC should assess whether these separate products meet the prioritization criteria and individually assess the economic impacts from being listed as a Priority Product. The different types of SPF systems have different exposure potentials, require personal protective equipment (PPE) types, and engineering controls, and can't be covered in one regulation. DTSC should affirm that SPF with MDI covers five product-chemicals.

DTSC Response:

The SCP framework regulations (22 CCR 69503.5(b)(1)(A)) require DTSC to describe a product-chemical combination so that a responsible entity may determine if “one or more of its products is a Priority Product,” clearly anticipating that a Priority Product listing may encompass more than one product manufactured or sold by the same responsible entity.

In this regulation DTSC defined the product broadly as two-component polyurethane foam systems designed for spraying, abbreviated as Spray Polyurethane Foam (SPF).

DTSC recognizes that there are numerous formulations and brands of SPF products that produce foams of different densities and for different uses, as applied using a variety of spray systems. All these formulations have an A-side containing isocyanates, with different components in the B-side to meet performance requirements for a specific use. These foam systems also share the potential for exposure to workers or consumers during normal use of the systems as well as the potential for that exposure to contribute to or cause significant or widespread adverse impacts. No changes were made to the proposed regulation or supporting documents based on these comments.

Comments: 15-10, 15-26, 30-2, 37-7

Comment Summary:

Condensing the EPA table depicting various types of SPF products from six products into one product allowed DTSC to evade the regulatory requirement for the initial Priority Products list to contain no more than five Priority Products (22 CCR 69503.6).

DTSC Response:

DTSC included the EPA table as a clear depiction of the various forms of SPF systems containing MDI. DTSC condensed the table to reflect the SPF systems included in the Priority Product definition. No changes were made to the proposed regulation or supporting documents based on these comments.

Comment: 15-37

Comment Summary:

This Priority Product differs from the other Priority Products named (nap mats with flame retardants and paint stripper with methylene chloride) in that the Chemical of Concern in SPF reacts to form a polymer bond after it is cured, while the Chemicals of Concern in the other Priority Products are more mobile.

DTSC Response:

DTSC agrees that this Priority Product is different from the other Priority Products named in that its potential for exposure is different and may occur at a different use phase than other products. The regulations require that DTSC consider adverse impacts from the product “due to potential exposures during the life cycle of the product.” In this case, the application phase of the product’s lifecycle results in the potential exposure. Thus, the product has been defined as SPF containing unreacted MDI and exposure occurs when unreacted isocyanates are released into the air during spraying events. DTSC did not base this Priority Product listing on potential exposure after the product cures. The basis for each Priority Product listing arises from the adverse impacts and exposures unique to its use; a given Priority Product is not necessarily comparable to other Priority Products. No changes were made to the proposed regulation or supporting documents based on this comment.

Comments: 15-2, 15-42, 15-45, 15-108, 15-110, 38-10, 38-11

Comment Summary:

The definition should separate SPF used on roofs from the definition of SPF used for insulation. The two products have different brick codes. Individual consumers are not using high pressure SPF used on roofs. SPF used on roofs should be removed from the listing.

DTSC Response:

The definition of the proposed Priority Product includes SPF used in roofing because it is a two-component system and the A-side contains MDI. The market data cited illustrate the expansion in the use of SPF systems and pertains to the entire SPF market. Although spray polyurethane foam used on roofs may be a relatively small part of the entire SPF market, there is potential for workers to be exposed to MDI during application. Although Do-It-Yourselfers (DIYers) may not apply SPF on roofing, DIYers may use a pressurized SPF system for other applications defined in the proposed regulations such as insulation. No changes were made to the proposed regulation or supporting documents based on these comments.

Comments: 15-11, 15-41

Comment Summary:

The definition should include one-component pre-mixed cans of SPF. It is the product most commonly marketed to the DIY community.

DTSC Response:

DTSC's decision to remove one-component pre-mixed cans of SPF from the definition of the proposed Priority Product was based on feedback provided during public workshops with SPF manufacturers and other stakeholders. One-component pre-mixed cans of SPF contain mostly pre-reacted, polymerized foam. In addition, the European Union (EU) considers the process of applying SPF via use of one-component pre-mixed cans as "beading," not spraying. This reflects the difference in the two product types wherein spraying results in a higher degree of aerosolized particles than beading. No changes were made to the proposed regulation or supporting documents based on these comments.

Comments: 38-6, 38-8, 38-9

Comment Summary:

The decision to exclude products from the definition seems to be based on engineering controls. This may result in alternatives, such as spray guns with internal impingement, that are intended to avoid the definition, but that do not make the product safer. Products that are cited as causing harm are excluded from the definition while products with no documented harm are included. This seems arbitrary and capricious.

DTSC Response:

There are many products containing Chemicals of Concern that potentially cause harm and that have not yet been listed as Priority Products. With each Priority Product listing DTSC balances the need to define the product broadly enough to capture the products that pose potential exposure and harm, with the need to keep the Priority Product focus narrow enough to make the definition clear. The overall intent of the Priority Product listing is to move manufacturers to perform Alternatives Analyses (AA). DTSC does not presume what potential outcome may result from the AA and the manufacturer's decision process. A manufacturer that changes its product or delivery system design to promote safer use or reduce the potential for adverse impacts would be responding to the framework regulations in a way intended by the regulations. Conversely, altering the product's delivery system to evade the definition without making the product safer is unlikely to be successful. No changes were made to the proposed regulation or supporting documents based on these comments.

Comment: 37-9

Comment Summary:

It is not clear whether “unreacted MDI” refers to MDI prior to application, or MDI that is not fully reacted after application.

DTSC Response:

Any MDI that is not fully polymerized is considered “unreacted” by DTSC. This is the case in multiple segments of the product life cycle. MDI remains unreacted prior to application and during spraying. Some unreacted MDI will be present for some period of time after spraying during the curing process. DTSC’s primary concern is unreacted MDI monomers and oligomers rather than polymerized (“reacted”) MDI in fully cured foam. Exposure to airborne unreacted MDI could occur either prior to application or if unreacted MDI remains after application. No changes were made to the proposed regulation or supporting documents based on this comment.

Comments: 38-5, PH6-1

Comment Summary:

The term “spray” describes a process (atomization of a liquid) not a product. Products excluded from the definition, such as factory fabricated rigid polyurethane sheets, are spray products.

DTSC Response:

The proposed regulations do not apply to SPF products after they are sprayed in place and cured. SPF products that are not two-component systems are not included in the definition of this Priority Product. Pre-fabricated flexible or rigid polyurethane foam and assembled products containing polyurethane foam are not included because they are manufactured in facilities under conditions that are more easily monitored and controlled. No changes were made to the proposed regulation or supporting documents based on these comments.

Comments Regarding Exposure and Personal Protective Equipment (PPE)

Comments: 15-29, 15-56, 15-57, 19-3, 19-6, 20-2, 23-3, 23-6, 30-14, 30-16, 30-41, 30-81, 36-2, 36-3, 38-12, 38-16, 39-5, PH1-3, PH2-2, PH2-4, PH5-1

Comment Summary:

DTSC should consider all the factors that mitigate applicator exposure potential during installation, including personal protective equipment (PPE). Also, existing training and certification programs for SPF installers and worker protection regulations adequately prevent exposures to MDI. The Spray Polyurethane Foam Association is not aware of any recorded incidents in the state of California where spray polyurethane foam has been attributed to work related asthma, asthma, sensitization, illness or otherwise.

DTSC Response:

DTSC considered all the factors associated with exposure potential, including PPE. DTSC conducted an extensive review of the hazard traits and exposure potential of methylene diphenyl diisocyanates (MDI) and evaluated the potential for these chemicals to contribute to or cause significant or widespread adverse impacts. DTSC presented its findings in the *Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product* (Technical Summary).

DTSC acknowledges that trained professionals using proper PPE and implementing good safety practices are less likely to be exposed to potentially harmful levels of MDI during application of SPF. However, although the SPF industry considers administrative controls and PPE to be sufficiently protective, the National Institute for Occupational Safety and Health (NIOSH) considers these two methods to be the least desirable approaches to controlling potential occupational chemical exposures. Of the five levels of protection within the hierarchy of exposure control, administrative controls and PPE are the least favorable because the original hazard remains present in the workplace and exposure can readily occur if the methods fail or are used improperly. Hence, training, certification, and PPE cannot eliminate exposure risks even if workers have access to these resources.

Furthermore, we know that not all workers and consumers of SPF with MDI have adequate training or work under industry stewardship programs. For example, individual consumers can purchase SPF systems that do not include PPE. Although independent contractors are subject to the provisions of California's labor and contracting laws, including compliance with OSHA requirements, sole proprietors and consumers are not.

DTSC believes there are occasions when PPE is less likely to be used properly. For example, workers and consumers may apply SPF in cramped spaces, where it could be hard to maneuver while wearing PPE. Such situations could lead to insufficient or improper protection from exposure to MDI while using SPF. Factors affecting the use of PPE by workers include PPE discomfort, heat, ill-fitting equipment, and personal beliefs

that any MDI exposures would be small and relatively harmless. There is no reason to assume that sole proprietors and individual consumers would undertake more stringent self-protective measures than workers who are trained within programs developed by industry trade groups. Also, costs associated with appropriate PPE, such as supplied air breathing apparatus, may discourage use – especially by small businesses.

