INITIAL STATEMENT OF REASONS
March 2017

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

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I. SUMMARY OF PROPOSED ACTIONS AND REGULATORY PROGRAM ACTIVITIES AFFECTED

The Department of Toxic Substances Control (DTSC) proposes to amend section 69511 and add section 69511.2 to Article 11,[1] Chapter 55, Division 4.5 of Title 22, of the California Code of Regulations (Safer Consumer Products (SCP) regulations) to add spray polyurethane foam (SPF) systems containing unreacted methylene diphenyl diisocyanates (MDI) as a Priority Product to the Priority Products List.

Pursuant to section 69503.2(b), DTSC may identify and list as a Priority Product one or more product-chemical combinations that it determines to be of high priority. DTSC's decision to identify and list a product-chemical combination is based on an evaluation of potential exposures and adverse impacts. DTSC has identified SPF systems containing unreacted MDI as a Priority Product. These systems contain liquid chemical mixtures, including unreacted MDI, in two separate containers that are sold or distributed together. Side A contains unreacted MDI, while Side B contains a mixture of polyols and other ingredients that may include catalysts, blowing agents, flame retardants, and surfactants. When the chemical mixtures are combined during spraying, they react to form polyurethane foam used for insulation, roofing, or sealing and filling voids and gaps. Unreacted MDI has been detected in aerosols, vapors, and mists generated while spraying SPF. Inhalation and dermal exposure to unreacted MDI is associated with adverse health effects including asthma and allergic sensitization. People who have become sensitized to isocyanates may also experience life-threatening asthma attacks when subsequently exposed to extremely low levels of isocyanates. The use of SPF systems for insulation and roofing are an effective means to reduce overall energy consumption for heating and cooling buildings. The wide use of this product creates potential for exposures to unreacted MDI by workers and consumers.

DTSC is required to establish and update the Priority Products List through rulemaking under the Administrative Procedures Act.

II. DETAILED STATEMENT OF THE SPECIFIC PURPOSE AND RATIONALE

A. Statutory Intent and Requirements

In April 2007, California's Secretary for Environmental Protection launched the California Green Chemistry Initiative, a six-part initiative to develop policy options to implement a

[1] *DTSC conducted separate rulemaking to list and identify children's foam-padded sleeping products containing tris(1,3-dichloro-2-propyl) phosphate (TDCPP) or tris(2-chloroethyl) phosphate (TCEP) as a Priority Product and adopt Article 11. This rulemaking was noticed but is not effective because it has not been approved by Office of Administrative Law and filed with the Secretary of State.*

green chemistry program and reduce public and environmental exposures to toxic chemicals through improved knowledge about and regulation of chemicals. In 2008, Assembly Bill 1879 (Chapter 559, Statutes of 2008) was signed into law to implement a key recommendation of the California Green Chemistry Initiative Final Report: accelerate the quest for safer consumer products. These statutory mandates are outlined in Health and Safety Code sections 25252 and 25253.

Specifically, Health and Safety Code section 25252 requires DTSC to establish a process to identify and prioritize chemicals or chemical ingredients in consumer products that may be considered as being Chemicals of Concern. This process is required to include consideration of the following factors:

- the volume of a chemical in commerce in California;
- the potential for exposure to a chemical in a consumer product; and
- potential effects on sensitive subpopulations, including infants and children.

Health and Safety Code section 25252 also requires DTSC to develop criteria by which chemicals and their alternatives may be evaluated. At a minimum, the criteria must include hazard traits, physicochemical characteristics, and toxicological endpoints identified by the California Office of Health Hazard Assessment (OEHHA) in regulations set forth in Chapter 54, Division 4.5 of Title 22, of the California Code of Regulations adopted pursuant to Health and Safety Code section 25256.1. DTSC is also required to reference and use, to the extent feasible, available information from other nations, governments, and authoritative bodies that have undertaken similar chemical prioritization processes.

Health and Safety Code section 25253 requires the establishment of a process to evaluate availability of potential alternatives to the use of Chemical(s) of Concern in a Priority Product, and potential hazards posed by those alternatives, through use of lifecycle assessment tools that take a range of factors into consideration. Health and Safety Code section 25253 also authorizes DTSC to implement a range of Regulatory Responses following completion of an evaluation and comparison of the Priority Product and alternatives by the manufacturer through an Alternatives Analysis (AA).

B. Safer Consumer Products Regulations

1. Overview

The SCP regulations (Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations, commencing with section 69501) were adopted in October 2013 to meet the statutory requirements outlined in Health and Safety Code sections 25252 and 25253. The

regulations outline a science-based process for evaluating Chemicals of Concern in consumer products and safer alternatives by:

- establishing a list of Candidate Chemicals and specifying criteria by which these may be designated a Chemical of Concern;
- establishing a process to identify and prioritize product and Candidate Chemical combinations that may be listed as Priority Products;
- requiring manufacturers to notify DTSC when their product is listed as a Priority Product;
- requiring manufacturers of a Priority Product to perform an Alternatives Analysis (AA) to determine how best to reduce exposures to or the level of adverse public health and environmental impacts posed by the Chemical(s) of Concern in the product;
- requiring DTSC to identify and require implementation of Regulatory Responses following the completion of an AA; and
- creating a process for persons to petition DTSC to add or remove chemicals from the Candidate Chemicals list, add or remove Candidate Chemicals lists in their entirety, or to add or remove a product-chemical combination from the Priority Products List.

2. *Initial Proposed Priority Products List*

The SCP regulations required DTSC to propose an initial list of Priority Products within 180 days from the effective date of the regulations. DTSC was required to consider products only if the Candidate Chemicals that were the basis for listing the products were included in one or more authoritative lists in sections 69502.2(a)(1) and (a)(2). As a result, each Candidate Chemical identified as the basis for listing each of the initial Priority Products appears in one or more authoritative lists based on hazard traits [section 69502.2(a)(1)] and in one or more authoritative lists based on potential exposure concerns [section 69502.2(a)(2)].

DTSC identified specific product-chemical combinations for the initial Priority Products List based on an evaluation of available scientific literature, analysis of known hazard traits of the Candidate Chemicals, and consideration of the potential for exposure to the chemicals in the product. DTSC also considered potential adverse impacts posed by the Candidate Chemicals in the product due to potential exposures during the life cycle of the product and the scope of other regulatory programs under which products and/or their Candidate Chemicals are regulated.

DTSC selected the following product-chemical combinations for the initial Priority Products List:

- Children's foam-padded sleeping products containing tris(1,3-dichloro-2-propyl) phosphate (TDCPP) or tris(2-chloroethyl) phosphate (TCEP);
- SPF systems containing methylene diphenyl diisocyanates; and
- Paint and varnish strippers containing methylene chloride.

