INITIAL STATEMENT OF REASONS

~~August 2021~~ July 2022

SAFER CONSUMER PRODUCTS REGULATIONS – Listing Nail Products Containing Toluene as a Priority Product

Department of Toxic Substances Control Reference Number: R-2019-04

Office of Administrative Law Reference Number: 2021-0921-06

Table of Contents

INTRODUCTION AND BACKGROUND

The Department of Toxic Substances Control (DTSC) proposes to amend section 69511 and add section 69511.6 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 nail products containing toluene 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~~ proposes to identify nail products containing toluene – including nail coatings and nail polish thinners – as a Priority Product and set an Alternatives Analysis Threshold (AAT) of 100 parts per million (ppm) for toluene in the Priority Product in accordance with section 69503.5(c).

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 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
- the potential effects of the Chemical of Concern 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, 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 life cycle 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

a) 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 decide whether 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~~ Allowing DTSC to identify and require implementation of Regulatory Responses following the completion on an AA, as needed; 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.

b) Priority Products List

DTSC previously placed ~~selected~~ the following product-chemical combinations ~~in~~ onto 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 unreacted methylene diphenyl diisocyanates;
- Paint or varnish strippers containing methylene chloride; ~~and~~
- Carpets and rugs containing perfluoroalkyl or polyfluoroalkyl substances; and
- Treatments containing perfluoroalkyl or polyfluoroalkyl substances for use on converted textiles or leathers.

DTSC is updating the Priority Product List by conducting this rulemaking to adopt nail products containing toluene as a Priority Product.

c) 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 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.

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 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 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.

d) 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 alternative, or stop selling the product in California. Section 69505.1(a) and section~~s~~ 69505.4, subdivisions (b), (c), and (d) identify the options a manufacturer must comply with in lieu of conducting an AA. Alternatively, if DTSC sets an Alternatives Analysis Threshold (AAT) and the concentration of the chemical of concern in the Priority Product does not exceed the AAT, the manufacturer may submit an AAT Notification in lieu of an AA, in accordance with section 69505.3. DTSC may set an AAT when the chemical of concern is present in the Priority Product as a contaminant, or if DTSC determines an AAT would be appropriate for a chemical of concern that is an intentionally added ingredient in a Priority Product.

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 call for importers, retailers, or assemblers 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 information provided by manufacturers in AA reports and proposed Regulatory Responses are tailored to address specific business situations, DTSC cannot predetermine which Regulatory Response, if any, will be proposed by DTSC after the AA process is complete. ~~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)).~~

DTSC's determination to set an AAT for the Priority Product

After consideration of comments received during the initial 45-day comment period, DTSC is proposing to set an AAT for toluene in nail products at 100 ppm based on the following:

- DTSC's goal in listing this Priority Product is to reduce the potential for nail salon workers and nail product consumers to be exposed to, and harmed by, toluene that is intentionally added in nail products as an ingredient.
- Data received in 2020 from nail product manufacturers and other entitles indicated that toluene was present in nail products as a contaminant, a residual, or an intentionally added ingredient.

- DTSC recently conducted analytical laboratory testing of 157 nail products and detected toluene in 27 nail products at concentrations ranging from 31.4 ppm to 187,000 ppm. These findings were consistent with the information from manufacturers reporting that toluene is in some products as an intentionally added ingredient where it was found at high concentrations, and present in other products as a contaminant or residual where it was found at much lower concentrations.
- During the 45-day regulatory public comment period, industry stakeholders requested that DTSC set an AAT above contaminant levels. When toluene is present as a contaminant in nail products, the concentration is generally 100 ppm or lower, according to these commenters.
- Several other states have enacted laws requiring that manufacturers report products marketed to children that contain toluene and other specified chemicals above a contamination threshold of 100 ppm, including:
    - Oregon Toxic Free Kids Act;
    - Washington Children's Safe Products Act; and
    - Vermont Chemicals of High Concern to Children Law.

DTSC is proposing to allow manufacturers of the Priority Product the option of demonstrating that their products qualify for the AAT Notification by providing testing data from ingredient suppliers. During adoption of the SCP framework regulations in 2012, DTSC stated, in responses to public comments related to the AAT, that it would not accept supplier declarations or certification of material content as a demonstration of a Priority Product meeting the AAT. However, DTSC has determined that it is appropriate in this instance, for nail products containing toluene, to allow manufacturers to use information from suppliers if the manufacturer determines and certifies that the supplier meets specified reporting and analytical requirements to measure the concentration of toluene in the supplied ingredients. DTSC believes it is appropriate to allow manufacturers to use information from suppliers for toluene in nail products due to toluene's likely presence in nail product supply chain ingredients at low concentration levels.

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)(6~~7~~) to identify nail products containing toluene as a Priority Product on the Priority Products list.

