

Appendix to DTSC's December 3, 2018 Letter to the American Chemistry Council  
Response to the ACC's Informal Dispute regarding listing of Spray Polyurethane Foam Systems with Unreacted  
Methylene Diphenyl Diisocyanates as a Priority Product

This Appendix responds to each of the issues raised by the American Chemistry Council (ACC) in its May 30, 2018, letter requesting informal dispute resolution under the Safer Consumer Products (SCP) Regulations. This Appendix provides information in outline format, with each comment from the ACC's May 30, 2018 letter set forth individually, followed by DTSC's response to that comment, including citations to the SCP Regulations, the Final Statement of Reasons, and/or other authority, where appropriate.

1. The ACC asserts that a precautionary approach is not authorized.

**DTSC Response: The SCP regulatory criteria are precautionary in nature.** The plain language of the SCP Regulations authorizes an approach that considers *potential* exposure and the *potential* for such exposure to cause significant or widespread adverse impacts to human health and the environment. (See Cal. Code Regs., tit. 22, § 69503.3, subds. (a) and (b), and FSOR, pp. 3-5, 28.) The process established by the SCP Regulations, which DTSC followed with respect to the listing of Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates (MDI) (SPF Systems) as a Priority Product, is therefore precautionary in its nature.

2. The ACC asserts that DTSC impermissibly interpreted its regulatory authority by listing SPF Systems as a Priority Product:

- a. ACC Assertion: DTSC failed to meet the key prioritization criteria.

**DTSC Response:**

**i. DTSC demonstrated the potential for exposure to MDI in SPF Systems.**

1. DTSC relied upon reliable information, as defined in section 69501.1(a)(57) of the SCP Regulations, as well as information provided by the industry showing that unreacted MDI was detected and measured in the breathing zone of SPF applicators during and after spraying- in some instances exceeding occupational thresholds. Those same studies showed that these levels of airborne MDI persist for the duration of spraying, which is often a continuous process that can last several hours. DTSC also relied on studies showing that inhalation and skin absorption are exposure routes for MDI. (See FSOR, p. 16.)
2. External Scientific Peer Reviewers confirmed that DTSC presented sufficient information to conclude there is potential for exposure to MDI. (See FSOR, pp. 3-4, 16.)

**ii. DTSC demonstrated the potential for significant or widespread adverse impacts from SPF Systems containing unreacted MDI.**

1. The known hazard traits of unreacted MDI, the effects of exposure to unreacted MDI, the link between exposure to unreacted MDI in SPF Systems and adverse health effects, and the fact that MDI has been found in breathing apparatus of workers applying the substance, all support DTSC's conclusion that there is a potential for exposure to unreacted MDI in SPF Systems to lead to significant adverse health effects. (See FSOR, p. 19.) Exposure to unreacted MDI can lead to 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. These potential impacts support DTSC's determination that the potential adverse human health impacts associated with exposure to MDI in SPF Systems

Appendix to DTSC's December 3, 2018 Letter to the American Chemistry Counsel  
Response to the ACC's Informal Dispute regarding listing of Spray Polyurethane Foam Systems with Unreacted  
Methylene Diphenyl Diisocyanates as a Priority Product

are significant. (See FSOR, p. 25.) DTSC also cited evidence demonstrating 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 individuals. (See FSOR, p. 36.)

2. The broad availability of SPF Systems demonstrates the potential for widespread adverse impacts, although the SCP Regulations are satisfied with a showing of either significant or widespread adverse impacts. (See FSOR, p. 28.)
3. External Scientific Peer Reviewers confirmed that DTSC's finding that exposure to MDI has the potential to cause significant or widespread adverse impacts is supported by adequate data. (See FSOR, pp. 3-4, 25.)

b. ACC Assertion: DTSC improperly failed to establish a threshold for exposure.