DTSC published the initial Priority Products List on March 13, 2014, and held public workshops throughout California to solicit stakeholder input. However, to formally identify and list a Priority Product on the Priority Products List, DTSC is required to establish and update the Priority Products List through rulemaking under the Administrative Procedure Act, as specified in Government Code, commencing in section 11340. DTSC is conducting this rulemaking to adopt SPF systems with unreacted MDI in regulation as a Priority Product.[2]

3. *Prioritization Criteria for Listing a Priority Product*

DTSC is required to use the identification and prioritization criteria and process specified in sections 69503.2, 69503.3 and 69503.5 to identify and add a Priority Product to the Priority Products List.

Section 69503.2 requires that any product-chemical combination listed as a Priority Product meet both key prioritization criteria:

- there must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
- there must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

Section 69503.2 is important because it ensures that DTSC is focused on product-chemical combinations that create the potential to expose people or the environment to the Candidate Chemical(s) and the potential for those exposures to contribute to or cause significant or widespread adverse impacts.

The first key prioritization principle requires DTSC to evaluate the potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product by considering routes of exposure to the product and the Candidate Chemical(s) in the product throughout its full life cycle. This evaluation takes into account available information regarding one or more exposure scenarios and an evaluation

[2] *DTSC conducted a separate rulemaking to list and identify children's foam-padded sleeping products containing tris(1,3-dichloro-2-propyl) phosphate (TDCPP) or tris(2-chloroethyl) phosphate (TCEP) as a Priority Product and adopt Article 11. This rulemaking was noticed but is not effective because it has not been approved by Office of Administrative Law and filed with the Secretary of State.*

of the extent and quality of the relevant available information and includes consideration of one or more of the exposure potential factors listed in section 69503.3(b).

The second key prioritization principle requires DTSC to evaluate whether one or more exposures to a Candidate Chemical in the product have a potential to contribute to or cause significant or widespread adverse public health and/or environmental impacts. Evaluating the potential for significant adverse impacts may include consideration of the Candidate Chemical's toxicity, and impacts on sensitive subpopulations or sensitive environmental receptors. Similarly, the evaluation of the potential for widespread adverse impacts could include consideration of the Candidate Chemical's mobility in different types of environmental media or how widely products containing that chemical are sold or used.

In the context of the SCP regulations, the ability of a chemical to cause an adverse impact depends on the hazard trait(s) of that chemical. The potential for an exposure to that chemical to result in an adverse impact depends on particular exposure factors, such as the route or pathway of exposure under evaluation. The term "potential" is a critical term because the regulations incorporate not only experienced harm but also address the possibility that a chemical could contribute to or cause harm. Section 69501.1(a)(51)(A) defines "potential" as "the phenomenon described is reasonably foreseeable based on reliable information." "Reasonably foreseeable" is a term of art in law that means a reasonable person would be able to predict or expect the ultimately harmful results. This ensures that assessment of adverse impacts is based on both reasonable grounds and evidence. Another criterion for the determination of "potential" is that consideration must be based on reliable scientific information, which is defined in section 69501.1 of the SCP regulations to mean scientific studies or scientific information.

Section 69503.3 describes the factors DTSC is required to consider in its evaluation of adverse impacts and exposure to the Candidate Chemical(s) in the product. DTSC's evaluation must include consideration of one or more adverse impact factors listed in section 69503.3(a) and one or more exposure factors listed in section 69503.3(b). Following this evaluation, DTSC uses procedures specified in section 69503.5 to identify and list product-chemical combinations as Priority Products.

4. Requirement to Conduct Alternatives Analysis

Following the adoption of a Priority Product in regulation, manufacturers are required to submit a Priority Product Notification and determine whether they will conduct an AA. An AA is a systematic process for evaluating the life cycle impacts of a Priority Product and any alternatives considered. In lieu of submitting an AA Report, a manufacturer could also remove the Chemical of Concern from their Priority Product, replace it with a safer chemical, or stop selling the product in California. Section 69505.1(a) and sections

69505.4(b), (c) and (d) identify the options a manufacturer has to comply with SCP requirements in lieu of conducting an AA. The duty to comply with the regulation falls first to the manufacturer. If a manufacturer fails to submit a Priority Product Notification, this responsibility shifts to the importer of the product, if applicable, and then to the retailers or assemblers of the product. Once a manufacturer has failed to comply with the regulation and DTSC provides notice of this noncompliance, the requirements for importers, retailers, or assemblers, as applicable, call for importers to cease placement of the product into the stream of commerce in California, and for retailers and assemblers to cease ordering the product.

The AA is a two-stage process that takes into account many facets of product manufacturing, including process engineering, environmental management, financial analysis, and research and development. In the first stage of the AA process, manufacturers are required to identify the goal, scope, legal, functional, and performance requirements of the Priority Product and the Chemical of Concern, and use this information to identify an array of alternatives to consider. When the first stage is completed, the manufacturer documents the findings in a Preliminary AA Report and submits this report to DTSC. During the second stage of the AA, the manufacturer compares the Priority Product with possible alternatives using a more in-depth analysis and considers additional factors, including life cycle and economic impacts. This information is then submitted to DTSC in the Final AA Report.

If, after completing the first five steps of the first stage of the AA, a manufacturer determines there are no functionally acceptable or technically feasible alternatives to the use of the Chemical of Concern in the Priority Product, they may submit an Abridged AA Report in lieu of submitting the Preliminary and Final AA Reports required by the two-stage process. The Abridged AA process requires the manufacturer to document their screening of potential alternatives. Because the Abridged AA process allows for the continued sales and use of the Priority Product, the Abridged AA Reports must include an implementation plan to carry out the following Regulatory Responses, which require:

- providing product safety information to consumers including information on chemical hazards, safe handling and disposal procedures, and other information needed to protect public health or the environment; and
- advancing green chemistry and green engineering principles, including initiating research and development projects or funding challenge grants to design safer alternatives or to improve performance, lower cost, or increase market penetration of existing safer alternatives.

Following submission of an Abridged AA Report or Final AA Report, DTSC shall post the report on its website and provide the public with an opportunity to submit comments. DTSC

is required to review the public comments and may require the manufacturer to address all substantive comments before initiating departmental review. DTSC must evaluate each report on its own merits, taking into consideration unique conclusions and proposals, and ensure that the responsible entity adequately supports claims that no alternatives exist. Because the reports and proposed Regulatory Responses address specific business situations, DTSC cannot predetermine the actions that manufacturers would need to take, either individually or collectively, to meet the goals of protecting people and the environment and advancing green chemistry or green engineering principles. Despite uncertainty surrounding individual AA Reports, DTSC's collective response to these submissions will maximize the use of alternatives of least concern industry-wide and give preference to Regulatory Responses that provide the greatest level of inherent protection to people and the environment.

