INITIAL STATEMENT OF REASONS

September 2021

SAFER CONSUMER PRODUCTS REGULATIONS – Listing Treatments Containing Perfluoroalkyl or Polyfluoroalkyl Substances for Use on Converted Textiles or Leathers as a Priority Product

Department of Toxic Substances Control Reference Number: R-2020-04

Table of Contents

INTRODUCTION AND BACKGROUND

The Department of Toxic Substances Control (DTSC) proposes to amend section 69511 and add section 69511.5 to Article 11, Chapter 55 of Division 4.5 of Title 22 of the California Code of Regulations [Safer Consumer Products (SCP) regulations] to add treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers as a Priority Product to the Priority Products List. The term "converted" indicates textile and leather that manufacturers and craftspeople have turned into consumer products such as carpets, upholstery, furnishings, clothing, shoes, etc.

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 treatments containing *any* perfluoroalkyl and polyfluoroalkyl substances (PFASs) for use on converted textiles or leathers as a Priority Product.

DTSC is required to establish and update the Priority Products List through rulemaking under the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Division 3 of Title 2 of the California Government Code).

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 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 Chemicals of Concern. This process must 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
- The potential effects of a chemical on sensitive subpopulations.

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 of Division 4.5 of Title 22 of the California Code of Regulations (CCR) 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 the 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. 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).

Safer Consumer Products Regulations Overview

The SCP regulations 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 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 on 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.

Priority Products List

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);
- Spray polyurethane foam (SPF) systems containing methylene diphenyl diisocyanates; and
- Paint or varnish strippers containing methylene chloride.

DTSC is updating the Priority Product List by conducting this rulemaking to adopt treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers as a Priority Product. On July 1, 2021, DTSC updated the Priority Product List by adopting carpets and rugs containing perfluoroalkyl or polyfluoroalkyl substances as a Priority Product.

Prioritization Criteria for Listing a Priority Product

DTSC is required to use the identification and prioritization criteria and process specified in California Code of Regulations, title 22, 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 the following two 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.

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 considers available information regarding one or more exposure scenarios, assesses 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) of 22 CCR 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 a given outcome. This ensures that an assessment of adverse impacts is based on both reasonable grounds and evidence. Additionally, the determination of "potential" must be based on reliable information, which is defined in section 69501.1 of the SCP regulations to mean scientific studies or scientific information that meets certain specified criteria.

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.

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 the Priority Product, replace it with a safer chemical, or stop selling the product in California. Section 69505.1(a) and section 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 placing 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 considers 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 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 additional 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, it 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 the screening of potential alternatives. Because the Abridged AA process allows for the continued sales and use of the Priority Product, the Abridged AA Report must include an implementation plan to carry out the following required Regulatory Responses:

- providing product safety information to consumers, including information on chemical hazards, safe handling and disposal procedures, and other information needed to protect public health and 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 will post the report using the Safer Consumer Products Information Management System (CalSAFER) located at https://calsafer.dtsc.ca.gov/ on the DTSC 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. 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. DTSC's response to these submissions from manufacturers 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 (Section 69506(b)).

DETAILED STATEMENT OF SPECIFIC PURPOSE AND RATIONALE

Amend Section 69511. General.

Purpose. Section 69511 describes the scope and purpose of article 11 and establishes a Priority Products List. This section is modified to add subsection (b)(5) to identify Treatments Containing Perfluoroalkyl or Polyfluoroalkyl Substances for Use on Converted Textiles or Leathers as a Priority Product on the Priority Products List.

Necessity. DTSC proposes to adopt treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers as a Priority Product because this product-chemical combination meets the criteria in section 69503.2(a), which requires that:

- 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 PFASs, DTSC concluded that there is a potential for humans and the environment to be exposed to PFASs during the manufacturing, normal use, and end-of-life of treatments for use on converted textiles or leathers, their containers, and the treated converted textiles or leathers. These exposures could potentially contribute to or cause significant adverse health 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

DTSC has identified treatments for use on converted textiles or leathers as major sources of human and ecological PFAS exposure. A large percentage of the PFASs produced worldwide are used to treat converted textiles or leathers such as carpets,

rugs, upholstery, furnishings, clothing, and shoes to impart stain-, soil-, oil- or water-resistance. U.S. EPA researchers studied the PFASs found in 13 consumer product categories and 116 household products. They concluded that many of the PFASs detected in household dust can be attributed to the use of treatment products applied to converted textiles and leathers. In particular, carpet and fabric care liquids were among the greatest sources of exposure. Manufacturers of converted textile and leather products generally recommend reapplication of treatment products every few years to ensure optimal stain and soil resistance. This suggests that over time PFASs migrate from converted textile or leather products.