DTSC acknowledges that the Spray Polyurethane Foam Alliance has developed a comprehensive training program for SPF workers and contractors. DTSC requested data on participation rates of California companies and workers. Although DTSC did not receive such information, it has been informed by SPFA that participation by California workers is small. It is possible that many SPF workers in the State of California have only limited access to industry-recommended training and certification. DTSC appreciates that clearly written and sufficiently descriptive product warnings that accurately reflect the exact type of PPE needed for protection against dermal and inhalation exposures may result in reduced exposures to MDI during the application of SPF. Unfortunately, the potential for harmful exposures to MDI during application of SPF continues to exist even though training programs and adequate PPE are commercially available.

The California Work-Related Asthma Prevention Program recorded 47 cases of work-related asthma associated with isocyanate exposure from 1993 to 2008, with eight cases specifically attributed to exposure to unreacted MDI. Although it is unknown whether these cases are directly attributable to SPF, studies illustrate that unreacted MDI has been detected and measured in the breathing zones of applicators, potentially exposing workers and bystanders to unreacted MDI during SPF application. DTSC has determined that unreacted MDI in the breathing zone of applicators, coupled with the hazard traits associated with MDI, results in the potential for adverse work-related health effects, such as work-related asthma. The framework regulations are intentionally protective and specify that the listing for a Priority Product must show the potential for exposure to the Candidate Chemical in the product and the potential for that exposure to contribute to or cause significant or widespread adverse impacts.

No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 33-8, PH1-7

Comment Summary:

DTSC should work with CalOSHA and other stakeholders to ensure its (DTSC's) concerns regarding safety controls and education are properly addressed.

DTSC Response:

DTSC's concerns with safety controls are inherent to the industry's approach of relying upon administrative controls and PPE. As described in the ISOR, within the hierarchy of protection, eliminating the hazard is the best solution. DTSC's Safer Consumer

Products program is designed to achieve that highest level of protection. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 30-34, 30-80

Comment Summary:

DTSC does not provide data to show 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.

DTSC Response:

It is difficult to determine or track the types of protection measures sole proprietors and individual consumers will use. However, DTSC knows of commercial contractors within the SPF industry who failed to use protection during SPF application and were identified and sanctioned. There is no reason to assume that sole proprietors and individual consumers will demonstrate more diligent compliance with exposure protections than those trained within the commercial industry. Even those who intend to fully comply may experience accidents or equipment failure. Also, costs associated with appropriate PPE, such as supplied air breathing apparatus, may be prohibitively high for small businesses. Finally, a 2016 report from U.S. EPA indicates that warning labels on hazardous products are not always effective, and typically the safety precautions needed for SPF with MDI are communicated to individual consumers through product labeling or use instructions.² No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 30-70

Comment Summary:

In the Technical Summary DTSC suggests that PPE may not be recommended or mandated; this claim should be removed.

DTSC Response:

DTSC acknowledges that the sentence referred to in the comment may not be entirely clear: “When neither engineering controls nor PPE are mandated, sole proprietors . . . and individual consumers . . . are at risk for exposure to MDI.” However, DTSC has not suggested that PPE may not be recommended. In this sentence DTSC is indicating that sole proprietors and individual consumers are not subject to state and federal worker protection standards and are of particular concern to DTSC. This is stated clearly in the

² U.S. EPA. “The Effectiveness of Labeling on Hazardous Chemicals and Other Products.” U.S. EPA, Office of Chemical Safety and Pollution Prevention. March 2016.

ISOR.³ No changes were made to the proposed regulation or the supporting documents based on this comment.

Comment: 15-86

Comment Summary:

Because it can be surmised that DTSC considers fiberglass insulation to be safe, there will continue to be underreporting of fiberglass injuries.

DTSC Response:

DTSC has not suggested in any documentation associated with this rulemaking that it considers fiberglass insulation to be safe. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 30-15, 30-17

Comment Summary:

DTSC's proposal will provide no meaningful increase in protection and might reduce the resources available to continue with voluntary protection programs.

DTSC Response:

It is unclear why the commenter asserts that the proposed Priority Product listing will not increase protection. One manufacturer, Gaco Western, has already announced what it describes as a safer isocyanate-free SPF to be launched in March 2018. Although the ultimate outcome of any Alternatives Analysis and the resulting regulatory responses may be uncertain, the mission of the SCP program and intent in listing SPF is for manufacturers to undertake the AA process and identify which, if any, protections may be viable options to meaningfully increase in protection. Resources for voluntary programs may or may not be reduced in the future, but mandatory state and federal worker protection standards will still apply. No changes were made to the proposed regulation or the supporting documents based on these comments.

³ DTSC. "Initial Statement of Reasons, Safer Consumer Products Regulations – Listing Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product." March 2017. Page 17.

Comments: 15-30, 15-91, 15-109, 33-7, 37-8

Comment Summary:

DTSC has not shown that workers or consumers could be exposed to MDI during spraying or mixing of SPF.

Response:

As described in the ISOR, studies – including some from the SPF industry – show that unreacted MDI was detected and measured in the breathing zone of SPF applicators during and after spraying. Some surveys showed concentrations of airborne, unreacted MDI exceeding various occupational thresholds. Airborne MDI may drop to undetectable levels if spraying stops, but spraying is often a continuous process that can span several hours depending on the size of the project or work shift. In these cases, isocyanates are continually being suspended in air during the entire spraying process. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 15-33, 15-89

Comment Summary:

DTSC does not support its claim that inhalation or skin contact is a major exposure route for MDI.

DTSC Response:

The Technical Summary presents findings from numerous studies verifying the inhalation and dermal exposure routes for MDI. DTSC used reliable information and considered the quality of information contained in each study as described in 22 CCR 69503.2((b)(1)(C)). Furthermore, the listing proposal in the regulation and the Technical Summary were evaluated by independent External Scientific Peer Reviewers who confirmed that DTSC presented sufficient information to conclude there is potential for exposure to MDI. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 15-6, 15-61, 15-66, 15-67, 15-68, 15-69, 15-74, 15-83, 15-87, 15-93, 15-97, 15-103, 15-106, 15-131, 15-132, 30-25, 37-12, 13-14

Comment Summary:

Exposures to MDI from non-SPF sources, such as truck bed liners, should not be used to establish MDI health effects, and references to inhalation exposures associated with foam roofs are not supported and should be removed.

DTSC Response:

Exposure to MDI from sources other than SPF are included to demonstrate the potential of isocyanates in SPF systems to cause adverse impacts when isocyanates become airborne. Studies show that airborne, unreacted MDI was observed in the breathing zone of applicators during application. The examples of exposure outcomes demonstrate the potential adverse effects that may occur as a result of SPF workers' potential exposure to MDI during application of SPF. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 15-36

Comment Summary:

Dust does not pose an exposure hazard because it is only generated by cutting or grinding after the product is fully cured.

DTSC Response:

Dust is mentioned only in the Table from U.S. EPA depicting the overview of SPF systems. DTSC did not rely on exposure to dust in the listing of this Priority Product. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 30-73, 30-74, 30-75

Comment Summary:

Exposure monitoring data is mischaracterized and undermines the proposed regulation.

DTSC Response:

DTSC evaluated the available data and presented it in the Technical Summary in an accessible format that could be easily understood. In summary and absent the study details, the industry monitoring studies have detected MDI in the breathing zone of applicators when SPF is sprayed. Concentrations can still be at elevated levels within this breathing zone, although airborne concentrations of MDI may diminish with distance from the foam application. Inhalation exposures to MDI are possible whenever MDI is present in the breathing zone of applicators or bystanders. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 30-72

Comment Summary:

The claim that monitoring data suggest workers may be exposed to MDI does not support prioritization. DTSC must demonstrate the product meets the prioritization criteria.

DTSC Response:

Studies have detected MDI in the breathing zone of applicators during spraying of SPF. Such exposure can lead to inhalation exposures to MDI for applicators or bystanders. The prioritization criteria require DTSC to demonstrate that there is potential exposure to the Candidate Chemical and potential for the exposure to cause significant or widespread adverse impact. DTSC has determined that exposure to MDI in SPF can cause a variety of adverse health effects and the monitoring data indicating the presence of MDI in the breathing zone of applicators demonstrates potential exposure to MDI. The criteria in the framework regulations do not require DTSC to prioritize a Priority Product by focusing on a worst- or best-case scenario. DTSC has determined that potential harm to workers warrants listing. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 30-19, 30-20, 30-21, 30-32, PH1-4

Comment Summary:

A product's availability and presence of a chemical in the product are not sufficient to show potential exposure for workers or consumers. DTSC must also consider other factors, such as how the product is used and the extent of the exposure.

DTSC Response:

The framework regulations clearly state that when evaluating a Priority Product DTSC shall evaluate potential exposure by considering one of four factors: market presence of the product, occurrence (or potential occurrence) of exposures to the Candidate Chemical in the product, the household and workplace presence of the product, and potential exposures to the Candidate Chemical in the product during the product's lifecycle.⁴ No changes were made to the proposed regulation or the supporting documents based on these comments.

⁴ 22 CCR 69503.3(b).

Comment: 30-76

Comment Summary:

The statement that not all workers will be protected from adverse effects even when exposures are below the PEL should be removed since the PEL is defined as the concentration to which “most workers can be exposed without adverse effect. . .”

DTSC Response:

The PEL protects “most” workers, not all workers because individuals will react to health effects differently. This is especially true of respiratory sensitization. It is accurate to state that not all workers will be protected, even at exposures below the PEL. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 15-30, 15-38, 15-52, 15-54, 15-94, 15-95, 15-98, 19-4, 23-4, 30-6, 30-13, 37-15, 39-3, PH1-2, PH3-1

Comment Summary:

The data do not demonstrate that workplace exposures result in health effects, including asthma. No NFPA data show significant inhalation injury attributable to SPF with unreacted MDI or from thermal decomposition of polyurethanes. DTSC provides no evidence of SPF injuries or increasing asthma rates in California. Recent data shows decreasing asthma and sensitization rates.