C. Rationale for Proposing Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product

This section describes the Candidate Chemical(s) and the product that comprise the product-chemical combination, and DTSC's rationale for proposing to list this Priority Product. This section also discusses products that are not included in the product-chemical description and describes the responsible entities impacted by this proposed regulation.

The information presented in this section was taken from the peer-reviewed report titled: "Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product." This report is one of the documents relied on for this rulemaking proposal.

1. Description of Unreacted Methylene Diphenyl Diisocyanates

DTSC identified the following Candidate Chemicals as the bases for proposing to list SPF systems as a Priority Product:

- 4,4′-methylene diphenyl diisocyanate (4,4′- MDI), Chemical Abstract Service Reference Number (CAS RN): 101-68-8, and
- Generic methylene diphenyl diisocyanate (generic MDI) mixed isomers, CAS RN: 26447-40-5.[3]

[3] *A list of synonyms and trade names for MDI can be found in the "Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product" document (DTSC, 2016).*

These chemicals belong to a group of chemicals called isocyanates. An isocyanate is any chemical that contains in its structure at least one isocyanate group (i.e., –N=C=O). A chemical containing two such isocyanate groups is referred to as a diisocyanate. The term "unreacted MDI" used throughout this document refers to MDI monomers and oligomers that are typically present in technical-grade MDI mixtures used in SPF systems. The purpose of using this term in the product-chemical description is to differentiate airborne unreacted MDI generated during spraying from polymerized MDI in cured SPF products. Polymerized MDI in finished SPF is not included in this Priority Product listing.
Consistent with section 69503.6(a), DTSC identified 4,4′- MDI and generic MDI as the Candidate Chemicals because these chemicals are included on both of the following types of authoritative lists in section 69502.2(a):

- hazard traits lists:
    - Classified by the European Union as a respiratory sensitizer Category 1 in Annex VI to Regulation (EC) 1272/2008 [section 69502.2(a)(1)(I)]; and
    - Identified as a Toxic Air Contaminant under sections 93000 and 93001 of title 17 of the California Code of Regulations [section 69502.2(a)(2)(C)]; and
- exposure concerns list:
    - Identified with non-cancer endpoints and listed with an inhalation or oral Reference Exposure Level by OEHHA under Health and Safety Code section 44360(b)(2) [section 69502.2(a)(2)(E)].

Exposure to unreacted MDI is associated with the following hazard traits and toxicological endpoints, respectively:

- dermatotoxicity, immunotoxicity, and respiratory toxicity, and
- asthma, respiratory irritation, extrinsic allergic alveolitis or hypersensitivity pneumonitis, interstitial and peribronchiolar fibrosis, allergic sensitization, dermal sensitization, and allergic contact dermatitis.

As required by the SCP regulations, a Candidate Chemical identified as the basis for a product being listed as a Priority Product is then designated the Chemical of Concern for that product. For clarity and consistency, the term "Chemical of Concern" will be used throughout the remainder of Section E.

2. *Description of Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates*

DTSC proposes to list SPF systems containing unreacted MDI as a Priority Product. SPF systems containing unreacted MDI are used to apply insulation, roofing, or sealing and

filling voids and gaps in both open and confined spaces. SPF systems are composed of two separate containers of chemical mixtures that are referred to as “sides” or “components” by the SPF industry.[4] The containers, or sides, are sold or distributed together, with Side A containing unreacted MDI and Side B containing polyols and other chemicals such as catalysts, flame retardants, and blowing agents. The chemicals in the two sides react to form polyurethane foam after they are mixed during application of SPF. The chemical mixtures used in SPF systems can be modified to produce a variety of foam types, including open-cell and closed-cell, which are used for different purposes (Table 1). This Priority Product includes high-pressure and low-pressure SPF systems.

Table 1. Overview of SPF Systems.[5]

Information on the Various Types of Spray Polyurethane Foam Products		
	Two-Component High-Pressure Systems	***Two-Component Low-Pressure Systems***
Uses	• Larger insulation applications • Air sealant in hybrid insulation • Installation with fiberglass or other insulation materials • Roofing applications	• Air sealant • Adhesive • Smaller insulation applications • Weatherization activities
Applicator	• Professional installer	• Professional installer • Weatherization worker • Available for do-it-yourself applicators, but the same precautions should be taken as with professional-use. DIY applicators are often unaware of inhalation and dermal hazards and may not have adequate knowledge, training and experience to wear adequate personal protective equipment.
Application Process	Sides A and B are pumped through heated hoses from supply tanks into a nozzle where the two components react and are spray applied at elevated temperatures (>150°F) and pressure (1200 psi).	Sides A and B combined at application site and sprayed on as a stream or bead. After the foam is applied, has expanded, and has cured, it may then be trimmed or cut, if needed.
Container Size	55 gallon drum containers	Typically three to five gallons per container from the system house, but can be purchased in larger containers over the internet or in some retail markets.

[4] *For purposes of this regulation, DTSC uses the term “side” or “sides” rather than the term “component” to describe the containerized chemical mixtures because “component” is a defined term in the SCP regulations.*

[5] *Information in this table was excerpted from the US EPA publication: https://www.epa.gov/sites/production/files/2015-08/documents/spf_product_types.pdf*

Information on the Various Types of Spray Polyurethane Foam Products		
	Two-Component High-Pressure Systems	***Two-Component Low-Pressure Systems***
SPF Types	• Open-Cell (low density, 1/2 lb.[6]) • Closed-Cell (medium density, 2 lb.) • Closed-Cell (high density, 3 lb.)	
Chemical Composition	SPF products contain approximately 50 percent Side A and 50 percent Side B. Side A contains very reactive chemicals known as isocyanates. Side B contains a polyol, which reacts with isocyanates to make polyurethane, and a mixture of other chemicals, including catalysts (which help the reaction to occur), flame retardants, blowing agents and surfactants. This chemical reaction generates heat.	
Chemical Exposure Potential	***Chemical exposures may occur***: • During application • After application • During fires	***Through***: • Aerosols • Vapors • Dust that may contain unreacted chemicals
Hazards	• Sensitization • Asthma • Lung damage • Other respiratory and breathing problems • Skin and eye irritation	

The chemical sides in high-pressure SPF systems are distributed in unpressurized drums and totes, which are preheated prior to spraying and pressurized to about 1,200 pounds per square inch (psi) during mixing and spraying. The chemical sides in low-pressure systems are distributed in pressurized containers, which are not heated and are operated under lower pressures than high-pressure systems. Due to the cost of the application equipment, high-pressure SPF systems are typically used by commercial SPF application businesses. By contrast, low-pressure systems are commonly used by sole proprietors and by consumers undertaking “do-it-yourself” projects. Low-pressure systems, including home-use kits, are widely available in California at home improvement stores and through the internet.[7]

The key defining elements of SPF systems that are the subject of this proposed regulation are: 1) the two sides are sold or distributed together; 2) the two sides are in separate containers until they are mixed during application; and 3) one side is composed of unreacted MDI. It is important to note that the hardware used in the SPF delivery system, such as the air compressors, tanks, hoses, spray foam guns, or nozzles, is not included in

[6] *The measurements included in this section refer to the average weight of a cubic foot of fully cured foam.*

[7] *Scientific and technical references supporting this section are included in the “Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product” document (DTSC, 2016).*

DTSC's proposed product-chemical description. These items may be sold or distributed along with the two separate chemical sides or may be offered for sale separately.