PFASs or their transformation products are highly persistent in the environment. Continued use of PFASs leads to accumulation of these chemicals in the environment, and results in increased potential for exposure to these chemicals. Many PFASs also display significant mobility in environmental media. Some members of the PFAS class bioaccumulate in animals or plants, including in foods consumed by humans, and undergo lactational or transplacental transfer from mothers to their offspring. Because of these characteristics, PFASs are now ubiquitous in the environment and biota, including indoor air and dust, surface water and groundwater, wastewater treatment plant effluent, sewage sludge and biosolids, sediments, soil, plants, animals, and humans. However, the full extent of the contamination remains poorly characterized.

In the general human population, PFAS exposure occurs mainly via ingestion of contaminated food and drinking water. This contamination is partly due to releases of PFASs from treated consumer products at various points in their lifecycle, including manufacturing, use, and disposal. The lifecycle of the PFAS-containing treatments and of the treated textiles or leathers contributes to this contamination, exposing humans and other living organisms to PFASs via ingestion, inhalation, and dermal contact. When used, treatments for converted textiles or leathers release PFASs into indoor air and dust, which people inhale or ingest. PFASs are also released into air, water, and soil during the manufacture of the treatments, the recycling of treatment product containers, as well as during the use, landfilling, incineration, or recycling of the treated converted textiles or leathers. These PFASs can enter waterways via direct release and discharge from manufacturers, wastewater effluent discharges, or land application of contaminated biosolids, resulting in PFAS-contaminated surface water and groundwater.

Manufacturers of treatments for converted textile or leather products recommend reapplication every few years to maintain stain-, soil-, oil- or water-resistance. These products are readily available for consumer use and are often applied without adequate engineering controls such as personal protective equipment and proper air ventilation, which amplifies the potential for exposure, particularly via inhalation. Throughout the

normal use of converted textiles or leathers, PFASs migrate into indoor air and dust, which people inhale or ingest. This impacts the general population, including infants and school children, since most people spend more than 90 percent of their time indoors, often in carpeted office buildings, classrooms, or residences. Converted textiles or leathers are a major source of exposure for infants and children via direct contact and incidental indoor dust ingestion. Young children have been shown to ingest more dust than adults, due to greater hand-to-mouth transfer, and this can result in higher exposure to PFASs. Workers, including carpet and upholstery cleaners; workers in upholstered furniture, furnishings, clothing, shoe, and carpet stores; auto dealership workers; and auto detailing technicians can experience high PFAS exposure levels on the job.

CalRecycle estimates that in California, converted textile or leather products such as clothing, carpets, rugs, shoes, and upholstery are among the top 5 components by weight of the single-family municipal waste stream. From landfills, they become sources of PFASs to the environment via leachates and gaseous emissions. Wastewater treatment plants that collect landfill leachates, surface runoff, and residential and commercial wastewater do not effectively remove PFASs. As a result, when wastewater effluent is discharged into surface waters, PFASs are released into the environment, contaminating aquatic ecosystems and drinking water sources. Sewage sludge also contains PFASs, thus the application of biosolids on soil can contaminate terrestrial ecosystems, drinking water, and human food supplies.

Once released to the environment during product manufacture, use, or disposal, PFASs become permanently present in our environment leading to lifelong human and ecological exposures. Their levels in the environment, humans, and biota are expected to rise with continued use of PFAS-containing consumer products such as the treatments for use on converted textiles or leathers.

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

All PFASs have at least one hazard trait as defined under the SCP regulations. At a very minimum, PFASs are either extremely persistent (e.g., perfluoroalkyl acids (PFAAs)), or are PFAA precursors (i.e., they degrade into PFAAs in the environment or in biota) and hence have extremely persistent degradation products.

The adverse impacts associated with PFAAs are relevant to the entire class of PFASs because other PFASs either: transform into PFAAs in humans, biota, or the environment (i.e., are PFAA precursors); form PFAAs during combustion; are manufactured using PFAAs; or contain them as impurities. While persistence alone warrants enough concern to include any member of the PFAS class in product

prioritization, the health hazards associated with exposure to PFAAs are additionally concerning and underlie our listing.

Longer-chain PFAAs such as perfluorooctanoic acid (PFOA) and perfluorosulfonic acid (PFOS) tend to bioaccumulate. These longer-chain PFAAs and their precursors have been phased out from domestic use following U.S. EPA's 2010/2015 voluntary Stewardship Program and are restricted (but not banned) in carpets and rugs by the U.S. Environmental Protection Agency's (U.S. EPA) significant new use rule (SNUR). Shorter-chain PFAAs such as perfluorohexanoic acid (PFHxA), appear not to bioaccumulate but are very mobile and persistent in environmental media.