DTSC Response:

Exposure to MDI can cause irreversible respiratory sensitization, leading to increased risk of asthma following subsequent exposures to MDI. Airborne MDI may drop to undetectable levels if spraying stops, but spraying is often a continuous process that can span several hours depending on the size of the project or work shift. In these cases, isocyanates are continually being suspended in air during the entire spraying process.

People who are sensitized to MDI can experience asthma when exposed to very low concentrations of MDI in air. Occupational health professionals repeatedly note that occupation-related chemical exposures, including those leading to symptoms of asthma, are systematically under-reported.

The California Work-Related Asthma Prevention Program recorded 47 cases of work-related asthma associated with isocyanate exposure from 1993 to 2008, with eight cases specifically attributed to exposure to unreacted MDI. Although these cases are not known to involve SPF, studies illustrate that unreacted MDI has been detected and measured in the breathing zones of applicators, potentially exposing workers and bystanders to unreacted MDI during SPF application. DTSC has determined that unreacted MDI in the breathing zone of applicators, coupled with the hazard traits associated with MDI, results in the potential for adverse work-related health effects,

such as work-related asthma. The framework regulations are intentionally protective and specify that the listing for a Priority Product must show the potential for exposure to the Candidate Chemical in the product and the potential for that exposure to contribute to or cause significant or widespread adverse impacts.

In the Technical Summary, as part of the summary of environmental fate, DTSC mentions that the cured foam may release toxic chemicals from thermal degradation such as fire. Because these chemicals, however, are not identified and do not form the basis for the listing, DTSC did not collect NFPA data to characterize significant inhalation injury attributable to SPF with unreacted MDI.

DTSC does not state that asthma rates in the state are rising. DTSC notes that as the demand for SPF products increases, the number of isocyanate-related illnesses or injuries could also increase. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 15-4, 15-60, 15-88, 15-111, 15-117

Comment Summary:

AB 1897 protects independent contractors and consumers who do not install two-component high pressure SPF.

DTSC Response:

The Priority Product definition includes both high-pressure and low-pressure SPF systems. Although independent contractors are subject to the provisions of California's labor and contracting laws, including compliance with AB 1897, sole proprietors and consumers are not. We acknowledge that consumers do not apply two-component high pressure SPF, but two-component low pressure SPF systems are available and marketed directly to consumers. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 15-75, 15-77, 15-78, 15-79, 15-80

Comment Summary:

SPF and MDI-related market data do not adequately characterize the SPF market or correlate to the potential for exposure to MDI in SPF, including SPF used on roofs.

DTSC Response:

The market data cited pertain to the entire SPF market and are used to illustrate the growth of the sector, expanded use by workers and consumers, and increased potential for exposures to MDI from SPF. Although spray polyurethane foam used on roofs may be a relatively small part of the entire SPF market, there is a potential for workers to be exposed to MDI during application. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 15-81

Comment Summary:

DTSC should disclose any non-public involvement in the SCP process with the glass fiber industry.

DTSC Response:

The Safer Consumer Products program has not knowingly met with the glass fiber industry. However, DTSC is willing to meet with any industry or manufacturing representatives, or other groups, who wish to provide input or seek clarification of the requirements. DTSC posts all comment received regarding the proposed regulation during the comment period on its website and is available to answer any and all questions regarding the proposed rule. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comment: 15-107

Comment Summary:

DTSC should not reference the National Institutes of Health Household Product database since none of the listed products are Priority Products.

DTSC Response:

The National Institutes of Health Household Products Database (HPD) identifies the increasing number of consumer products containing MDI. In the framework regulations one of the factors that can be used to demonstrate the potential for exposure describes the household and workplace presence of the product, *and other products containing the same Candidate Chemical*. This provision allows DTSC to consider exposures to other products with the Candidate Chemical, as well as cumulative exposures to a Candidate Chemical, which is especially pertinent in the case of MDI, a potent

respiratory sensitizer. For example, a non-occupational exposure to MDI in a household product could sensitize a worker, who could later develop asthma after an occupational exposure to MDI, or vice versa. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comment: 15-48

Comment Summary:

High pressure systems are typically applied at higher temperatures resulting in a lower vapor phase half-time than indicated in the Technical Summary.

DTSC Response:

The proposed regulation addresses potential exposure and adverse health impacts of SPF on workers and consumers for both low- and high-pressure SPF systems. Monitoring studies include exposures from both low- and high-pressure systems. DTSC is aware of the differences between high and low-pressure systems, or between ambient and elevated temperatures in relation to airborne MDI concentrations, exposures, and risks, as well as differences in susceptibility among the exposed. Although DTSC will not attempt to compare risks among scenarios, DTSC has determined there is reasonably expected potential for exposure and adverse impacts from both high and low-pressure systems. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 15-49, 15-50, 15-71, 15-72, 15-73, 15-92

Comment Summary:

DTSC's claim of significant adverse exposure due to welding via thermal decomposition is not substantiated. DTSC provides no data on welders on SPF roofs developing occupational asthma. DTSC should remove references to thermal decomposition of finished products.

DTSC Response:

DTSC does not make a claim of significant adverse exposure due to welding via thermal decomposition. DTSC mentions potential exposures to airborne degradation chemicals that might result from fires or other heat-generating activities, such as welding in the Technical Summary as part of the description of environmental fate. These are examples that form part of the description of the overall understanding of MDI in SPF systems. However, DTSC did not use these exposures as part of the demonstration of potential significant adverse effects. In the ISOR, DTSC concludes that SPF with unreacted MDI meets the criteria for listing as a Priority Product, due to the following factors: the availability of SPF systems, the potential for exposure to unreacted MDI during spraying, and the significant adverse health impacts associated with exposure to unreacted MDI. Hence, DTSC's claim of potential significant adverse impact focuses on

the hazard traits associated with MDI and the exposure potential of SPF with MDI during application of the two-part systems. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 25-2, 25-3, 27-1, 27-2, 27-3

Comment Summary:

There is a potential for workers or consumers to be exposed to MDI during use of SPF systems, which presents a health hazard.

DTSC Response:

DTSC agrees with the claim that the potential for exposure can present a health hazard. Indeed, DTSC found that the availability of SPF systems, the potential for exposure to unreacted MDI during spraying, and the significant adverse health impacts associated with exposure to unreacted MDI meets the criteria for listing as a Priority Product. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 25-4

Comment Summary:

“The small unventilated spaces in which foam insulation is applied present a serious challenge to implement engineering controls and PPE – a challenge better met through informed substitution.”

DTSC Response:

DTSC agrees that there are occasions when PPE or engineering controls are less likely to be used properly. For example, workers and consumers may apply SPF in cramped spaces, where it could be hard to maneuver while wearing PPE. Such situations could lead to insufficient or improper protection from exposure to MDI while using SPF. Within the hierarchy of protection, eliminating the hazard is the best solution. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 34-1, 34-5, 34-6

Comment Summary:

SPF curing is poorly understood and poorly controlled and likely to lead to exposures, and adverse effects, to workers, occupants, and potentially to unborn children. ASTM is developing a new test method for estimating emission from SPF insulation.

DTSC Response:

DTSC agrees that there is no generally accepted curing time and precise measurement of MDI exposure potential during curing remain uncertain, despite anecdotal evidence of exposure. DTSC looks forward to more definitive data results from a new ASTM test method for estimating emissions from SPF insulation. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 34-8, 35-5

Comment Summary:

It's time to invoke the hierarchy of workplace safety controls and prioritize substitution and elimination.

DTSC Response:

DTSC agrees that within the hierarchy of protection, eliminating the hazard is the best solution. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 34-4

Comment Summary:

OSHA has identified serious adverse health effects from isocyanate exposure, with symptoms experienced months or years after exposure through inhalation or touch.

DTSC Response:

DTSC agrees with the commenter's and OSHA's findings that exposure to unreacted MDI can result in significant adverse health impacts. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 25-1, 35-3

Comment Summary:

Homeowners and installation workers have become ill due to SPF, as described in six cases presented by Occupational Health Clinical Centers. Also, case summaries from the states of Washington, Michigan, and Massachusetts give examples of a "consistent pattern of respiratory disease caused by MDI from spray foam in workers in the construction industry, whether they are applicators or simply working in vicinity of an application."

DTSC Response:

DTSC appreciates the contribution of information about health outcomes. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments Regarding Significant or Widespread Adverse Impacts

Comments: 19-2, 23-2, 29-1, 30-4, 30-7, 30-26, 30-27, 30-28, 30-29, 30-30, 30-31, 30-33, 30-35, 30-36, 31-1, 31-3, 33-2, 33-3, 33-5, 37-11, 39-2, PH1-1, PH2-1, PH4-3

Comment Summary:

DTSC has not provided adequate information to show that SPF with unreacted MDI has the potential to contribute to or cause significant or widespread adverse impacts, and should suspend the rulemaking. California's Department of Public Health reported only 23 cases of work-related asthma resulting from isocyanate exposure over 15 years, with zero cases from 2006-2014, showing a decline in occupational asthma rates. More recent NIOSH data also show declining asthma attributed to diisocyanates. Controls will prevent exposure from happening.