3. *Products not Included in the Product-Chemical Description*

Following publication of the initial Priority Products List in March 2014 and during subsequent public workshops held throughout California, stakeholders expressed concern about specific products that would be subject to this rulemaking. To address stakeholders' concerns, the following list includes examples of products that are not included in the product-chemical description and are not subject to this proposed regulation:

- *One-component polyurethane foam materials sold in cans*.
  This product is not included in the product-chemical description because the chemicals, including unreacted MDI, are pre-mixed in the container 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.

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

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

4. *Responsible Entities with the Principal Duty to Comply with the Safer Consumer Products Regulations*

Per section 69501.2, manufacturers have the principal duty to comply with requirements applicable to a responsible entity. Typically, SPF systems manufacturers, also known as "systems houses" by the industry, purchase chemicals from chemical manufacturers; formulate and package the liquid chemical mixtures as "Side A" and "Side B"; and then sell or distribute the sides together as an "SPF system." These manufacturers will have the principle duty to submit a Priority Product Notification and prepare an AA. In lieu of preparing an AA, manufacturers may notify DTSC that they intend to remove or replace the

Chemical of Concern from the Priority Product or remove the Priority Product from the California marketplace.

If manufacturers do not comply, the duty to comply falls to importers, if any, and then to retailers or assemblers. These entities are required to comply with the requirements applicable to a responsible entity only if the manufacturer has failed to comply and DTSC provides notice of such non-compliance by posting the information on the Failure to Comply List on the SCP website. Compliance by importers, retailers, and assemblers does not involve the AA process and seeks to remove the product from the stream of commerce in California. End-users, such as contractors or consumers, are not responsible entities and do not have a duty to comply with the SCP regulatory requirements.

5. *Rationale for Listing Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyantes as a Priority Product*

DTSC proposes to adopt SPF systems containing unreacted MDI as a Priority Product because this product-chemical combination meets the criteria in section 69503.2(a), which requires:

- there must be potential public and/or aquatic, avian, or terrestrial animal, or plant organism exposure to the Candidate Chemical(s) in the product; and
- there must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

Following an extensive review of the scientific literature and analysis of the known hazard traits of unreacted MDI, DTSC concluded that 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. These exposures could potentially contribute to or cause significant adverse impacts. Each prioritization criterion is discussed below.

Potential for public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the Priority Product

In evaluating the potential for exposures to the Candidate Chemical(s), DTSC considers the factors set out in section 69503.3(b)(1) through (4) that relate to the market presence of the product, household and workplace presence of the product, and the potential for exposures during the product's life cycle. SPF systems with unreacted MDI are widely available throughout the California marketplace and the use of SPF is rapidly expanding due to energy efficiency requirements. In 2015, the SPF industry reported between 460 and 490 million pounds of SPF were used for roofing and insulation in the U.S. and Canada.

Additionally, demand for SPF for residential construction and home renovation grew about 15% per year from 2013 to 2015. During normal use of SPF systems, materials containing unreacted MDI, including vapors, aerosols, dusts, and respirable particles, become airborne. Inhalation of airborne unreacted MDI is a route of exposure during and soon after use of either high- or low-pressure SPF systems.

Studies – including some from the SPF industry – illustrate that workers and bystanders can be exposed to unreacted MDI during spraying, especially if they do not use adequate personal protective equipment (PPE). During 13 separate indoor applications using high-pressure SPF systems, unreacted MDI was detected in the applicators' breathing zones at concentrations ranging from 12 to 570 $\mu g/m^3$. Other studies detected measurable levels of airborne unreacted MDI up to 20 feet from the applicators' breathing zones for a considerable amount of time after spraying. A recent review of European and US workplace monitoring studies found that airborne unreacted MDI concentrations ranged from 0.1 to 1,320 $\mu g/m^3$. In some of the studies, concentrations exceeded 51 $\mu g/m^3$, which is both the Threshold Limit Value (an 8-hour time weighted average) set by the American Conference of Governmental Industrial Hygienists and the Permissible Exposure Limit (PEL) of the California Department of Industrial Relations' Division of Occupational Safety and Health (Cal/OSHA). In other studies, unreacted MDI exceeded the federal Occupational Safety and Health Administration's (OSHA) PEL (ceiling) of 200 $\mu g/m^3$.

Workers often apply SPF in confined spaces for hours at a time. Regardless of the level of ventilation, SPF aerosols and particles containing unreacted MDI can still be present in workers' breathing zone during the entire work shift. In addition to exposure during spraying, workers may also be exposed to unreacted MDI through dermal contact during handling activities and accidental spills or leaks and during cleaning and maintenance of the application equipment.

Consumers can also be exposed to unreacted MDI by inhalation or dermal contact during and soon after SPF applications. The wide availability of SPF products coupled with their expanding use clearly demonstrates the potential for exposure to unreacted MDI by workers and consumers.

Potential for one or more exposures to the Candidate Chemical to contribute to or cause significant or widespread adverse impacts

DTSC conducted an extensive literature review on the hazard traits and toxicological endpoints associated with exposure to unreacted MDI and the potential for exposure to unreacted MDI through use of SPF products to contribute to or cause significant or widespread adverse impacts. The factors considered in this evaluation are outlined in

section 69503.3(a)(1)(A) through (G) and relate to the chemical's hazard traits or environmental or toxicological endpoints, toxicity profile, physical properties and mobility in the environment.

Isocyanates are low molecular weight chemicals that can trigger an immune response. These small molecules known as haptens bind with larger proteins such as albumin or glutathione and may elicit an immune response known as respiratory sensitization. Respiratory sensitization can elicit asthma in subsequent exposures to isocyanates from any source, even when concentrations in air are very low (< 1ppb). Therefore, it is generally accepted by the scientific community that isocyanates, including unreacted MDI, are asthmagens and are associated with work-related asthma.