The toxicological hazard traits of longer-chain PFAAs, which may still be present in imported treatments for use on converted textiles or leathers, have been well established in animal and human epidemiologic studies. In humans, these include one or more of the following:

- carcinogenicity (kidney and testicular cancers);
- cardiovascular toxicity (increased serum cholesterol);
- endocrine toxicity (thyroid disease);
- immunotoxicity (immune dysregulation); or
- reproductive toxicity (pregnancy-induced hypertension).

The toxicological hazard traits of the shorter-chain PFAAs are still emerging, based on more recent rodent, zebrafish, *in vitro*, and toxicokinetic modeling studies. These include:

- developmental toxicity (e.g., tail deformation and uninflated swim bladders in zebrafish; delayed eye opening in rodents);
- endocrine toxicity (e.g., thyroid disruption);
- hematotoxicity (e.g., reduced red blood cell count, hemoglobin, and hematocrit in rodents);
- hepatotoxicity (e.g., increased liver weight in rodents);
- neurodevelopmental toxicity (e.g., suppression of neuronal differentiation *in vitro*);
- ocular toxicity (e.g., delayed pupil response in rodents); and
- reproductive toxicity (e.g., fetal resorption in rodents).

PFAAs also display environmental hazard traits:

- phytotoxicity (observed in green algae);

- wildlife developmental, reproductive, or survival impairment (observed especially in aquatic invertebrates).

PFAAs bioaccumulate in phyto- and zooplankton and are toxic to green algae, which are the foundation of the aquatic food chain. In general, aquatic invertebrates, which comprise the largest percentage of animal biomass in aquatic ecosystems, are particularly susceptible to adverse impacts because they are often exposed to complex mixtures of waterborne contaminants. The ubiquitous presence of PFASs in aquatic environments and the limited toxicological knowledge about cumulative impacts to aquatic species have led to increasing concern about the potential for irreversible adverse aquatic impacts.

In conclusion, exposing humans and aquatic, avian, or terrestrial animal or plant organisms to PFASs associated with the treatments for use on converted textiles or leathers has the potential to cause significant and widespread adverse impacts to sensitive subpopulations, including fetuses, infants, young children, pregnant women, individuals with certain preexisting conditions (e.g., elevated cholesterol, high blood pressure, poor kidney function), carpet and upholstery cleaners, workers in upholstered furniture, furnishings, clothing, shoe, and carpet stores, and auto dealership workers and detailing technicians; to environmentally-sensitive habitats; and to threatened and endangered species. Given the known hazard traits, replacing currently used PFASs in treatments for use on converted textiles or leathers with other members of the PFAS class could be equally problematic.

Therefore, considering the (i) ubiquity of textiles and leathers in buildings including offices, school classrooms, and homes, (ii) the wide availability of treatments for use on converted textiles or leathers containing members of the class of PFASs, (iii) the potential for exposure to PFASs during product manufacturing, use, and end-of-life, and (iv) the significant and widespread adverse health impacts associated with exposure to PFASs, DTSC has concluded that the treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers meet the criteria specified in section 69503.2(a) for listing as a Priority Product.

Add Section 69511.5. Treatments Containing Perfluoroalkyl or Polyfluoroalkyl Substances for Use on Converted Textiles or Leathers.

Purpose. In its entirety, this section identifies treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers as a Priority Product.

Necessity. This section is necessary because it describes the product-chemical combination being listed as a Priority Product, therefore informing responsible entities and the public which products are subject to regulation.

Benefits. The primary goal of SCP regulations is to protect public health by reducing exposures to potentially harmful chemicals. By listing treatments containing any PFASs for use on converted textiles or leathers as a Priority Product, DTSC sets in motion a strategy to reduce human exposure to PFASs from the manufacturing, use, and end-of-life of this product. A reduction in exposure to PFASs could benefit the health of California's residents and wildlife. The development of safer alternatives benefits California workers, consumers, employers, and the environment.

DTSC cannot pre-determine the alternatives that each manufacturer will propose; therefore, it is impossible to accurately predict or quantify the full range of potential benefits associated with their development. DTSC will maximize the use of alternatives of least concern and give preference to those that provide the greatest level of inherent protection. In general, economic benefits to California workers and business owners may include expanded employment opportunities in the fields of consulting, worker and consumer education, and marketing. Additional benefits may accrue because of increased research and product development collaboration between manufacturers and California-based research entities. Institutional and corporate financial support of chemical and material science programs focused on developing safer alternatives to PFASs could advance the field. These research initiatives could provide manufacturers with employees that are highly skilled in the research and design of products for newly emerging global markets.