DTSC Response:

Following an extensive review of the scientific literature and analysis of the known hazard traits of unreacted MDI, DTSC concluded there is a potential for workers and consumers to be exposed to unreacted MDI during normal use of both high-pressure and low-pressure SPF systems because airborne MDI was observed in the breathing zone of applicators during use. The External Scientific Peer Reviewers supported DTSC's findings. As described in the Statement of Reasons and Technical Summary, these exposures could potentially contribute to or cause significant adverse impacts. Engineering controls and PPE may reduce the incidence of exposure, but they will not prevent exposure.

Exposure to unreacted MDI can lead to significant adverse human health impacts, including asthma, hypersensitivity pneumonitis, respiratory irritation, pulmonary inflammation, and contact dermatitis. People who have become sensitized to isocyanates may also experience significant, life-threatening asthma attacks when subsequently exposed to extremely low levels of isocyanates from any source. The two-step mechanism involving sensitization and expression poses a challenge when attributing asthma to occupational exposures.

Occupational MDI-related asthma has been documented in California, though it is unknown if those occurrences are attributable to spray foam use. MDI-related asthma is misdiagnosed and under-reported, in part because most people don't realize their asthma is linked to MDI since asthma has many causes and MDI-related asthma isn't easily distinguished from the other asthma causes. In addition, delays are common before an onset of asthma. Finally, poor occupational health reporting systems hinder data collection and employers, and employees, may be reluctant to report occupational illnesses. DTSC did not use asthma cases to demonstrate the potential for widespread impacts. The wide availability of SPF systems with MDI provides evidence that the potential for adverse impacts is widespread. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 15-14, 37-12

Comment Summary:

To prioritize a product-chemical combination, DTSC must differentiate between the potential for exposure to a Chemical of Concern, and the potential for that Chemical of Concern, in the product-chemical combination, to cause adverse impacts. DTSC did not present this analysis and instead relies on exposures to non-SPF products.

DTSC Response:

The commenter has reversed the adverse impacts and exposure demonstrations in the regulatory process. The adverse impacts demonstration applies to the Candidate Chemical itself and the exposure demonstration applies to the Candidate Chemical in the Priority Product.

The prioritization process outlined in the framework regulations (22 CCR 69503.2) specifies that a Priority Product must meet the following criteria: (1) potential exposure to the Candidate Chemical in the product and (2) potential for one or more exposures (to the Candidate Chemical) to contribute to or cause significant or widespread adverse impact. In DTSC's analysis the potential exposure to the Candidate Chemical in the product occurs when releases of airborne unreacted MDI potentially cause exposure, as has been shown in various cited studies. The potential for exposure to cause adverse impact is demonstrated by the adverse health impacts associated with exposure to unreacted MDI.

When DTSC cites adverse impacts associated with MDI in non-SPF products, it is properly demonstrating the adverse impacts associated with the Candidate Chemical. The framework regulations provide adverse impact and exposure factors (22 CCR 69503.3) for evaluating Priority Products. These factors explicitly state that the assessment of the adverse impact to the Candidate Chemical focuses solely on the Candidate Chemical and is independent of the product (22 CCR 69503.3(a)). No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 15-32, 15-89, 15-125, 15-126

Comment Summary:

DTSC does not present information that exposure to SPF used for roofing has the potential to cause significant or widespread adverse impacts.

DTSC Response:

DTSC used available data to support the listing of this Priority Product. The Priority Product is used in a variety of applications and circumstances. If a responsible entity believes that the exposure scenario for a particular use, like SPF used for roofing, is unique and poses no potential to cause significant or widespread adverse impacts, such

factors should be included in the Alternatives Analysis and form the rationale for applicable regulatory responses. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 30-38, 15-125

Comment Summary:

SPF systems are professionally installed; consumers may purchase a system, but will hire a professional installer. Concerns about DIYers and bystanders are irrelevant on rooftops. The potential for widespread adverse effects cannot be attributed to consumer use.

DTSC Response:

Internet searches show availability of two-part SPF systems with MDI marketed to consumers for home use, independent of commercial installers. Some SPF systems with MDI are marketed to DIY homeowners for the repair and maintenance of roofing systems. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 30-37

Comment Summary:

DTSC has not demonstrated that there is potential for significant adverse health effects where “significant” is defined as either statistically significant effects, or serious, permanent effects.

DTSC Response:

As described in the ISOR for the proposed regulations, DTSC believes the adverse health effects associated with exposure to unreacted MDI are significant. Exposure to unreacted MDI can lead to respiratory sensitization, asthma, hypersensitivity pneumonitis, respiratory irritation, pulmonary inflammation, and contact dermatitis. Many of these health effects are serious, irreversible, and can result in death. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comment: 30-23

Comment Summary:

The regulations need defined threshold limits to define the determination of the potential for significant or widespread impacts; the process for making this decision is not clearly described and limits informed participation.

DTSC Response:

The framework regulations are intentionally precautionary and flexible. They do not contain threshold requirements for establishing Priority Products. The framework regulations allow an option for DTSC to establish an Alternatives Analysis Threshold under certain conditions (22 CCR 69503.5(c)). However, such a threshold is not appropriate for SPF with MDI given the extremely low levels at which MDI may harm workers if exposed. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 15-21, 15-23, 15-55, 15-70, 30-24

Comment Summary:

DTSC cannot use market data to demonstrate that exposure to the Chemical of Concern in the Priority Product causes significant or widespread adverse impacts. It is not sufficient to demonstrate potential for exposure. DTSC must also demonstrate that the exposure has the potential to cause significant or widespread impacts. Also, DTSC should not use industry safety programs as evidence for potential for significant or widespread adverse impact.

DTSC Response:

DTSC uses market data to properly demonstrate the potential for exposure to the Candidate Chemical consistent with the framework regulations.⁵ The specified information is a valuable surrogate for measures of potential exposure for which there is little data. DTSC believes the health effects associated with exposure to MDI demonstrate the potential for significant adverse impacts; the wide availability of SPF systems demonstrates the potential for widespread adverse impacts. It is important to note that although DTSC has demonstrated a potential for both significant and widespread adverse impacts, the framework regulations would be satisfied with a demonstration of the potential for either significant *or* widespread adverse impacts.

DTSC did not use industry safety programs as evidence of potential for significant or widespread adverse impact. These programs were developed because of the inherent risks associated with the product. DTSC's discussion of safety programs focuses on industry's argument that such programs are sufficient to prevent exposure; DTSC is concerned with exposure that could occur among those who do not employ safety

⁵ 22 CCR 69503.3(b)(1).

measures and those for whom the measures fail. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 30-27, 31-2, 33-1, PH6-3

Comment Summary:

One of the ESPR reviewers, Dr. B. Nemery, asserted that the terms “significant” and “widespread” are not appropriate and questions if they are necessary. DTSC did not respond to Dr. Nemery’s suggestion that the terms be removed.

DTSC Response:

This comment misinterprets Dr. Nemery’s assessment and erroneously implies that Dr. Nemery did not support the findings of the Technical Summary. In fact, Dr. Nemery argues that the health effects associated with MDI exposure obviate the need to demonstrate significant or widespread impact. Dr. Nemery questioned whether it is even necessary to evaluate MDI’s adverse effects using these terms because the health hazards associated with MDI exposure are so well known and documented. DTSC did not remove the terms because the framework regulations specify the determination of significant or widespread adverse impacts to identify Priority Products. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 33-4, 36-4

Comment Summary:

OSHA discontinued its National Emphasis Program on isocyanates in 2016 after not finding many overexposures attributable to isocyanates.

DTSC Response:

OSHA recognized the potential harm associated with exposure to isocyanates, and developed a National Emphasis Program (NEP) specifically designed for protecting workers from exposure to isocyanates in June 2013. The OSHA Isocyanates NEP was discontinued because it was designed as a limited, temporary enforcement action that expired in May 2016. Each OSHA Area Office was required to conduct only three inspections per year. Despite multiple attempts, DTSC could not gather any further information on program implementation and the number of inspections in the State of California. These inspections targeted all uses of isocyanates, not just SPF. The NEP did not cover sole proprietors or individual consumers. OSHA’s recent Alliance with the American Chemistry Council’s Center for the Polyurethanes Industry to improve awareness of occupational safety laws, training and education around the hazards of diisocyanates affirms the potential harm that workers still face. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 15-29

Comment Summary:

If engineering and administrative controls reduce exposure concerns and the potential for significant and widespread impacts, then DTSC should consider this a factor against prioritizing SPF with MDI.

DTSC Response:

Engineering and administrative controls are not used universally by the applicators of SPF with MDI and they do not represent a permanent reduction in exposure concern or potential for adverse impact. OSHA's established hierarchy of hazard protection in order of preference is: 1) eliminate the hazard; 2) substitute a different chemical; 3) implement engineering controls; 4) implement administrative controls; and 5) use personal protective equipment.⁶ No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments: 15-76, 15-82

Comment Summary:

DTSC overestimated the market share for SPF roofing because the SPF sector is not a single product.

DTSC Response:

DTSC defined the Priority Product as two-component SPF systems with unreacted MDI and performed the market analysis for this group as a whole. The framework regulations clearly anticipate that a responsible entity might manufacture more than one product that meets the definition of any given Priority Product (22 CCR 69503.5(b)(1)(A)). DTSC recognizes that there are numerous formulations and brands of SPF products that produce foams of different densities and for different uses. All formulations have one side that contains isocyanates. Thus, it's appropriate that roofing is not broken out separately as it contains the essential attributes of the Priority Product. No changes were made to the proposed regulation or the supporting documents based on these comments.