Work-related asthma is defined by the California Department of Public Health as asthma that is caused or aggravated by conditions or substances in the workplace. In order to qualify as work-related asthma, the asthma needs to be diagnosed by a physician and shown to have started after the possible workplace exposure began. 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. Given recent growth in the demand for SPF for residential construction and home renovation, it would be reasonable to assume that the number of isocyanate-related occupational illnesses or injuries could also increase.

In addition to respiratory sensitization, scientific evidence demonstrates that exposure to unreacted MDI in the workplace can cause dermatotoxicity, immunotoxicity, and respiratory toxicity. Fatalities from exposure to unreacted MDI have been documented for workers using spray polyurethane paints. Although those affected workers were applying polyurethane paint and not polyurethane foam, their deaths were caused by inhalation of unreacted MDI from the spray polyurethane product. This common exposure pathway illustrates the severity of potential adverse health effects from inhalation of unreacted MDI during application of SPF.

Occupational exposures to harmful substances such as unreacted MDI in SPF materials are typically addressed via hazard control methodology widely accepted by the industrial hygiene profession and safety organizations, including Cal/OSHA and federal OSHA. Following this approach, hazards are controlled via a "hierarchy" of potential solutions. This hierarchy, in order of preference, is: 1) elimination of the hazard; 2) substitution with a different chemical; 3) engineering controls, including processes and systems such as exhaust ventilation, which are designed to remove the hazard at the source, before it comes in contact with the worker; 4) administrative controls, including the implementation

of policies, procedures, and employee training; and 5) the use of PPE. Currently, exposures to unreacted MDI while using SPF are controlled primarily by solutions 4 and 5.

Eliminating the chemical hazard entirely, or substituting a less hazardous chemical, is the most effective means of minimizing potential occupational exposures to workers. Engineering controls can be effective when implemented in combination with appropriate administrative controls and PPE. The use of administrative controls and PPE, alone or in combination, are the least desirable approaches to controlling occupational exposure to chemical hazards because their effectiveness depends almost entirely on employees' ability to comply and employers' ability to supervise. Lack of training, experience, or supervision, as well as a range of physical and environmental variables, can significantly decrease the effectiveness of these methods. Worker exposure that can lead to injuries or illness is often a consequence of failing to use PPE, using it improperly, or failing to follow administrative controls. Workers may not use PPE because it is uncomfortable, particularly under hot conditions. Workers also report that PPE often fits poorly and is bulky, which can reduce mobility and productivity. Additionally, employers may not supply workers with adequate PPE or enforce its use. Even when worn properly, PPE may place workers at risk due to reduced dexterity, visual acuity, and mobility, which could increase the likelihood of trip, slip, and fall accidents or heat-related illnesses. Because the original chemical hazard is still present in the workplace, when employees fail to follow administrative controls or to use PPE properly they risk exposure to chemical hazards that can lead to injuries or illnesses.

Although DTSC does not know how many workers have completed SPF professional certification programs, it is assumed that workers who operate high-pressure systems are more likely to complete industry-recommended training programs, follow employer-developed safety procedures, and use PPE. However, as stated above, administrative controls and use of PPE are at the bottom of the hierarchy of control methods, and therefore are the least effective in protecting workers from exposures to occupational hazards. DTSC has determined that industry recommended engineering and administrative controls and use of PPE reduces the likelihood of exposure, but does not eliminate the potential for worker exposure to unreacted MDI during normal use of high or low-pressure spraying systems.

Sole proprietors and consumers using SPF systems at home are of particular concern to DTSC. These groups are exempt from state and federal worker protection standards and, as a result, are unlikely to invest in engineering controls and PPE, utilize industry recommended administrative controls, or receive adequate safety training. Even when workers and consumers use PPE during spraying of SPF, improper use, imperfect fit, and malfunction of PPE can occur and result in exposure to unreacted MDI.

In conclusion, SPF application produces measurable concentrations of airborne unreacted MDI in the breathing zone, and any person involved in or near the application risks inhalation exposure to unreacted MDI, even when protective measures are used. Exposure to unreacted MDI from the use of SPF systems has the potential to harm workers of highly specialized commercial operations, sole proprietors, and individual consumers in California. Exposure to unreacted MDI can lead to 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 life-threatening asthma attacks when subsequently exposed to extremely low levels of isocyanates.

Therefore, due to the wide 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, DTSC concluded that SPF systems with unreacted MDI meet the criteria specified in section 69503.2(a) for listing as a Priority Product.

D. Additions to Chapter 55. The Safer Consumer Products Regulations

Amend section 69511. General.[8]
Section 69511 describes the scope and purpose of article 11 and establishes a Priority Products List. This section is modified to add subsection (b)(2) to identify SPF systems containing unreacted MDI as a Priority Product on the Priority Products List.

Add section 69511.2. Spray Polyurethane Systems Containing Unreacted Methylene Diphenyl Diisocyanates. In its entirety, this section identifies SPF systems containing unreacted MDI as a Priority Product. This section is necessary because it describes the product-chemical combination being listed as a Priority Product, therefore informing responsible entities and the public what type of SPF systems are subject to regulation.

Add section 69511.2(a). This section describes the product-chemical combination. “Spray polyurethane foam systems containing unreacted methylene diphenyl diisocyanates” means SPF systems containing liquid chemical mixtures in two separate containers that are sold or distributed together. The two separate containers are commonly referred to as Side A and Side B. Side A of the system contains unreacted MDI. Side B of the system contains a mixture of polyols and other ingredients, which may include catalysts, blowing

[8] *DTSC conducted a separate rulemaking to list and identify children’s foam-padded sleeping products containing tris(1,3-dichloro-2-propyl) phosphate (TDCPP) or tris(2-chloroethyl) phosphate (TCEP) as a Priority Product and adopt Article 11. This rulemaking was noticed but is not effective because it has not been approved by Office of Administrative Law and filed with the Secretary of State.*

agents, flame retardants, and surfactants. The separate chemical mixtures in the sides react when mixed and sprayed together to form polyurethane foam that is used for insulation, roofing, or sealing and filling voids and gaps. The key defining elements of SPF systems that are the subject of this proposed regulation are: 1) the two sides are sold or distributed together; 2) the two sides are in separate containers until they are mixed during application; and 3) one side is composed of unreacted MDI.

The product-chemical combination includes high-pressure and low-pressure SPF systems. High-pressure SPF systems are distributed in unpressurized drums and totes, which are preheated and pressurized to between 1,000 to 1,600 pounds per square inch (psi) during mixing and spraying. Low-pressure fillable systems and one-time use kits are sold pressurized at about 250 psi and passively mixed through the spray gun. Inhalable materials containing unreacted MDI, including vapors, aerosols, dusts, and other respirable particles, are generated using either high- or low-pressure systems, including home use SPF kits.