Necessity. DTSC proposes to adopt nail products containing toluene 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 toluene, DTSC concluded that there is a potential for exposure to toluene during the manufacturing and use of nail products containing toluene. These exposures could potentially contribute to or cause significant or widespread 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

Nail products and professional manicure/pedicure services are popular in the United States. In California alone, there are more than 9,000 nail salons with 130,336 licensed manicurists. Nail products, including ones containing toluene, are also widely used at home. Retail sales of nail products exceed $1 billion per year in the U.S. In 2015-16, nail polish sales represented $741 million of this amount.

Analytical testing data confirms the use of toluene in nail products. One study detected toluene in 26 out of 34 nail products analyzed, including base coat, top coat, nail polish thinner, gels, remover, and nail polish products, with concentrations ranging from 1.36 to 173,000 ppm (µg/g by weight) (up to 17.3 percent). DTSC found comparable concentrations in its own testing of nail products in 2012. In that study, 10 of 12 nail coating products labeled “toluene-free” contained toluene, ranging in concentration from 42 to 177,000 ppm (17.7 percent). Further, eight of 13 nail coating products that made no claims to be toluene-free contained toluene at levels ranging from 110 to 120,000 ppm (0.011 percent to 12 percent). More recently, DTSC conducted analytical laboratory testing of 157 retail and professional-use nail products and detected toluene in 27 nail coatings and nail polish thinners at concentrations ranging from 31.4 ppm to 187,000 ppm.

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

DTSC has determined that exposure to toluene through normal use of nail products may contribute to or cause significant or widespread adverse impacts to Californians, including sensitive subpopulations such as nail salon workers, pregnant women and their fetuses, infants, children, and adolescents. This determination is based on toluene's volatility and the potential for inhalation exposure in nail salons and at home, the hazard traits associated with toluene, and data showing measured toluene levels in air samples collected in homes and nail salons. Inhalation is the primary toluene exposure route of nail industry workers and nail product consumers. However, toluene exposure may also occur through dermal application of products and orally, from accidental ingestion and hand-to-mouth behavior.

Exposures to nail products containing toluene may contribute to or cause significant or widespread adverse impacts because:

- Toluene is a neurotoxicant with endpoints including dizziness, fatigue, headache, and decreased manual dexterity;
- Toluene is a developmental toxicant and toluene exposure is linked to adverse effects in developing fetuses and has the potential to cause birth defects;
- Toluene is a neurodevelopmental toxicant and animal studies show that inhalation exposure to toluene during brain development resulted in prolonged neurodevelopmental toxicity and adverse impacts on cognitive function;
- Toluene is a respiratory toxicant and nephrotoxicant and exposure to toluene causes harm to respiratory tract and kidneys; and
- Toluene is an immunotoxicant, ocular toxicant, and ototoxicant and exposure to toluene causes adverse impacts to the immune system and vision and hearing impairment.

Toluene is a liquid at room temperature and readily volatilizes into indoor air. Several studies conducted in nail salons detected toluene at concentrations higher than California's chronic Reference Exposure Levels. Further, a 2011 personal air monitoring study of 80 workers from 20 nail salons in California detected toluene and other VOCs in salon workers' breathing zones. Additionally, in 2016, another research study sampled indoor air over a four-hour duration in a number of Los Angeles-area nail salons and detected toluene in 75 percent of the salons. The highest detected toluene concentration of 130 ppb (490 $\mu g/m^3$) was above the chronic OEHHA Reference Exposure Level (REL) of 110 ppb (420 $\mu g/m^3$).

Chemical exposure of nail industry workers is an environmental justice issue, as a large majority of nail industry workers are people of color and lower socioeconomic status. Nail salon workers' potential for exposure to toluene is exacerbated by several factors: They often work in excess of eight-hour days or 40-hour weeks; they are often not

provided with adequate information concerning chemical safety; they are often not provided with proper personal protective equipment (PPE); and their workplaces often lack appropriate ventilation.

Pregnant nail technicians and their fetuses are especially sensitive to adverse impacts of toluene exposure from nail products. Infants and children of nail technicians often accompany their parents to the workplace and may be exposed to toluene-containing nail products. Even if they are not directly exposed to toluene-containing nail products, nursing infants and children may be exposed to toluene, as indicated by detected toluene in human milk. Infants and young children are more susceptible than adults to adverse impacts from toluene due to physiological differences.

Add Section 69511.6. Nail Products Containing Toluene.

Purpose. In its entirety, this section identifies nail products containing toluene 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 nail products containing toluene as a Priority Product, DTSC sets in motion a strategy to reduce human exposure to toluene from use in nail products. A reduction in exposure to toluene could benefit the health of California's residents, especially nail salon workers. 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 69511.6(a).