**DTSC response: SPF Systems with MDI meet the regulatory criteria for prioritization, which do not include a threshold.**

- i. The SCP Regulations do not require DTSC to establish a minimum exposure threshold to determine whether there exists a potential for exposure but, rather, require DTSC to evaluate one or more of the non-numeric factors identified in the SCP Regulations. DTSC thoroughly documented this evaluation in the *Summary of Technical Information and Scientific Conclusions for Designating Spray Polyurethane Foam Systems with Unreacted Methylene Diphenyl Diisocyanates as a Priority Product*, Revised February 2017. (Cal. Code Regs., tit. 22, § 69503.3, subd. (b); see also, FSOR, p. 28.)
- ii. DTSC's determination that a threshold is not appropriate was verified by External Scientific Peer Reviewers. (See FSOR, pp. 3-4.)
- iii. DTSC noted that a numeric threshold is even less appropriate here, given the low levels at which MDI may harm workers. (See FSOR, p. 28.)

c. ACC Assertion: SPF is not a "consumer product" because it is primarily used by "professional workers."

**DTSC Response: SPF Systems with MDI are a consumer product as defined in the California Health and Safety Code.**

- i. The definition of "consumer product" is broad, and includes all products used by "a person" – which includes workers. (Health & Saf. Code, § 25251; Cal. Code Regs., tit. 22, § 69501.1, subd. (a)(24).)
- ii. Some SPF Systems are marketed to Do-It-Yourself homeowners who are not subject to state and federal worker protection standards. (See FSOR pp. 14-15, 27.)

d. ACC Assertion: DTSC improperly grouped multiple products into one listing regulation.

**DTSC Response: The SCP regulations allow a Priority Product listing to include multiple products.**

- i. The SCP Regulations "clearly anticipat[e] that a Priority Product listing may encompass more than one product manufactured or sold by the same responsible entity." (FSOR, p.

Appendix to DTSC's December 3, 2018 Letter to the American Chemistry Counsel  
Response to the ACC's Informal Dispute regarding listing of Spray Polyurethane Foam Systems with Unreacted  
Methylene Diphenyl Diisocyanates as a Priority Product

8, citing Cal. Code Regs., tit. 22, § 69503.5, subd. (b) [DTSC "shall specify in the proposed and final Priority Products lists the following for each listed product-chemical combination: (1)(A) A description of the product-chemical combination that is sufficient for a responsible entity to determine *whether one or more of its products is a Priority Product.*" (emphasis added)].)

- ii. "[A]ll these formulations [and brands of SPF Systems] have an A-side consisting of isocyanates..." and they "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 or adverse impacts." (See FSOR, p. 8.)
  - iii. In this case, as the regulations require, "DTSC balance[d] 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." (See FSOR, p. 10.)
- e. ACC Assertion: DTSC failed to consider SCP Regulations section 69501, subdivision (b)(3)(A).

**DTSC Response: DTSC considered all relevant regulatory authorities and determined that the listing would meaningfully enhance protection of public health.**

- i. Section 69501, subdivision (b)(3)(A), explains that the SCP Regulations do not apply to consumer products that are "regulated by one or more federal and/or California State regulatory programs, and/or applicable treaties or international agreements with the force of domestic law that" DTSC determines would address the same adverse health impacts as a Priority Product listing or that provide a greater level of environmental and public health protection than would a Priority Product Listing.
- ii. DTSC noted that no state or federal regulations 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. (See FSOR, p. 53.) DTSC explained how the Listing Regulation is not duplicative of existing laws and sets forth below why the non-duplication determination set forth in Section 69501, subdivision (b)(3)(A), does not apply. (See FSOR, p. 48.)
- iii. DTSC addressed the inadequacy of existing regulations to protect consumers and workers from potential exposure to unreacted MDI, and explained that there are potential adverse impacts and exposure pathways that are not captured by current regulations. (See FSOR, p. 48.)
  - 1. Current regulations rely on the use of personal protective equipment (PPE), which is the least preferred option within OSHA's established hierarchy of hazard protection<sup>1</sup>, whereas, eliminating the hazard "is the best solution." It is possible that such a solution may be identified through the Alternatives Analysis (AA) process. (See FSOR, p. 30, 52-53.)
  - 2. DTSC also provided evidence that SPF Systems may be marketed to and purchased by individual consumers and sole proprietors, who are not subject to compliance with Cal/OSHA requirements and may not be aware of either the

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<sup>1</sup> <https://www.cdc.gov/niosh/topics/hierarchy/>

Appendix to DTSC's December 3, 2018 Letter to the American Chemistry Counsel  
Response to the ACC's Informal Dispute regarding listing of Spray Polyurethane Foam Systems with Unreacted  
Methylene Diphenyl Diisocyanates as a Priority Product

potential hazards associated with use of SPF Systems, or the SPF System industry's stewardship and training programs. (See, e.g., FSOR pp. 12-14.)