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

Add section 69511.2(b). This section identifies 4,4'-methylenediphenyl diisocyanate (CAS RN 101-68-8) and generic methylene diphenyl diisocyanate mixed isomers (CAS RN 26447-40-5) as the Candidate Chemical(s) identified as the basis for SPF systems with unreacted MDI being listed as a Priority Product. These chemicals belong to a group of chemicals called isocyanates and are collectively referred to as MDI.

As per section 69503.6(a), DTSC identified 4,4'-methylenediphenyl diisocyanate (CAS RN 101-68-8) and generic methylene diphenyl diisocyanate mixed isomers (CAS RN 26447-40-5) as the Candidate Chemicals because they are included on both of the following types of authoritative lists included in section 69502.2(a):

- hazard traits lists:
    - Classified by the European Union as a respiratory sensitizer Category 1 in Annex VI to Regulation (EC) 1272/2008 [section 69502.2(a)(1)(I)]; and
    - Identified as a Toxic Air Contaminant under sections 93000 and 93001 of title 17 of the California Code of Regulations [section 69502.2(a)(2)(C)]; and

- exposure concerns list:

- Identified with non-cancer endpoints and listed with an inhalation or oral Reference Exposure Level by the California Office of Environmental Health Hazard Assessment under Health and Safety Code section 44360(b)(2) [section 69502.2(a)(2)(E)].

This section is necessary to clearly identify to responsible entities and the public that 4,4'-methylenediphenyl diisocyanate (CAS RN 101-68-8) and generic methylene diphenyl diisocyanate mixed isomers (CAS RN 26447-40-5), collectively referred to as unreacted MDI, are the Candidate Chemicals identified as the basis for listing in SPF systems as a Priority Product.

Add section 69511.2(c). This section indicates the hazard traits known to be associated with the Candidate Chemicals, unreacted MDI. Section 69503.5(b)(2)(A) specifies that DTSC evaluate, at a minimum, the hazard traits of the Candidate Chemicals that are the basis for the product-chemical combination being listed as a Priority Product following the identification and prioritization criteria and process specified in sections 69503.2 and 69503.3. The hazard traits associated with unreacted MDI include dermatotoxicity, immunotoxicity, and respiratory toxicity. This section is necessary because it identifies why exposure to unreacted MDI from the use of SPF systems has the potential to harm California workers and consumers.

Add section 69611.2(d). This section indicates toxicological endpoints associated with exposure to unreacted MDI, in accordance with section 69503.5(b)(2)(A). These toxicological endpoints include asthma, respiratory irritation, extrinsic allergic alveolitis or hypersensitivity pneumonitis, interstitial and peribronchiolar fibrosis, allergic sensitization, dermal sensitization, and allergic contact dermatitis. Based on a review of authoritative scientific studies and reports, DTSC determined that unreacted MDI is an asthmagen and can be associated with work-related asthma. It is necessary to identify toxicological endpoints associated with exposure to unreacted MDI so that manufacturers and users of SPF systems are aware of potential adverse impacts that could occur with normal use of SPF products containing unreacted MDI.

Add section 69511.2(e). This section designates the Candidate Chemicals, collectively referred to as unreacted MDI, as the Chemicals of Concern for the Priority Product. Section 69503.5(b)(2)(B) states that any Candidate Chemical that has been identified as the basis for a product being listed as a Priority Product is then designated as the Chemical of Concern for that product. This section is necessary to clearly identify to responsible entities and the public that 4,4'-methylenediphenyl diisocyanate (CAS RN 101-68-8) and generic methylene diphenyl diisocyanate mixed isomers (CAS RN 26447-40-5), collectively referred to as unreacted MDI, are the Chemicals of Concern in SPF systems affected by this

proposed regulation. Clearly identifying the Chemicals of Concern in a Priority Product ensures that responsible entities understand DTSC's concerns with their product and take the appropriate steps to comply with the notification and reporting requirements included in the SCP regulations.

Add section 69511.2(f). This section provides responsible entities a due date for submission of the Preliminary AA Report. This section is necessary to comply with section 69503.5(b)(3)(B) and to provide responsible entities with a time frame for complying with the notification and reporting requirements included in the SCP regulations.

III. ECONOMIC IMPACT ANALYSIS

As required by Government Code section 11346.3, DTSC assessed the potential for this proposed regulation to cause adverse economic impacts to California businesses and individuals. Following a review of available information and survey of affected manufacturers and industry organizations, DTSC determined the proposed regulation was not a major regulation and would not have a significant adverse impact on business.[9] This Economic Impact Analysis is also based on the assumption that SPF systems manufacturers will comply fully with the SCP regulations by submitting Priority Product Notifications and AAs to DTSC by the dates specified in regulation.

SPF systems manufacturers that do not submit AAs must: 1) remove MDI from their SPF systems, 2) replace MDI with a safer chemical, or 3) stop selling their SPF systems in California. If manufacturers fail to take one of these actions by the dates specified in the SCP regulations, DTSC will notify importers, retailers, or assemblers (as applicable) of the noncompliance and prohibit them from distributing or selling SPF systems with MDI in California.

A. Cost Impacts on Representative Private Persons or Businesses

Based on results from a survey of SPF manufacturers and industry representatives, DTSC assumes that manufacturers will opt to submit Abridged AA Reports. DTSC estimates that it would cost a total of $1,067,600 to $3,107,600 for all SPF systems manufacturers to submit Priority Product Notifications and Abridged AA Reports and to respond to DTSC's

[9] *Government Code section 11342.548 defines a '"major regulation" as any proposed adoption of a regulation that will have an economic impact on California businesses in an amount exceeding $50 million dollars as estimated by the adopting agency. Per Government Code section 11346.3(a)(3), if the economic impacts are estimated to be less than $50 million dollars, the adopting agency may prepare an economic impact assessment rather than a standardized regulatory impact analysis described in section Government Code 11346.36. For more information, please refer to: STD 399 - Economic and Fiscal Impact Assessment*

Abridged AA Report reviews. DTSC assumed that only businesses licensed by California Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation (BEARHFTI) to sell SPF systems in California would be impacted by this proposed regulation.[10] Based on this assumption, DTSC estimates there are 17 manufacturers of SPF systems with unreacted MDI that make or sell their products in California who would be required to comply with this regulation. Fourteen of the 17 affected businesses are headquartered in states other than California.

Each manufacturer is required to submit a Priority Product Notification to DTSC via the online Safer Consumer Products Information Management System (CalSAFER)[11] that includes their business contact information and the type, brand name(s), and product name(s) of the SPF systems they produce. This is a one-time requirement. DTSC estimates that manufacturers would require a maximum of 16 hours to prepare a Priority Product Notification at a cost of approximately $50/hour. DTSC estimates that each manufacturer could spend up to $800 to complete the required notification with total costs for the 17 affected SPF systems manufacturers estimated to be $13,600.