Add Section 69511.5(a).

Purpose. This section provides a description of the product-chemical combination. "Treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers" means any product containing PFASs placed into commerce in California that may be marketed or sold for the purpose of:

- Eliminating dirt or stains from carpets, rugs, clothing, shoes, upholstery, or other converted textiles and leathers; or
- Repelling stains, dirt, oil, or water from carpets, rugs, clothing, shoes, upholstery, or other converted textiles and leathers.

These products are sometimes also referred to as impregnating agents or aftermarket treatments, though they can also be used by retailers (e.g., upholstery, furnishings, shoe, auto retailers) prior to selling to the consumer.

Products that fall under this product description include:

- Cleaner: a product marketed or sold for the purpose of eliminating dirt or stains;
- Protectant: a product marketed or sold to protect a surface from soiling when in contact with dirt or other impurities, or to reduce liquid absorption;
- Spot remover: a product marketed or sold to clean localized areas, or to remove localized spots or stains; and
- Water proofer or water repellant: a product marketed or sold to repel water.

Treatments containing any perfluoroalkyl and polyfluoroalkyl substances (PFASs) for use on converted textiles or leathers does not include products marketed or sold exclusively for use during the manufacturing of carpets, rugs, clothing, shoes, furniture, or other textiles and leathers.

Necessity. This description is necessary for a responsible entity to determine whether one or more of its products is a Priority Product, as required by section 69503.5(b)(1)(A). DTSC selected these products because of their widespread use in California and high potential to lead to human and ecological PFAS exposures.

Add Section 69511.5(b).

Purpose. This section identifies PFASs as the Candidate Chemical and the basis for proposing to list treatments containing PFASs for use on converted textiles or leathers as a Priority Product. PFASs are a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom. PFASs vary in chain length (the number of carbon atoms forming the backbone of their molecule) from a chain of two carbons to large molecular weight polymers.

Necessity. This section is needed to clearly identify to responsible entities and the public that the class of PFASs is the Candidate Chemical that is the basis for listing treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers as a Priority Product.

Consistent with section 69503.6(a) of the SCP regulations, DTSC identified the class of PFASs as a Candidate Chemical because it is included on California Environmental Contaminant Biomonitoring Program's Priority Chemicals list, one of the authoritative lists specified in section 69502.2(a), and because all PFASs exhibit one or more exposure potential, toxicological, or environmental hazard traits as specified in sections 69402 through 69405 of Chapter 54 of Division 4.5 of Title 22 of the California Code of Regulations (Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse), including:

- Carcinogenicity;
- Cardiovascular toxicity;
- Developmental toxicity;
- Endocrine toxicity;
- Hepatotoxicity;
- Immunotoxicity;
- Nephrotoxicity;
- Ocular toxicity;
- Reproductive toxicity;
- Phytotoxicity;
- Wildlife developmental, reproductive, or survival impairment; Environmental persistence;
- Bioaccumulation;
- Mobility in environmental media; and
- Lactational and transplacental transfer.

Based on common characteristics, and for the purposes of this designation, PFASs can be roughly subdivided into four main categories:

- **PFAAs:** These are perfluorinated substances in which fluorine atoms have replaced all hydrogen atoms attached to carbon atoms, except for those associated with functional group(s). As a result, these compounds are recalcitrant to degradation and extremely persistent in the environment. This subgroup includes:

    - Perfluoroalkyl carboxylic acids (PFCAs) such as perfluorooctanoic acid (PFOA);
    - Perfluoroalkyl sulfonic acids (PFSAs) such as perfluorooctane sulfonic acid (PFOS);
    - Perfluoroalkyl sulfinic acids (PFSiAs);
    - Perfluoroalkyl phosphonic acids (PFPAs);
    - Perfluoroalkyl phosphinic acids (PFPiAs);
    - Perfluoroether carboxylic acids (PFECAs); and
    - Perfluoroether sulfonic acids (PFESAs).

- **PFAA precursors:** These are mostly polyfluoroalkyl substances, meaning fluorine atoms have replaced all hydrogen atoms attached to at least one (but not all) carbon atoms. Polyfluorinated substances have the potential to degrade into perfluoroalkyl substances in the environment and in living organisms, i.e., they

are precursors to perfluoroalkyl substances. Examples include the side-chain fluorinated polymers commonly used for surface treatments.

- **Perfluoropolyethers (PFPEs)**: These are perfluoroalkyl substances that are highly persistent in the environment, with large molecular sizes (oligomers, polymers, and copolymers), and ether linkages. They are unlikely to degrade to PFAAs under typical environmental conditions, but may contain PFAA impurities and may release PFAAs during combustion.