⁶ CDC (2015) Workplace Safety & Health Topics, *Hierarchy of Controls*, Centers for Disease Control and Prevention. Available at <https://www.cdc.gov/niosh/topics/hierarchy/>

Comment: 34-3

Comment Summary:

Using SPF systems in homes, schools, offices, and other buildings less regulated than factories, increases the likelihood that workers and occupants will be exposed to unreacted components.

DTSC Response:

DTSC determined the wide availability of SPF systems with unreacted MDI demonstrates the potential for widespread adverse impacts. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comment: 35-2

Comment Summary:

DTSC appropriately considered the factors in the framework regulations to demonstrate the potential for exposure and adverse impacts and correctly names SPF systems as Priority Products.

DTSC Response:

DTSC appreciates the concurrence offered by the comment. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comment: 35-4

Comment Summary:

Cases of consumer illness and injury associated with SPF systems illustrate the potential for significant adverse impacts.

DTSC Response:

DTSC bases its determination of potential significant adverse effects on the health effects associated with exposure to MDI. DTSC appreciates additional case studies of health effects associated with SPF exposure. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments Regarding the Use of Cited Information in the Technical Summary

Comments: 15-2, 15-3, 15-7, 15-39, 15-40, 15-96, 15-99, 15-100, 15-101, 15-102, 15-114, 30-22, 30-69, 30-74, 30-85, 30-8

Comment Summary:

Some references cited in the Technical Summary do not provide enough information or evidence to support DTSC's conclusions regarding health effects or its decision to prioritize SPF.

Response:

DTSC toxicologists reviewed all studies referenced in the comments using the toxicological endpoints specified in Chapter 54 of Title 22 of the California Code of Regulations to determine hazard traits. For this Priority Product, the hazards cited relate to exposure to the Candidate Chemical, MDI. The studies were presented correctly. Furthermore, no single reference provides the basis for the decision to prioritize SPF; the totality of the information about the health effects of MDI and potential for exposure lead DTSC to propose the regulation. The External Scientific Peer Reviewers also concurred with DTSC's conclusions regarding health effects and its decision to prioritize SPF. DTSC made no changes to the proposed regulation or supporting documents in response to these comments.

Comment: 15-113

Comment Summary:

Some references use subjective terms like "unexpected" or "surprising." This indicates a lack of scientific detachment and serves to justify additional research.

DTSC Response:

DTSC used reliable information and considered the quality of information contained in each study as described in 22 CCR 69503.2((b)(1)(C)). The writing style and word choices in the references were not the basis for the listing; rather, the evidence contained therein, was. DTSC does not consider it unusual for a study's conclusion to call for additional research or study. DTSC made no changes to the proposed regulation or supporting documents in response to this comment.

Comment: 15-5

Comment Summary:

DTSC cited no NFPA data showing significant inhalation injuries associated with fighting fires or from thermal decomposition of SPF.

DTSC Response:

The proposed regulation is focused on airborne MDI released during the spraying process and the Priority Product is described in the regulation as the two-component spray foam system. In the Technical Summary as part of the summary of environmental fate, DTSC mentions that the cured foam may release toxic chemicals from thermal degradation such as fire. Because these chemicals, however, are not identified and do not form the basis for the listing, DTSC did not collect NFPA data to characterize significant inhalation injury attributable to fighting fires or thermal decomposition of SPF. DTSC made no changes to the proposed regulation or supporting documents in response to this comment.

Comments: 15-18, 15-62, 15-63, 15-83, 30-75, 30-79

Comment Summary:

National Institute of Occupational Safety and Health (NIOSH) reports and other studies that focus on MDI exposure, fatalities, and monitoring data in other industry sectors, such as auto, mining, and engineered wood products, are not directly associated with the SPF industry and should be removed.

DTSC Response:

The cases cited in the Technical Summary demonstrate the “reasonably foreseeable” potential of isocyanates in spray polyurethane foam (SPF) systems to cause adverse impacts when they become airborne. The cases demonstrate SPF workers’ potential exposure to airborne isocyanates in two-component SPF systems, which are delivered in a similar manner as in the cited cases. DTSC made no changes to the proposed regulation or supporting documents in response to these comments.

Comments: 15-34, 15-35, 30-77, 30-78, 38-2

Comment Summary:

If DTSC uses the Reference Exposure Level (REL) developed by Office of Health Hazard Assessment (OEHHA) to prioritize SPF, the studies it is based upon should be subject to the Reliable Information standard in 22 CCR 69501.1(A)(57)(B). Also, the RELs in air for MDI are not designed for SPF applicators and should not be referenced.

DTSC Response:

DTSC did not use any threshold concentrations, including threshold limit values, permissible exposure limits, or reference exposure levels, for prioritization; rather, DTSC used information about the health effects of MDI and potential for exposure to form the basis for the regulation. DTSC mentions such thresholds in the Technical Summary only to provide context and relevance to reported monitoring values. DTSC made no changes to the proposed regulation or supporting documents in response to these comments.

Comments: 15-129, 15-130

Comment Summary:

The study design for some citations is not appropriate, as specified in the regulations (22 CCR 69501.1(a)(57)(B)).

DTSC Response:

DTSC agrees that a study design, as described in 22 CCR 69501.1(a)(57)(B), must be appropriate and DTSC has determined that each study it relied upon was appropriately designed to address the study hypothesis of the study. DTSC used reliable information and considered the quality of information contained in each study as described in 22 CCR 69503.2((b)(1)(C)). DTSC made no changes to the proposed regulation or supporting documents in response to these comments.

Comment: 16-1

Comment Summary:

Citing Arcury et al., (2014) implies that Latino roofers are not using PPE. The commenter states that DTSC is implying that the “SPF roofing industry is unsafe due to the heritage of our hardworking labor force.”

DTSC Response:

DTSC cites a number of cases to demonstrate that Health and Safety programs do not always adequately protect workers. This failure of protection can be attributed to a variety of reasons, such as accidents or failure to comply – none of which involve the ethnicity or heritage of the workers. That the workers included in the Arcury citation are Latino does not in any way influence DTSC’s concern with over-reliance on Health and Safety programs and personal protective equipment for worker protection. The proposed regulation seeks to better protect all workers, and consumers, by seeking alternatives to MDI. DTSC made no changes to the proposed regulation or supporting documents in response to this comment.

Comment: 30-71

Comment Summary:

DTSC states that not many monitoring studies have been conducted to measure airborne concentrations of MDI during SPF application. Industry has conducted extensive monitoring of SPF applications, both outdoor and indoor. Exposure to MDI from SPF is well-researched and -understood and is used to establish return times after application. Further, a lack of data cannot serve as justification for DTSC's prioritization decision.

DTSC Response:

Although industry conducts monitoring, those data are not widely available and, as a result, there are few citable MDI monitoring studies. Also, data from available studies vary widely due to differences including sampling, MDI recovery techniques, and analytical methods. Nevertheless, monitoring data show that MDI has been detected in the applicators' breathing zones and at measurable levels up to 20 feet from the applicators' breathing zones. In addition, U.S. EPA reports that current test methods underestimate air concentrations. Therefore, based on available studies, MDI's sensitizing nature, the fact that MDI becomes airborne during spraying, the duration of time SPF can be sprayed during a project, and the variation in personal protection usage or compliance, DTSC believes there is clear potential for exposure and potential adverse impacts to some workers and consumers. DTSC made no changes to the proposed regulation or supporting documents in response to this comment.

Comment: 30-83

Comment Summary:

DTSC statements regarding sensitization and asthma are supported by a secondary reference, which should be removed from the record.

DTSC Response:

DTSC is not limited to using only primary data sources as reliable information; secondary sources that meet the definition of reliable information are also acceptable data sources. DTSC made no changes to the proposed regulation or supporting documents in response to this comment.

Comment: 30-84

Comment Summary:

“. . . studies 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.” (sic)

DTSC Response:

DTSC did not use any threshold concentrations for prioritization; rather, DTSC used information about the health effects of MDI and potential for exposure to form the basis for the regulation. Furthermore, it is known that some individuals are more susceptible to sensitization than others, and that MDI levels as low as 1 part per billion (ppb) may be problematic to some, while others can tolerate much higher concentrations and a much longer duration of exposure. DTSC has evidence that MDI does become airborne during SPF application and concludes that there is a reasonably anticipated risk of sensitization as a result. DTSC made no changes to the proposed regulation or supporting documents in response to this comment.

Comment: 30-87

Comment Summary:

DTSC failed to meet prioritization criteria as shown by the claim that “The DTSC ignored a citation provided 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.’ ”

DTSC Response:

DTSC agrees with the comment that allergic contact dermatitis may not be the major health hazard associated with MDI. In the regulation DTSC listed in alphabetical order all the toxicological endpoints associated with exposure to the Candidate Chemical. In the alphabetical regulation list, allergic contact dermatitis is listed first, but that position in the regulation list does not correlate to any order of importance. Allergic contact dermatitis is correctly included for completeness as a part of the basis for prioritization. DTSC made no changes to the proposed regulation or supporting documents in response to this comment.

Comments: 30-82, 30-84

Comment Summary:

DTSC has mischaracterized or misrepresented some information, including OSHA’s National Emphasis Program (NEP) and studies about the respiratory toxicity of MDI.