SPF systems with unreacted MDI is DTSC's second proposed Priority Product and the first product that will likely result in manufacturers conducting an AA. To better assess economic impacts of the proposed regulation, DTSC surveyed affected SPF systems manufacturers and the American Chemistry Council's Center for the Polyurethanes Industry. Respondents indicated that there are currently no known functionally equivalent or technically feasible alternatives to the use of unreacted MDI in SPF and suggested that an Abridged AA, prepared individually or by a consortium of manufacturers, was a likely response to the proposed regulation.

Since there are few precedent regulations of this nature and no previously conducted AAs to use as guides for this economic analysis, DTSC derived the estimated costs for each component of an AA utilizing the following authoritative sources of information:

- Interstate Chemicals Clearinghouse AA Guide,
- State of Washington's AA Guide for Small and Medium Businesses,
- University of California-Santa Barbara's Life Cycle Analysis and Pilot AA studies,
- European Chemicals Agency,[12]
- SPF systems manufacturers, and
- Center for the Polyurethanes Industry.

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[10] *The California Bureau of Electronic and Appliance Repair, Home Furnishings and Thermal Insulation (BEARHFTI) regulates and licenses manufacturers of thermal insulation, as per California Business and Professions Code Sections 19049 and 19050. http://www.bearhfti.ca.gov/consumers/ti_directory.pdf*

[11] *https://calsafer.dtsc.ca.gov/*

[12] *https://echa.europa.eu/documents/10162/21825501/afa_201502_1_dancet_en.pdf*

DTSC estimates that costs could range from $48,000 to $78,000 to produce an individual Abridged AA Report, while estimates provided by manufacturers and the Center for the Polyurethanes Industry range from $50,000 to $150,000 to prepare an Abridged AA and from $120,000 to $250,000 to prepare a two-stage AA. Some SPF systems manufacturers indicated they might elect to participate in a consortium of manufacturers to meet regulatory requirements, which would allow them to share costs.

Given the high degree of uncertainty in these estimates, DTSC used the higher cost estimates provided by SPF systems manufacturers and the American Chemistry Council for conducting the Abridged AA and cost estimates developed by DTSC for submitting the Priority Product Notification. Given a lack of data and uncertainties surrounding the effort required to complete the AA process defined in the SCP regulations, these costs may be underestimated. Likewise, if some or all of the affected manufacturers form a consortium to conduct an industry-wide Abridged AA, overall costs would likely be lower.

More information regarding potential costs and benefits of this proposed regulation is provided in an attachment to the Economic and Fiscal Impact Statement (STD. 399).

B. Creation or Elimination of Jobs within California

This regulation is not expected to result in the elimination of jobs in the SPF systems manufacturing sector within California. The SPF market is rapidly expanding due to energy efficiency requirements in the building construction sector. In the U.S. and Canada, demand for SPF for residential construction and updating grew about 15% per year from 2013 to 2015. Rather than removing their products from the California market, SPF systems manufacturers indicated they would likely respond to this proposed regulation by conducting Abridged AAs because they have not yet identified functional alternatives to the multiple functions of SPF nor have they identified commercially viable alternative chemicals to the use of unreacted MDI to manufacture SPF.

The Abridged AA process requires manufacturers to implement Regulatory Responses. The formulation and implementation of these Regulatory Responses could result in the creation of jobs in the fields of consulting services, and chemical and material science research and product development. New employment opportunities could result from increased collaboration between manufacturers and California-based university research laboratories. These research initiatives could result in the development of products for the global market.

An expansion in training and certification programs for worker safety may also result from implementation of Regulatory Responses. Teaching opportunities in these training programs could result. Increased employment in manufacturing and sales of PPE for workers and consumers could also occur.

C. Creation of New Businesses or Elimination of Existing Businesses within California

This regulation is not expected to result in the creation or elimination of SPF systems manufacturers within California. In response to DTSC outreach, SPF systems manufacturers have indicated they will likely respond to this proposed regulation by conducting Abridged AAs, which require the evaluation and identification of safer alternatives, rather than remove their products from the market place. Manufacturers that opt to conduct Abridged AAs must evaluate and propose Regulatory Responses that are specific to their Priority Product, which must include measures to increase access to product information for consumers and funding of research initiatives that use green chemistry or green engineering principles to develop a safer alternative to SPF with unreacted MDI.

Businesses could be created to provide consulting services to assist SPF systems manufacturers in meeting regulatory obligations or to conduct chemical and material science research and development support. Employment opportunities for product safety specialists and marketing consultants could increase. Business opportunities could result from the design of products for expanded global markets. Expansions in worker education and training program development could occur, with creation of new or expanded SPF installer certification programs. An increased focus on health and safety may lead to increased manufacturing of PPE for workers and consumers.

D. Expansion of Current California Businesses

The SPF market grew about 15% in the U.S. and Canada between 2013 and 2015. The principle impact of this proposed regulation is to require SPF systems manufacturers to comply with the notification and reporting requirements in the SCP regulations. DTSC anticipates that the proposed regulation, or the existing notification and reporting requirements, will not expand the current popularity of SPF for insulation, roofing, or filling voids and cracks.

It is important to note that SPF systems manufacturers that do not submit AAs must: 1) remove MDI from their SPF systems, 2) replace MDI with a safer chemical, or 3) stop selling their SPF systems in California. If manufacturers fail to take one of these actions by the dates specified in the SCP regulations, DTSC will notify importers, retailers, or

assemblers (as applicable) of the noncompliance and prohibit them from distributing or selling SPF systems with MDI in California.

Since the Abridged AA process is new, there could be expansion in existing businesses that provide research and consulting services to SPF systems manufacturers to help them meet new regulatory requirements. Business expansions could also occur in the areas of chemical and material science research and development. Collaboration between California-based SPF systems manufacturers and university-based research laboratories could result in increased financial support of California educational institutions. Employment opportunities for product safety specialists and marketing consultants could increase. Business opportunities in worker education and training program development could occur, with expansion in SPF installer certification programs. An increased focus on health and safety may lead to increased manufacturing and sales of PPE for workers and consumers.

E. Effects on Small Businesses

To evaluate the potential economic impacts associated with this proposed regulation, DTSC surveyed SPF systems manufacturers that are licensed by BEARHFTI to sell their products in California. Although DTSC's survey did not include questions about business size, two respondents self-identified as small businesses and indicated that, due to their limited resources, they would need to participate in a consortium to prepare the required Abridged AAs. One of these manufacturers is located in California; the other is located in North Carolina.

DTSC estimates that each Priority Product Notification could cost up to $800 to prepare and an Abridged AA could cost between $50,000 and $150,000, regardless of the size of the business. If a manufacturer chooses to submit an Abridged AA Report prepared by a consortium or trade association, their individual costs may be lower than estimated.