- iv. As a result, DTSC found that the Listing Regulation will increase the level of public health protection compared with that provided by current regulations. The Listing Regulation requires product manufacturers to perform an AA to identify safer alternatives for the listed Priority Product. If the outcome of the AA does not reveal a safer alternative(s), the SCP Regulations provide a variety of potential regulatory responses to address the impacts associated with the Priority Product.

3. The ACC asserts that DTSC failed to fulfill its procedural obligations when adopting the Listing Regulation:

- a. ACC Assertion: DTSC's economic analysis was inadequate.

**DTSC Response: DTSC met all requirements for the economic analysis.**

- i. DTSC has complied with the requirement to complete an economic analysis pursuant to Government Code sections 11346.2, 11346.3, and 11346.5, Health and Safety Code section 57005, and the requirements of the State Administrative Manual. (See FSOR, pp. 40-45.)
- ii. The ACC argues that DTSC should have provided cost estimates for preparing multiple Alternatives Analyses because "SPF" encompasses numerous products that vary in formulation and application. All SPF Systems contain MDI in the A-side of the system. Variations among products in the B-side may not need separate AAs if the alternative 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. (see FSOR, pp. 42-43.)
- iii. The ACC argues that the economic analysis does not adequately estimate the cost to California of potentially losing SPF as an insulator and air sealant for roofing products. However, the Listing 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. (See FSOR, p. 46.)

- b. ACC Assertion: DTSC failed to consider alternatives to the Listing Regulation.

**DTSC Response: DTSC considered alternatives to listing both during rulemaking and in response to the ACC's 2015 proposal.**

- i. DTSC expressly considered and rejected an alternative to achieve the goals of the listing regulations through voluntary actions and product stewardship efforts. (See FSOR, pp. 2, 52-53, and Letter from Barbara Lee to Lee Salamone, dated November 17, 2015.)

- c. ACC Assertion: DTSC's Issuance of a Notice of Exemption under CEQA is Unlawful.

**DTSC Response: DTSC's CEQA exemption is warranted.**

- i. The ACC's comments suggest that the ACC believes that "project" here must be defined to include not just the Listing Regulation, but also the AA and any potential, future

Appendix to DTSC's December 3, 2018 Letter to the American Chemistry Counsel  
Response to the ACC's Informal Dispute regarding listing of Spray Polyurethane Foam Systems with Unreacted  
Methylene Diphenyl Diisocyanates as a Priority Product

regulatory response by DTSC. The "project" is the promulgation of the Listing Regulation, which is exempt from CEQA because it will not result in a potential significant environmental effect. As set forth in the FSOR, the Listing Regulation is unlikely to increase adverse environmental and health impacts associated with the Priority Product. (See FSOR, p. 55.) Additionally, the Listing Regulation requires product manufacturers to perform an AA to identify safer alternatives for the listed Priority Product. If the outcome of the AA does not reveal safer alternatives, the framework regulations provide a variety of regulatory responses to address the impacts associated with the Priority Product. DTSC will conduct a further analysis at the regulatory response stage to determine whether the regulatory response is a "project" under CEQA and whether further CEQA analysis is required.

- d. ACC Assertions: Listing SPF Systems as a Priority Product is not authorized under, and conflicts with, state and federal laws. DTSC's Regulatory Response(s) may conflict with federal requirements.

**DTSC Response: Listing SPF Systems as a Priority Product is authorized under, and does not conflict with, state and federal laws. Any DTSC regulatory response is undefined. Thus, it would be speculative to determine now whether a regulatory response conflicts with state or federal laws.**

- i. Listing SPF Systems as a Priority Product is expressly authorized by Chapter 55, section 69501 et seq. of the SCP Regulations, and does not conflict with state or federal requirements.
- ii. The ACC argues that the potential, future regulatory response imposed by DTSC has the potential to be an unlawful extraterritorial regulation because the majority of the SPF manufacturers are located outside of California. The ACC also argues that if DTSC's regulatory response requires regulated entities to fund third-party research on alternatives through a challenge grant, that would constitute an unconstitutional taking. DTSC's position is that it is too speculative to determine now whether any potential regulatory response to an AA might violate state or federal law. (See FSOR, p. 57.)