- **Fluoropolymers**. These polymers are materials (as opposed to surface treatments), and are highly persistent in the environment. They cannot degrade to PFAAs under typical environmental conditions, but certain PFAAs have been used in their manufacturing and can occur as impurities. Fluoropolymers may also release PFAAs during combustion.

Thus, while PFAAs constitute a small subset (approximately one percent) of PFASs, they are terminal degradation products, manufacturing aids/feedstocks, or impurities of other PFAS class members, which makes their hazard traits relevant to the entire class. PFAAs and some of their precursors are frequently subdivided into longer- and shorter-chain PFASs. The longer-chain PFSAs have six or more perfluorinated carbons; longer-chain PFCAs, PFPAs, and PFPiAs have seven or more perfluorinated carbons.

Add Section 69511.5(c).

Purpose. This section indicates the hazard traits associated with PFASs. Section 69503.5(b)(2)(A) specifies that DTSC evaluates, 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.

Necessity. The identified hazard traits support DTSC's conclusion that exposure to PFASs in treatments for use on converted textiles or leathers has the potential to harm Californians, including consumers, workers, infants, school children, pregnant women, as well as wildlife, and is required by section 69503.5(b)(2)(A). The hazard traits associated with PFASs include carcinogenicity, cardiovascular toxicity, hepatotoxicity, endocrine toxicity, immunotoxicity, reproductive and developmental toxicity, nephrotoxicity, ocular toxicity, and environmental persistence.

Add Section 69511.5(d).

Purpose. This section indicates toxicological endpoints associated with exposure to PFASs, in accordance with section 69503.5(b)(2)(A). These toxicological endpoints

include the following: kidney and testicular cancers, increased serum cholesterol, thyroid disease, compromised immune response, renal disease, pregnancy-induced hypertension, and decreased fertility.

Necessity. This section is necessary to identify toxicological endpoints associated with exposure to PFASs as required by section 69503.5(b)(2)(A). Clearly describing the toxicological endpoints of the Candidate Chemical associated with exposure to PFASs in treatments for use on converted textiles or leathers allows those who could be exposed to be aware of potential adverse impacts that could occur.

Add Section 69511.5(e).

Purpose. This section designates the Candidate Chemical PFASs as the Chemical 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.

Necessity. This section is necessary to clearly identify to responsible entities and the public that the class of PFASs is the Chemical of Concern in treatments for use on converted textiles or leathers affected by this proposed regulation. Clearly identifying the Chemical 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 69511.5(f).

Purpose. This section provides responsible entities a due date for submission of the Preliminary AA Report.

Necessity. This section is necessary to comply with section 69503.5(b)(3) and to provide responsible entities with a time frame for complying with the notification and reporting requirements included in the SCP regulations.

ECONOMIC IMPACT ASSESSMENT

Summary of Non-Major Regulation

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 market data for converted textile and leather treatments and surveys of affected manufacturers and industry organizations, DTSC determined the proposed regulation is not a major regulation and is unlikely to have a significant adverse impact on business (see the definition of a major regulation

at the end of this subsection). This Economic Impact Assessment is also based on the assumption that manufacturers of treatments containing any PFASs for use on converted textiles or leathers will comply fully with the SCP regulations by submitting Priority Product Notifications and AA Reports to DTSC by the dates specified in regulation.

Manufacturers of treatments containing any PFASs for use on converted textiles or leathers that do not submit AA Reports must: 1) remove the PFASs from their treatment products for use on converted textiles or leathers; 2) replace the PFASs with a different chemical that meets certain regulatory requirements for those products; or 3) stop selling treatments containing PFASs for use on converted textiles or leathers in California. If a manufacturer fails 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 placing the product into the stream of commerce in California, and for retailers and assemblers to cease ordering the product.

DTSC estimates the implementation of the proposed regulation will result in a total economic impact on the state's businesses of less than $10 million. This proposal is not a major regulation as defined by Health and Safety Code section 57005.

DTSC estimates the cumulative cost for all affected California manufacturers of treatments with any PFASs for use on converted textiles or leathers to submit Priority Product Notifications, AA Reports, and to respond to DTSC's reviews of these submittals to be from $2,598,080 to $7,014,080. DTSC estimates there are a maximum of 23 manufacturers of treatments containing PFASs for use on converted textiles or leathers that make and sell their products in California that would be required to comply with this regulation. All manufacturers of treatments containing PFASs for use on converted textiles or leathers that sell their products in California, or their distributors in some instances, must submit Notifications and AA reports. Costs incurred by out-of-state businesses, however, fall outside the scope of the Economic Impact Analysis. The DTSC SCP program considers a business "California-based" if the business is incorporated or headquartered in California or employs over 50 percent of its employees in California.