F. Anticipated Benefits of the Regulation

The primary goal of the SCP program is to significantly reduce adverse health and environmental impacts of chemicals used in commerce, as well as the overall costs of these impacts to the state's society. By listing SPF systems with unreacted MDI as a Priority Product, DTSC asks manufacturers to evaluate whether unreacted MDI is necessary in SPF systems and whether there are safer alternatives that would reduce harm from or exposure to unreacted MDI during normal use of SPF systems. A reduction in airborne unreacted MDI means healthier air quality and safer workplaces and homes. Reducing exposure to unreacted MDI could reduce the incidence of workplace-related asthma and the number of workdays lost to health effects associated with unreacted MDI

exposure. The development of safer alternatives benefits California workers, consumers, and the businesses that employ workers who use SPF systems.

To meet the requirements of this proposed regulation, SPF systems manufacturers who intend to sell their products in California must conduct AAs to identify viable, safer alternatives to the use of unreacted MDI in these products. Manufacturers that opt to conduct Abridged AAs must propose Regulatory Responses that increase consumer and worker information on the safe use of SPF products and support research into development of safer SPF systems based on green chemistry or green engineering principles.

Each Abridged AA will reflect each SPF systems manufacturer's distinct technical and business considerations, constraints, and opportunities. As such, DTSC cannot pre-determine the Regulatory Responses that each manufacturer will select nor can the department accurately predict or quantify the full range of potential benefits associated with their implementation. DTSC will maximize the use of alternatives of least concern and give preference to Regulatory Responses that provide the greatest level of inherent protection.

Given the SCP program goal of improved product safety, benefits are expected to include reduced occupational and non-occupational illnesses and injuries, reduced medical costs and workers' compensation claims, and reduced safety training and personal protective equipment cost. Should a safer alternative be identified, manufacturers may benefit from reduced costs associated with the reduced need for and use of PPE. There may also be expanded public and private employment opportunities in research, education, and consulting focused on the advancement of green chemistry, green engineering, and lifecycle and alternatives assessment.

IV. REPORTS RELIED ON

DTSC relied on the Economic Impact Assessment, per Government Code section 11346.3(b) in proposing this regulatory action.

Assembly Bill 1879 (Feuer, Chapter 559, Stats. 2008) was signed into law on September 29, 2008, laying the critical foundation for the Green Chemistry Program. This bill provides the authority and mandate to adopt proposed SCP regulations.

DTSC (2016). Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product, last revised February, 2017.

V. REASONABLE ALTERNATIVES CONSIDERED

DTSC considered the following alternatives to the proposed regulatory action:

Regulation: List two-component SPF systems with unreacted MDI as a Priority Product.

Normal use of high- or low-pressure SPF systems with unreacted MDI has been shown to expose applicators, including workers and consumers, to levels of unreacted MDI that could be harmful to their health. These exposures have the potential to contribute to or cause significant adverse impacts to human health.

Alternative 1: Systems with TDI and MDI. List 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.

Alternative 2: Pre-Mixed Cans. List 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.

Alternative 3: Voluntary Industry Initiative. Allow SPF systems manufacturers to take voluntary actions to minimize potential worker and consumer exposures to unreacted MDI.

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.

DTSC developed the Abridged AA process because the department anticipated that some manufacturers would determine that acceptable alternatives were not available. The Abridged AA process provides the structure for a binding regulatory agreement that secures investment funds for development of safer alternatives to the Priority Product; minimizes adverse impacts to people who continue to use the Priority Product as allowed by the regulations; and provides the necessary level of enforceability to ensure a level playing field among the regulated community. Had DTSC agreed to the proposed voluntary initiative, there would be no assurance that the SPF industry would vigorously pursue safer alternatives to the use of unreacted MDI in SPF products. DTSC needs to be able to take effective actions to ensure that workplaces are safe and that all SPF applicators, including sole proprietors and consumers, have access to health and safety information.

DTSC did not attempt to quantify costs or benefits associated with Alternative 1 or Alternative 2. Since both alternatives would have affected a greater number of manufacturers, it is likely that costs for each of these alternatives would exceed those associated with the proposed regulation. Since the manufacturers potentially affected by these alternatives likely would have conducted Abridged AAs with, at a minimum, the two required Regulatory Responses, the benefits would have been similar to those described for the proposed regulation and may have impacted a greater number of people. DTSC also did not quantify costs or benefits associated with Alternative 3 due to a lack of authority to implement this alternative.

VI. DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

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

The California Labor Code and the California Occupational Safety and Health Act require all employers, regardless of size, to provide and maintain a safe and healthful workplace for employees. The hazard communication regulations require employers to inform employees about hazardous substances that they may handle or be exposed to at their workplace. The regulations also require employers to provide employees with safety training and information, which includes material safety data sheets, product labels and other forms of warning, and the employers' written hazard communication materials. Additionally,

Cal/OSHA and the federal OSHA have established permissible exposure limits (PEL) for unreacted MDI of five parts per billion (ppb) and 20 ppb, respectively. PELs are the maximum levels of isocyanate permitted in air in a worker's breathing zone. Employers must determine if employees are exposed to isocyanates and must maintain exposures below these limits. Cal/OSHA and the federal OSHA regulate hazards that workers may encounter in their workplaces; their requirements focus on hazard elimination or mitigation through a hierarchical hazard control methodology. This methodology could result in specific products not being used in the workplace if employers cannot control the hazards to their workers. By contrast, the SCP program seeks to make these specific products safer by removing the chemical hazard from the product.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act (2016) amended the Toxic Substances Control Act (TSCA), Title 15, United States Code, section 2601 et seq. Although there have been significant changes to TSCA because of the recent amendment, including risk-based safety standards and mandatory chemicals evaluations, current regulation of MDI under TSCA is limited to a significant new use rule (SNUR). The SNUR applies to workplace uses of MDI that are not already covered by a program whereby a worker would be required to wear specified National Institute for Occupational Safety and Health (NIOSH)-certified respirators. There is no regulation of MDI under TSCA pertaining to hazard reduction or a restriction on the use of the chemical, and therefore there is no conflict or duplication between regulation under TSCA and this proposed rule.

State and federal worker protection standards do not apply to consumers or sole proprietors who apply SPF containing unreacted MDI through pressurized systems. This potentially large population of applicators is less likely to have received safety training or information about the hazards posed by unreacted MDI; not knowing the hazards makes this group of applicators less likely to use 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 the ongoing efforts to protect California workers by preventing worker and consumer injuries.

MDI is also regulated under the Clean Air Act as a hazardous air pollutant. This regulation involves emissions from industrial facilities, and therefore there is no conflict or duplication with the proposed rule.