DTSC Response:

DTSC did not rely on the Occupational Safety and Health Administration’s (OSHA) isocyanates NEP as a justification for listing SPF systems as Priority Products. However, the termination of OSHA’s NEP and a lack of more protective federal action support the need for DTSC’s proposed regulation. Federal OSHA’s recent

announcement⁷ of an Alliance with the American Chemistry Council's Center for the Polyurethanes Industry to improve awareness of occupational safety laws, training and education around the hazards of diisocyanates affirms the potential harm that workers face when working in this sector. No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: 30-89

Comment Summary:

“All of the physicochemical properties listed for MDI should cite values from the European Chemicals Agency (ECHA) registrations.”

DTSC Response:

DTSC cited available physicochemical properties data from authoritative bodies that were current when the Technical Summary was completed. No changes were made to the proposed regulation or supporting documents based on this comment.

⁷ <https://www.osha.gov/dcsp/alliances/acc/acc.html>

Comments Regarding the External Scientific Peer Review

Comments: 38-14, 38-17

Comment Summary:

The role of Dr. Lockey as an independent reviewer is compromised because he received research support from the HTIW Coalition, a group that represents the North American High Temperature Insulation Wool Industry. This industry group produces materials needed to produce fiberglass insulation, which DTSC has identified as an alternative to SPF systems. Also, DTSC included Dr. Lockey's primary sources in the Technical Summary.

DTSC Response:

DTSC is not involved in any part of the ESPR process, including coordinating, reviewing, or selecting reviewers. The ESPR process is mandated in California law (Health & Safety Code §57004). State Water Resources Control Board (SWRCB) coordinates external science peer review (ESPR) on behalf of CalEPA. Until the review is completed, the identities of the reviewers are confidential to all except the ESPR coordinator.

For this ESPR, the SWRCB ESPR coordinator contacted UC Berkeley, who selected qualified and available review candidates⁸. Each candidate submitted a Conflict of Interest (COI) Disclosure form to the coordinator for review along with their Curriculum Vitae, and the ESPR coordinator selected the reviewers. DTSC received the relevant Curriculum Vitae and disclosures for each of the reviewers with their review conclusions at the end of the review. DTSC included all the ESPR information it received as part of the background documents provided with the rulemaking package.

Dr. Lockey's expertise and research focus involves occupational and environmental exposures and adverse human health outcomes. His ongoing research focuses on health effects associated exposure to asbestiform fibers, and other exposures. According to the Bibliographical Sketch provided with the ESPR, Dr. Lockey's research funding from the HTIW Coalition ended December 31, 2015, and involved a study of pulmonary health surveillance of workers at refractory ceramic fiber production facilities. Dr. Lockey completed the ESPR Conflict of Interest form, certifying that he was able to provide a neutral and objective review of DTSC's work product.

DTSC has not promoted any alternatives to the Priority Product. DTSC has no reason to doubt Dr. Lockey's self-certified objectivity. It is to be expected that research professionals will receive research funding from a variety of sources and Dr. Lockey's support from the HTIW Coalition ended before the ESPR request began. DTSC believes Dr. Lockey's extensive experience and research in the field of occupational

⁸ <http://ceparev.berkeley.edu/>

and environmental exposures establishes his credentials to review DTSC's scientific basis for listing SPF with unreacted MDI as a Priority Product. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 38-15

Comment Summary:

Neither Professor Kimber, nor DTSC, disclosed that Professor Kimber is on the Board of Directors of SenzaGen, maker of an in vitro assay for identifying respiratory sensitizers. Professor Kimber's assessment that SPF may cause respiratory sensitization has the potential to increase the market value of SenzaGen.

DTSC Response:

DTSC is not involved in any part of the ESPR process, including coordinating, reviewing, or selecting reviewers. Until the review is completed, the identities of the reviewers are confidential to all except the ESPR coordinator. DTSC does not believe that Professor Kimber's position on the Board of Directors of SenzaGen negates his statements regarding respiratory sensitization of MDI. All the external scientific reviewers, and many sources cited in the Technical Summary, confirmed that MDI is associated with respiratory sensitization. Professor Kimber's observation is consistent with the body of knowledge gathered about the health effects associated with MDI and should not be discounted based on Professor Kimber's association with SenzaGen. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comment: 38-1

Comment Summary:

That Dr. Nemery and Dr. Lockey referred to a "paucity and lack of reliable information" confirms that DTSC did not provide clear and convincing scientific evidence to support the prioritization of SPF.

DTSC Response:

This comment mischaracterizes the conclusions of the peer reviewers. In both cases the reviewers observe that the adverse effects associated with MDI are well known and documented, making the demonstration of potential significant effects unnecessary. In fact, Dr. Lockey stated: "The inadequacy of exposure and health data from workers and consumers who use MDI SPF systems is sufficient justification for adopting SPF systems with MDI as a Priority Product." And Dr. Lockey stated: "I agree that the information that DTSC relied upon to evaluate exposures is sufficient to conclude that there is a potential for exposure to MDI related to the use of SPF products containing these Chemicals of Concern." No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments Regarding Economic Impact

Comments: 19-1, 19-7, 23-1, 23-7, 26-2, 30-47, 30-57, 37-3, 39-1, 39-6

Comment Summary:

The economic impact of the proposed regulation has not been adequately quantified. Prioritizing SPF systems stigmatizes the product, potentially resulting in economic harm to the brand and leading to loss of business.

DTSC Response:

DTSC prepared an economic impact assessment for a non-major regulation and provided all required information in the Economic and Fiscal Impact Statement (EFIS), included as a background document with the rulemaking package. The actual costs and benefits associated with the regulations will depend on future choices made by manufacturers.

DTSC's analysis of potential economic impact relied heavily on information provided by industry. DTSC surveyed SPF systems manufacturers and the American Chemistry Council's Center for the Polyurethanes Industry using information provided by these industry experts to form the basis for the assumptions used to assess the economic impacts. The cost estimates for conducting an Abridged AA or two-stage AA are based on data from manufacturers and industry representatives.

As manufacturers have pointed out, users of the SPF systems are aware that the product contains MDI and that people should follow safety precautions when using it. The information that DTSC has compiled in support of the regulations is established and well known; this action is unlikely to stigmatize any product.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comments: 30-44, 30-48

Comment Summary:

DTSC has not fully estimated the cost of compliance since it is not clear how DTSC will evaluate the AAs and other means of compliance. DTSC also presented a mismatched analysis of costs and benefits by omitting some items on the cost side while including them on the benefits side.

Response:

DTSC estimated the costs associated with the notification and AA steps, which result directly from the Priority Product regulations, as outlined in the framework regulations. DTSC assumes in its costs analysis that manufacturers will comply with those requirements. The framework regulations clearly state that DTSC will review the various AA Reports and determine compliance, deficiency, or disapproval. DTSC has prepared

guidance to help responsible entities complete the AA and will work closely with manufacturers to assist with compliance. Because DTSC cannot know the specific AA details and compliance options for a specific manufacturer at this stage in the process, DTSC relies on general assumptions to estimate the costs associated with the notification and AA steps.

In the Economic and Fiscal Impact Statement DTSC described benefits from the perspective of the goals of the Safer Consumer Products program. Hence, DTSC views increased capacity among consultants to perform AAs as a benefit of the program. While manufacturers who hire such consultants see this as a cost, DTSC assumes that cost is already factored into the compliance costs estimates that industry provided. Listing it again as a cost would be double counting. Furthermore, increased capacity to perform AAs increases the supply of expertise and might drive down the overall costs of compliance. No changes were made to the proposed regulation or supporting documents based on these comments.

Comment: 30-49

Comment Summary:

Reduced worker safety costs cannot be included as a benefit if no evidence is presented that alternatives are safer.

DTSC Response:

The potential benefit of reduced worker safety costs is listed as a *potential* benefit of making SPF products safer.⁹ If, after the AA, a manufacturer asserts that an alternative is safer, DTSC will evaluate the AA to ensure that the manufacturer has provided evidence that the alternative is safer. No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: 30-51

Comment Summary:

Benefits should not include increased employment opportunities; the SCP regulation is not a job creation tool.

DTSC Response:

DTSC clearly states the primary goal of the regulation is to protect public health by requiring SPF systems manufacturers to evaluate ways to make SPF products safer for consumers and workers. The economic impact analysis for rulemaking expressly requires DTSC to evaluate different categories of impacts, including “Creation or

⁹ Economic and Fiscal Impact Statement (STD 399), page 6.

Elimination of Jobs in California.” No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: 30-50

Comment Summary:

The ISOR should not assume that the outcome of an Abridged AA is to initiate research and development or fund challenge grants.

DTSC Response:

Initiating research and development or funding challenge grants are among the minimum regulatory responses that are required for an Abridged AA Report. The framework regulations specify that the proposed regulatory responses applicable to an Abridged AA Report shall include at a minimum the regulatory responses required by 22 CCR 69506.3 (Product Information for Consumers) and 22 CCR 69506.8 (Advancement of Green Chemistry and Green Engineering). No changes were made to the proposed regulation or supporting documents based on this comment.

Comments: 30-3, 30-45, 30-46

Comment Summary:

The economic analysis provided by DTSC anticipates manufacturers will only need to conduct one two-stage AA or an Abridged AA, when there may be several products made by the same manufacturer, each necessitating a separate AA and leading to increased costs, possibly resulting in classification as a major regulation. If manufacturers conduct an Abridged AA, this requires manufacturers to expend financial resources for “green chemistry alternatives,” which are not accounted for in the Economic Impact Statement. The method DTSC used to estimate costs for conducting AAs and producing an AA report is not adequately described. Costs should also include an estimate of the time to become familiar with vaguely defined requirements.