Each manufacturer is required to submit an online Priority Product Notification to DTSC using CalSAFER, that includes business contact information and the type, brand name(s), and product name(s) of the treatments that contain any PFASs for use on converted textiles or leathers. 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 $60/hour. DTSC estimates that each manufacturer could spend up to $960 to complete the required notification.

DTSC derived the estimated costs of an AA utilizing authoritative sources of information. These included the Interstate Chemicals Clearinghouse (IC2) Alternative Assessment guide, the State of Washington's Alternative Assessment Guide for Small and Medium Businesses, University of California Santa Barbara's Life Cycle Analysis and Pilot AA studies, as well as guidance from the European Chemicals Agency. DTSC's estimated costs to individual manufacturers based on these sources range from $48,000 to $78,000 for an Abridged AA and $86,000 to $161,000 for a two-stage AA.

DTSC surveyed manufacturers of paint or varnish strippers containing methylene chloride in a previous DTSC regulatory action for their expected costs of submitting an AA. Those interviewed indicated that they expect the first stage of an AA to cost from $100,000 to $135,000. This estimate does not include the second stage of a two-stage AA or responses to public comments and DTSC reviews. DTSC also conducted similar interviews with manufacturers for other potential Priority Products. Manufacturers of these other products estimated that it would cost from $50,000 to $150,000 to prepare an Abridged AA Report or $120,000 to $250,000 to prepare a two-stage AA Report.

Given the high degree of uncertainty in the estimated cost of an AA, DTSC opted to use the higher range of estimates provided by manufacturers of proposed Priority Products ($100,000 to $150,000 for an Abridged AA and $120,000 to $250,000 for a two-stage AA). For an individual manufacturer, the estimated total cost to comply with the Priority Product Notification and the AA report requirements, including responding to DTSC's review, ranges from $112,960 to $182,960 for an Abridged AA and $139,960 to $304,960 for a two-stage AA. Feedback from the author of one AA submitted to DTSC confirms that this estimate remains reasonable.

Given a lack of data and many uncertainties surrounding the effort required to complete the AA process defined in the SCP regulations, these costs may be underestimated. Likewise, if multiple affected manufacturers 1) form a consortium, or 2) work with their industry association (e.g., Carpet and Rug Institute) to submit a combined AA Report, overall costs could 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).

Major regulation: 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. Section 57005 of the Health and Safety Code further requires DTSC (as part of the California Environmental Protection Agency, "CalEPA") to evaluate alternatives to a "major regulation." Section 57005(b) defines a "major regulation" as any rulemaking that will have an economic impact on business enterprises exceeding $10 million.

Creation or Elimination of Jobs

The requirement to submit Priority Product Notifications and Abridged AA Reports or two-stage AA Reports is not likely to result in the creation or elimination of jobs in California. DTSC anticipates zero ongoing costs associated with this proposed regulation. DTSC expects that the one-time costs associated with the Priority Product Notifications and AA Reports are low enough for all potentially impacted manufacturers to comply without impacting the number of jobs at their businesses. Manufacturers can significantly reduce their individual costs of compliance by submitting a combined AA Report through a consortium.

The AA process requires manufacturers to provide DTSC with data and analysis to determine whether reasonable alternatives exist. DTSC reviews each AA Report on its own merits, taking into consideration each manufacturer's unique conclusions and proposals. Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that manufacturers of treatments for use on converted textiles or leathers would need to take, either individually or collectively, to meet the goals of protecting people and the environment and advance green chemistry or green engineering principles. While it is impossible to accurately predict or quantify the full range of potential benefits associated with the implementation of this proposed regulation, DTSC anticipates that it could lead to additional jobs in consulting services, chemical and material science research and support, product research and design, marketing, and the development of consumer product safety information and training materials.

Creation of New Businesses or Elimination of Existing Businesses

DTSC determined that this proposal is unlikely to result in the elimination of any treatments for use on converted textiles or leathers manufacturers. DTSC anticipates zero ongoing costs associated with this proposed regulation. DTSC expects that the one-time costs associated with the Priority Product Notifications and AA Reports are low enough for all potentially impacted manufacturers to comply without eliminating their businesses. Manufacturers can significantly reduce their individual costs of compliance by submitting a combined AA Report through a consortium.

The AA process requires manufacturers to provide DTSC with data and analysis to determine whether reasonable alternatives to the use of the Chemical of Concern in the Priority Product exist. DTSC reviews each AA Report on its own merits, taking into consideration each manufacturer's unique conclusions and proposals. Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that manufacturers of treatments for use on converted textiles or leathers would need to take, either individually or collectively, to meet the goals of

protecting people and the environment and advance green chemistry or green engineering principles. While it is impossible to accurately predict or quantify the full range of potential benefits associated with the implementation of this proposed regulation, DTSC anticipates that it could lead to creation of new businesses in consulting services, chemical and material science research and support, product research and design, marketing, and the development of consumer product safety information and training materials.