Response:

In the economic analysis DTSC prepared estimates of cost impacts to businesses and individuals affected by the proposed regulation using cost figures provided by industry. The impact estimates assumed that manufacturers will comply with the regulations and submit the Priority Product Notification and AA Reports, and presented the cost impacts as a range of estimates to reflect the range of numbers provided by industry.

DTSC acknowledged in the analysis that the actual costs could be higher or lower depending on a variety of factors, such as the number of alternatives, data availability, and expertise needed. Indeed, costs may also be higher if a manufacturer identifies its products as unique, necessitating individual AAs. It is important to note, however, that DTSC’s concern with SPF containing MDI lies with the side of the system that contains the Chemical of Concern – the A-side. Variations among products in the B-side may not

need separate AAs if the alternatives to the A-side in each case is the same and interacts with the various B-sides in the same way. Manufacturers with multiple product formulations should consider carefully which factors in the AA would both change *and* affect the consideration and selection of alternatives.

DTSC has prepared and posted online an Alternatives Analysis Guide. This Guide presents information about the AA process and provides useful approaches, methods, resources, and tools for AAs. This resource will help stakeholders clarify the requirements and identify the appropriate AA scope for a particular product scenario.

Subsequent compliance activities can vary widely depending on the quality of the AAs and the level and extent of participation and cooperation. To begin estimating the costs associated with different compliance scenarios would be speculative and would measure impacts associated with the framework regulations rather than the Priority Product regulations. No changes were made to the proposed regulation or supporting documents based on these comments.

Comment: 30-56

Comment Summary:

DTSC assumes manufacturers would choose to conduct an Abridged AA, which gives the appearance that DTSC wants an AA for a product that the department has already concluded has no alternative.

DTSC Response:

DTSC has not concluded that no alternatives to SPF with MDI exist. According to an announcement in February 2017, Gaco Western has developed a “safer” isocyanate-free spray foam, which will launch in 2018.¹⁰

DTSC included Abridged AA Reports in its economic analysis because SPF manufacturers and industry representatives indicated that SPF manufacturers were likely to submit Abridged AA Reports in response to the regulatory requirements. The SCP regulations provide some avenues for significantly reducing costs associated with conducting AAs, such as forming consortia to pool data and potentially fund research into alternatives. No changes were made to the proposed regulation or supporting documents based on this comment.

¹⁰ Gaco Western Shatters the Spray Foam Isocyanate Ceiling at SPFA, February 1, 2017, <https://gaco.com/gaco-western-shatters-spray-foam-isocyanate-ceiling-spfa-week/>

Comments: 28-1, 28-3, 36-5, PH4-1

Comment Summary:

The proposed listing ignores the impact on small business and will likely result in the elimination of jobs and businesses in California, and higher energy costs.

DTSC Response:

DTSC prepared an economic impact assessment for a non-major regulation and provided all required information in the Economic and Fiscal Impact Statement (EFIS), included as a background document with the rulemaking package. As part of this EFIS, DTSC considered impacts to small businesses within California and provided qualitative descriptions of possible economic costs and benefits derived by the regulation. The actual costs and benefits associated with the regulations will depend on future choices made by manufacturers. Employees of the California Energy Commission have indicated to DTSC that the contribution of SPF toward achieving California's climate and energy goals is small when compared to other, more significant, actions. No changes were made to the proposed regulation or supporting documents based on these comments.

Comment: PH3-2

Comment Summary:

The listing will reduce the use of SPF by creating uncertainty in the SPF market and raising questions about the regulatory outcome of the listing process.

DTSC Response:

The framework regulations clearly establish the regulatory process that follows the Priority Product listing: responsible entities will submit a Priority Product Notification and those who continue to use SPF in their products will complete some form of an AA. Ultimately, the goal of the Safer Consumer Products program is to encourage manufacturers to develop safer alternatives to Priority Products. DTSC recognizes that change occurs incrementally and with that change, uncertainty in the market may also occur. However, this outcome results from the regulatory framework of the program and is not unique to this regulation. No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: PH7-2

Comment Summary:

This listing will drive members to use less efficient products or drive up prices of the product.

DTSC Response:

DTSC anticipates changes in user behavior may occur if the formulation of the Priority Product changes, for example, after the AA is completed. At this point in time, it is not clear what changes in behavior will result from the Priority Product listing. Depending on the outcome of the AA, costs may increase or decrease, especially if a safer option results in safer working conditions. Predicting the effect on product pricing before an AA has been completed is highly speculative. DTSC has presented no new, previously unknown, information in the listing regulation. No changes were made to the proposed regulation or supporting documents based on this comment.

Comment: 20-3

Comment Summary:

DTSC should withdraw the regulation to avoid negative effects on the industry and California's economic growth.

DTSC Response:

DTSC prepared an economic impact assessment for a non-major regulation and provided all required information in the Economic and Fiscal Impact Statement (EFIS), included as a background document with the rulemaking package. The economic analysis did not demonstrate exclusively negative impacts. The economic analysis estimated both costs and benefits using, in part, data provided by the industry. The actual costs and benefits associated with the regulations will depend on future choices made by manufacturers. No changes were made to the proposed regulation or supporting documents based on this comment.

Comments Regarding Energy Efficiency

Comments: 19-5, 20-1, 23-5, 24-1, 26-1, 29-2, 30-10, 30-11, 30-55, 31-4, 33-6, 37-5, 39-4, PH2-3

Comment Summary:

SPF improves energy efficiency in buildings. Any regulatory requirement that reduces the availability of SPF would have a negative impact on California's ability to meet its energy efficiency and greenhouse gas reduction goals and reduce heating and cooling bills.

DTSC Response:

The proposed regulation does not ban the use of SPF products and will not prevent SPF products from remaining available in the marketplace and contributing to the accomplishment of California's energy efficiency goals. Employees of the California Energy Commission have indicated to DTSC that the contribution of SPF toward achieving California's climate and energy goals is small when compared to other, more significant, actions. Furthermore, the AA process includes consideration of a multitude of factors, including impacts on greenhouse gas emissions and energy efficiency. Finally, it is clear that alternatives to SPF insulation currently exist and isocyanate-free spray foam alternatives are currently being developed, as envisioned when the framework regulations were initially developed. These developments have the potential to support California's energy efficiency goals with a safer product. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 32-3, 34-2, 34-7

Comment Summary:

Many alternative technologies can perform the function of SPF.

DTSC Response:

DTSC acknowledges that alternatives to SPF with MDI currently exist and a new formulation of SPF without MDI is currently being developed. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 35-6, 35-7

Comment Summary:

Listing SPF systems with unreacted MDI as a Priority Product will support innovative research and development of non-isocyanate technologies for use as insulation. Green chemistry labs can help develop non-hazardous alternatives and industry stakeholders could form a consortium to share the cost of development.

DTSC Response:

DTSC agrees that listing SPF systems with unreacted MDI can provide an incentive to manufacturers to explore alternatives to the product and its formulation. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments Regarding Duplication with Existing Law

Comments: 30-39, 30-40, PH4-1

Comment Summary:

The proposed regulation is duplicative of existing laws that provide adequate protection against potential adverse impacts and exposure pathways.

DTSC Response:

DTSC respectfully disagrees that current laws applicable to SPF provide adequate protection against potential exposures and adverse impacts. This is discussed at length in the above section on “Exposure and PPE.” Eliminating the chemical hazard entirely, or substituting a less hazardous chemical, is the most effective means of minimizing potential occupational chemical exposures and is also the primary goal of the SCP regulations. This proposed regulation is an important supplement to current state and federal exposure standards and supports the ongoing effort to protect human health by preventing worker and consumer injuries. No changes were made to the proposed regulation based on these comments.

Comments in Support of the Rulemaking

Comments: 18-1, 21-1, 22-1, 35-1

Comment Summary:

Support listing SPF with unreacted MDI, as these chemicals are known to be toxic to people and the environment.

Comment: 32-2

Comment Summary:

Support the goal of DTSC's Safer Consumer Products (SCP) program to reduce "toxic chemicals in products in favor of safer alternatives."

Comments: 32-1, 35-1, 35-2

Comment Summary:

DTSC's proposal meets SCP guidelines for listing a Priority Product and MDI has the potential to cause significant or widespread adverse health impacts, such as respiratory sensitization and asthma.

Comment: PH8-2

Comment Summary:

Workers and consumers who use SPF systems with MDI are at risk of disease and that "DTSC presented robust scientific evidence" supporting the proposal.

Comment: 35-5

Comment Summary:

Voluntary industry guidelines to reduce worker and consumer exposures to MDI are insufficiently protective.

Comment: PH8-3

Comment Summary:

"DTSC's proposal and the Safer Consumer Products process is a win-win situation for product innovation and safer building insulation products, as well as building energy efficiency, safer and healthier buildings, and the health of the people of California and California communities."

Comment: 35-5

Comment Summary:

Challenges of ensuring use of personal protective equipment (PPE) by workers, the high uncertainties about safe re-entry times, and major risks of serious health effects to SPF users indicate that it's time to invoke the hierarchy of controls for workplace safety and prioritize elimination and substitution.

DTSC Response:

DTSC acknowledges the support offered by these comments. DTSC made no changes to the proposed regulation or supporting documents in response to these comments.

Comments Regarding General Disagreement with the Proposal

Comments: 19-8, 23-8, 30-42, 36-1, 37-1, 37-2, 37-4, 37-6, 37-16, PH7-1

Comment Summary:

Do not list SPF; do not disparage a product that contributes to energy saving and employment in the state. Listing SPF will be a waste of time and resources. The listing is not necessary and will provide no benefit.

DTSC Response:

DTSC has a legislative mandate to protect California's people and environment from the harmful effects of toxic substances. The goals of the SCP program are to reduce toxic chemicals in consumer products, stimulate innovation and the adoption of green chemistry product design, and build consumer confidence about the chemical safety of products they buy for their families and customers.

The overall intent of the Priority Product listing is to move manufacturers to perform Alternatives Analysis. The AA process includes consideration of a multitude of factors, including impacts on greenhouse gas emissions and energy efficiency, so that the contributions that the Priority Product makes toward energy savings can be weighed against other considerations such as worker safety. DTSC does not presume what potential outcome may result from the AA and the manufacturer's decision process, but the purpose of this proposed regulation is to protect workers and consumers and identify safer options.

No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 29-4, 30-1, 30-5, 30-8, 30-18, 30-68

Comment Summary:

Many facets of this proposed listing have not been appropriately or fully considered, including the definition of the Priority Product, misrepresentation of health and environmental data, and incomplete economic analysis.

Response:

DTSC clearly defined the Priority Product, identified the data that form the basis for the demonstration of potential significant adverse impacts, and performed the economic analysis prescribed by the rulemaking process. All of these elements are presented in the ISOR, the Technical Summary, and in many of the responses to comments DTSC received regarding this regulatory proposal. The process established in the regulations, and completed in this rulemaking, is thorough. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 27-4, 27-5, 27-6

Comment Summary:

As an alternative, the spray foam industry should work with OSHA to complete and implement a comprehensive product stewardship program, and educate the public on possible health consequences of spray foam insulation.

DTSC Response:

DTSC encourages the industry to continue to strengthen safety practices. DTSC evaluated several alternative approaches to meeting programmatic goals, including an industry proposal to undertake voluntary actions to educate SPF applicators about workplace safety regulations, SPF product stewardship, and general health and safety. After discussing this proposal with industry representatives, DTSC rejected this option because it does not advance the goals of the SCP regulations in general, and of this proposed regulation. Additionally, voluntary initiatives are not enforceable should they fail to meet their goals. DTSC looks forward to working with SPF manufacturers in the implementation of measures that increase the safety of workers and consumers using SPF systems, in accordance with the SCP regulations. No changes were made to the proposed regulation or supporting documents based on these comments.

Comments: 30-43, PH1-6

Comment Summary:

Listing SPF systems is a speculative exercise because there are no known alternatives to SPF with MDI.

DTSC Response:

DTSC cannot predict the outcome of the Alternatives Analyses, and in some instances, there might not be an alternative. One intent of the SCP regulations is to spur innovation. DTSC is aware that isocyanate-free spray foam alternatives are currently being developed and are expected to be available soon, as envisioned when the framework regulations were initially developed. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comments: 30-52, 30-53, 30-54

Comment Summary:

DTSC did not select the least burdensome alternative to adopting the regulations, namely, implementing an industry stewardship program.

DTSC Response:

The regulatory process does not require DTSC to select a least burdensome alternative. DTSC acknowledges that trained professionals using proper PPE and implementing

good safety practices are less likely to be exposed to potentially harmful levels of MDI during application of SPF. However, although the SPF industry considers administrative controls and PPE to be sufficiently protective, the National Institute for Occupational Safety and Health (NIOSH) considers these two methods to be the least desirable approaches to controlling potential occupational chemical exposures. Of the five levels of protection within the hierarchy of exposure control, administrative controls and PPE are the least favorable because they leave the original hazard present in the workplace and exposure can readily occur if the methods fail or are used improperly. DTSC prefers to implement the alternative that may result in eliminating the hazard. DTSC's Safer Consumer Products program is designed to achieve that highest level of protection. No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment: 31-5

Comment Summary:

The DTSC proposal duplicates existing requirements and will result in a financial burden.

Response:

The SCP requirements are a unique approach to regulating chemicals in products. DTSC's proposal does not duplicate any existing regulatory requirements. As described in the ISOR, there are no state or federal regulations that require manufacturers to determine if a chemical is necessary or if a safer alternative exists, and to take steps to protect human health and the environment. Much of the data analyses outlined in an AA are similar to product development and improvement activities, and may already be performed by manufacturers, thereby lowering the cost of the AA. In addition, the AA process may result in actions that may reduce financial burdens, depending on the AA outcomes. No changes were made to the proposed regulation or the supporting documents based on this comment.

Comments Requesting an Extension of the Comment Period

Comments: Letters 1-14

Comment Summary:

The commenters requested a 60-day extension to the comment period.

DTSC Response:

DTSC extended the initial comment period from 53 days to 75 days so that prospective commenters would have sufficient time to review the documents supporting the proposal.

Comments Regarding the California Environmental Quality Act (CEQA)

Comment: 17-1

Comment Summary:

The draft CEQA Notice of Exemption (NOE) should be uploaded to the CalSAFER website.

DTSC Response:

DTSC added the draft CEQA NOE as a supporting document on the comment page of the CalSAFER website. DTSC made no changes to the proposed regulation or supporting documents in response to this comment.

Comments: 30-65, 30-66, 30-67

Comment Summary:

It is too early in the process to know whether listing SPF systems with unreacted MDI as a Priority Product will result in any environmental effects. DTSC should not issue a Notice of Exemption (NOE) without identifying and evaluating the environmental effects of alternatives.

DTSC Response:

The proposed regulation lists a Priority Product, which in turn triggers the requirements to notify DTSC and perform an Alternatives Analysis to identify safer alternatives for the listed Priority Product. If the outcome of the Alternative Analysis does not reveal safer alternatives, the framework regulations provide a variety of regulatory responses to address the impacts associated with the Priority Product. DTSC determined the listing activity would not result in significant environmental effect since the regulations reduce the likelihood of adverse environmental and health impacts associated with the Priority Product. DTSC made no changes to the proposed regulation or supporting documents in response to these comments.

Comments Regarding the Safer Consumer Products Framework Regulations

Comment: 30-90

Comment Summary:

DTSC's prioritization scheme and conclusions appear to arise from an "arbitrary and capricious approach lacking an objective, scientific systematic process."

Comment: 38-7

Comment Summary:

DTSC's prioritization process discriminates against small businesses, violates Article 5 of the APA, and violates due process under Article 1 (sections 3 and 7) of the California Constitution.

DTSC Response:

These comments do not relate to the proposed rule and are commenting on the process DTSC uses to prioritize product-chemical combinations for listing as Priority Products. That process was established through a rulemaking process, which included public comment, and was completed in August of 2013. DTSC refers to this process as its Framework Regulations.¹¹ Please refer to the July 2012 Response to Comments document, available on DTSC's website, for DTSC's responses to similar comments received during that rulemaking process.¹² No changes were made to the proposed regulation or supporting documents based on these comments.

¹¹ 22 CCR 69501 *et seq.*

¹² <http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/Response-To-Comments-July-2012.pdf>

Comments Regarding Regulatory Responses

Comments: 30-58, 30-59, 30-60, 30-61, 30-62, 30-63, 30-64

Comment Summary:

DTSC's Regulatory Responses may constitute a violation of the federal Commerce Clause, extraterritorial regulation, or place an undue burden on interstate commerce because some of the manufacturers that may be affected by the proposed regulations are headquartered outside of California. Also, Regulatory Responses that involve challenge grants may represent an "unconstitutional taking under the Fifth Amendment."

DTSC Response:

DTSC cannot evaluate the potential for a regulatory response to violate any federal law because DTSC has not proposed a regulatory response at this time. Regulatory responses, if any, will be identified after the completion of an AA Report or Abridged AA Report, and will be determined on a case-by-case basis with individual manufacturers. As a result, comments on potential regulatory responses are not within the scope of this proposed regulation. The proposed regulation adds SPF containing MDI as a Priority Product to the Priority Products List. Following the adoption of this regulation, manufacturers are required to submit a notification and determine whether they will conduct an Alternatives Analysis (AA) or take other action. DTSC cannot predetermine the actions a manufacturer will take among the many options available to comply with the applicable requirements. No changes were made to the proposed regulation or supporting documents based on these comments.

Comments Regarding the Obsolete Priority Product Profile

Comments: 15-1, 15-7, 15-13, 15-16, 15-19, 15-20, 15-22, 15-24, 15-27, 15-28, 15-31, 15-46, 15-47, 15-51, 15-53, 15-64, 15-65, 15-84, 15-85, 15-88, 15-98, 15-115, 15-116, 15-118, 15-119, 15-120, 15-121, 15-122, 15-123, 15-124, 15-127, 15-128, 15-133, 15-134, 15-135, 15-136, 15-137, 15-138, 15-139, 15-140, and 15-141

Comment Summary:

These comments were first provided to DTSC November 11, 2015, and refer to statements or citations contained solely in the Revised Priority Product Profile, dated September 2014.

DTSC Response:

DTSC developed the Priority Product Profile during the pre-rulemaking process. After gathering additional information and conducting additional research, the profile was revised as the *Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product* (referred to as the Technical Summary) revised in February 2017. The Technical Summary underwent peer review and formed the basis for the proposed regulation. The Technical Summary supersedes the Priority Product Profile referred to by the commenter. These comments refer to statements or citations that appeared only in the obsolete Priority Product Profile and that either are not included in the current Technical Summary or addressed by the current Technical Summary. No changes were made to the proposed regulation or supporting documents based on these comments.