Expansion of Businesses Currently doing Business

The AA process requires manufacturers to provide DTSC with data and analysis to determine whether reasonable alternatives exist. DTSC reviews each AA Report on its own merits, taking into consideration each manufacturer's unique conclusions and proposals. Because each manufacturer's proposal will address its specific business situation, DTSC cannot predetermine the actions that manufacturers of treatments for use on converted textiles or leathers would need to take, either individually or collectively, to meet the goals of protecting people and the environment and advance green chemistry or green engineering principles. While it is impossible to accurately predict or quantify the full range of potential benefits associated with the implementation of this proposed regulation, DTSC anticipates that it could lead to expanded business opportunities in consulting services, chemical and material science research and support, product research and design, marketing, and the development of consumer product safety information and training materials.

Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment

The primary goal of SCP regulations is to protect public health by reducing exposures to potentially harmful chemicals. By listing treatments containing any PFASs for use on converted textiles or leathers as a Priority Product, DTSC sets in motion a strategy to reduce human exposure to PFASs from the manufacturing, use, and end-of-life this product. A reduction in exposure to PFASs could benefit the health of California's residents and wildlife. The development of safer alternatives benefits California workers, consumers, employers, and the environment.

DTSC cannot pre-determine the alternatives that each manufacturer will propose; therefore, it is impossible to accurately predict or quantify the full range of potential benefits associated with their development. DTSC will maximize the use of alternatives of least concern and give preference to those that provide the greatest level of inherent protection. In general, economic benefits to California workers and business owners may include expanded employment opportunities in the fields of consulting, worker and consumer education, and marketing. Additional benefits may accrue because of

increased research and product development collaboration between manufacturers and California-based research entities. Institutional and corporate financial support of chemical and material science programs focused on developing safer alternatives to PFASs could advance the field. These research initiatives could provide manufacturers with employees that are highly skilled in the research and design of products for newly emerging global markets.

While some of these economic benefits will arise from individual DTSC regulatory responses crafted for specific responsible entities, many of the benefits will also arise from the Alternatives Analysis (AA) process. For example, responsible entities that explore safer alternatives, as opposed to simply removing the product from the market, will need to perform rigorous scientific research into alternative chemical-product combinations during the AA development process. This research will stimulate economic activity.

REASONABLE ALTERNATIVES CONSIDERED

Government Code section 11346.2, subdivision (b)(4) requires DTSC to consider and evaluate reasonable alternatives to the proposed regulatory action and provide reasons for rejecting those alternatives. This section discusses alternatives evaluated and provides reasons why these alternatives were not included in the proposal. As explained below, no alternative proposed was found to be less burdensome and equally effective in achieving the purposes of the regulation in a manner than ensures full compliance with the authorizing law. DTSC has not identified reasonable alternatives that would lessen any adverse impact on small business.

Alternative 1: List treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers as a Priority Product.

This is the chosen alternative, because it is the only alternative effective in achieving the purposes of the regulation.

Alternative 2: List treatments containing long-chain perfluoroalkyl acids (PFAAs) and their precursors for use on converted textiles or leathers as a Priority Product.

While they may be present in imported treatment products for use on converted textiles or leathers, long-chain PFAAs and their precursors have been phased out from domestic use following U.S. EPA’s 2010/2015 voluntary Stewardship Program. Shorter-chain PFAAs, which form the basis for currently used PFASs in treatments for use on converted textiles or leathers, show potential for some of the same adverse health hazards as their longer-chain counterparts, including developmental toxicity, endocrine toxicity, hematotoxicity, hepatotoxicity, neurodevelopmental toxicity, and reproductive

toxicity. To meaningfully protect California's people and environment, DTSC decided to include treatments containing any PFASs for use on converted textiles or leathers in its Priority Product designation.

Alternative 3: List treatments containing perfluoroalkyl acids (PFAAs) and their precursors for use on converted textiles or leathers as a Priority Product.

Side-chain fluorinated polymers, which are PFAA precursors, are the main type of PFAS in treatments for use on converted textiles or leathers. However, perfluoropolyethers, which may not be PFAA precursors, can also be used in these products. DTSC is concerned about perfluoropolyethers as well, because they are persistent, may contain PFAAs as impurities, and may degrade into PFAAs if incinerated. Incineration for energy recovery is a common end-of-life fate for converted textiles or leathers in California. Additionally, in a letter submitted during DTSC's regulatory public comment period for another proposed Priority Product, 3M, one of the manufacturers of treatments for converted textiles and leathers, explained that there is at least one fluoropolymer emulsion used as an aftermarket cleaning product for carpets and other such textile products. Fluoropolymers are manufactured using PFAAs, leading to extensive environmental contamination, contain PFAA impurities, and may degrade to PFAAs if incinerated. Given the known hazard traits, replacing currently-used PFASs in treatments for converted textiles or leathers with other members of the PFAS class could constitute a regrettable substitution. Therefore, to adequately protect California's people and environment, DTSC decided to include treatments containing any PFASs for use on converted textiles or leathers in its Priority Product designation.

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. DTSC has determined that no federal regulations overlap or conflict with this proposal to list treatments containing members of the class of PFASs for use on converted textiles or leathers, nor with any subsequent regulation that may result from such listing.

Section 5 of the Toxic Substances Control Act (TSCA) authorizes U.S. EPA to issue Significant New Use Rules (SNURs) for new chemicals or existing chemicals used in a significant new way. A SNUR requires companies to notify U.S. EPA at least 90 days prior to manufacturing, importing, or processing substances for a significant new use, and to submit a notification including information about the chemical's identity, physical

characteristics, processing and use, and available toxicity data. U.S. EPA has 90 days to evaluate the new use and can request more data, prohibit or limit the manufacture, or allow the use. The following SNURs relate to PFASs:

- December 9, 2002 – SNUR regarding any future manufacture (including imports) of 75 PFASs specifically included in the 2000-2002 voluntary phaseout of PFOS by 3M;

- March 11, 2002 – SNUR regarding any future manufacture (including imports) of 13 PFASs specifically included in the 2000-2002 voluntary phaseout of PFOS by 3M;

- October 9, 2007 – SNUR for 183 PFASs believed to no longer be manufactured, imported, or used in the U.S.;

- October 22, 2013 – SNUR requiring companies to report their intent to manufacture certain PFOA-related chemicals to treat carpets, as well as their intent to import carpets containing these PFASs;

- (Proposed) January 21, 2015 – proposed SNUR affecting manufacturers (including importers) of PFOA and PFOA-related chemicals, including as part of articles, and processors of these chemicals;

- (Proposed) February 20, 2020 – supplemental to a SNUR issued on certain PFASs in 2015; amendment includes regulation on imported products that contain certain PFASs used as part of surface coatings; and

- June 22, 2020 – final SNUR requiring notice before anyone can (1) resume the manufacturing or processing of specific long-chain PFASs that have been phased out in the U.S. or (2) import products containing certain long-chain PFASs as surface coatings or import carpets containing perfluoroalkyl sulfonates.

Since 2000, U.S. EPA has reviewed hundreds of substitutes for PFOA, PFOS, and other longer-chain PFASs, particularly regarding their toxicity, fate, and bioaccumulation under the New Chemicals Program. For many PFASs, U.S. EPA has worked with individual submitters pursuant to TSCA section 5(e) to develop Consent Orders, which typically contain certain requirements such as testing, while allowing production and use.

Section 5 of TSCA and pursuant consent orders do not provide the same level of public health and environmental protection that would be provided by designating a Priority Product. TSCA is based on a risk assessment approach. SCP, however, considers the

potential human and ecological exposures and the potential for significant or widespread adverse impacts, which provides a greater level of protection. TSCA's focus is solely on prohibiting or limiting the manufacture, processing, distribution in commerce, use, or disposal of a substance. It does not address the creation of safer products.

On January 27, 2010, U.S. EPA amended the Polymer Exemption Rule for new chemicals under TSCA to exclude certain side-chain fluorinated polymers due to potential risk to human health or the environment.

The National Defense Authorization Act for Fiscal Year 2020 (NDAA), signed into law on December 20, 2019, contains multiple PFAS-related amendments, including a ban on the use of PFASs in food packaging for military ready-to-eat meals and the phaseout of PFAS-containing firefighting foam. Additionally, section 7321 of the NDAA added several PFASs to the Toxics Release Inventory (TRI) under section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA), effective January 1, 2020.

To date, no federal regulation has been developed to address the class of PFASs nor the PFASs commonly used in treatments for use on converted textiles or leathers, and therefore there is no conflict or duplication between federal regulation and this proposed rule.

REFERENCES

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. Division 4.5, Title 22, California Code of Regulations, Chapter 55. Safer Consumer Products.

DOCUMENT RELIED ON

DTSC (2021) Product-Chemical Profile for Treatments Containing Perfluoroalkyl or Polyfluoroalkyl Substances for Use on Converted Textiles or Leathers.

APPENDIX

A. Proposed Regulatory Text.