Purpose. This section provides a description of the product-chemical combination of nail products containing toluene, which includes nail coatings and nail polish thinners that contain toluene as an added ingredient, a residual, or a contaminant.

Necessity. DTSC describes "nail products containing toluene" to mean nail products containing toluene, which includes nail coatings and nail polish thinners that contain toluene as an added ingredient, residual, or a contaminant. Any responsible entity that manufacturers, sells, imports, or assembles a nail product containing toluene as an added ingredient or as a known or suspected contaminant or residual is required to submit a Priority Product Notification.

"Nail coating" means any clear or colored paint, polish, lacquer, enamel, or gel product marketed or sold for application to fingernails or toenails.

There are two types of nail coatings: solvent-based nail coatings and UV gel nail coatings.

"Solvent-based nail coatings" are clear or colored nail coatings that form a hard coating on nails upon evaporation of their solvents. Subproducts include nail polishes, lacquers, enamels, base coats, undercoats, top coats, and gel nail polishes.

- "Nail polish" is a varnish or paint applied to the fingernails or toenails to color them or make them shiny.
- "Lacquer" or "enamel" is a coating that dries by means of solvent evaporation.
- "Base coat" or "undercoat" is a clear or milky-colored coating that is used before applying other coatings to the nail. It may be marketed for strengthening or protecting the nail, restoring moisture to the nail, or helping other coatings to adhere to the nail.
- "Top coat" is a clear coating that is used after applying other coatings to the nail. It may be used to protect underlying coatings or to add shine, gloss, or matte to the nail.
- "Gel nail polish" or "gel polish" is a gel varnish coating with a look and feel similar to UV gel nail coatings but that does not require an ultraviolet (UV) or a light-emitting diode (LED) lamp to dry. Gel nail polish typically contains color but can also be a clear nail coating.

"UV gel nail coatings" are clear or colored gel nail coatings that are cured or hardened on nails using a UV or an LED lamp rather than solvent evaporation. Subproducts include UV gel nail polish, UV gel topcoat, UV gel base coat, hard gel, and Shellac.

- “UV gel nail polish” or “UV gel” or “Gel” or “nail gel” is a premixed coating that is hardened using a UV or an LED lamp. UV gel nail polish typically contains color but can also be a clear coating.
- “UV gel base coat” is a clear coating that is used before applying other UV gel coatings to the nail; it is cured using a UV or an LED lamp.
- “UV gel top coat” is a clear coating that is used after applying other UV gel coatings to the nail; it is cured using a UV or an LED lamp.
- “Hard gel” is a premixed coating with high solvent resistance; it is hardened using a UV or an LED lamp. It can be applied directly onto natural nails to provide additional strength or sculptured using nail enhancements.
- “Shellac” is the brand name for a nail product created by Creative Nail Design. It is a hybrid which is a combination of nail polish and gel. Shellac is applied directly onto natural nails, and it is cured through UV light.

Nail coatings include “nail art paint,” which is any decorative paint including various solvent-based or UV gel nail coating overlays of nail polish, UV gel, or hybrid coatings like Shellac or airbrush paint applied to fingernails, toenails, or both by any technique. “Airbrush nail art paint” is a subcategory of “nail art paint.”

- “Airbrush nail art paint” means a nail art paint that is designed or intended to be sprayed onto the nail by a device using compressed air. This product may also be labeled as ink, polish, paint, or pigment for airbrush nail art.

“Nail polish thinner” means any liquid product that is marketed or sold for the use of reducing viscosity of nail coatings. It may be marketed for the use of increasing the fluidity or restoring the consistency of nail coatings.

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). Clearly describing the product-chemical combinations allows responsible entities and the public to understand the Priority Product being listed.

Add Section 69511.6(b).

Purpose. This section describes the rationale DTSC used to identify toluene as the Candidate Chemical and the basis for proposing nail products containing toluene being listed as a Priority Product. For purposes of this chapter, toluene is identified as a chemical meeting the following definition: toluene is identified by the chemical abstract service (CAS) registry number 108-88-3, and common synonyms or trade names

include methylbenzene, phenylmethane, benzene methyl-, toluol, methylbenzol, methacide, and antisal 1A. Toluene is a clear, colorless, flammable volatile liquid that has a sweet and pungent odor. Toluene is used as a solvent in a variety of nail products such as nail polish, nail hardeners, and nail polish thinners.

Necessity. Consistent with section 69503.6(a) of the SCP regulations, DTSC identified toluene as the Candidate Chemical because toluene is included on authoritative lists as specified in section 69502.2(a) and meets the following criteria:

- Identified as a Toxic Air Contaminant under sections 93000 and 93001 of title 17 of the California Code of Regulations.
- Identified on the Centers for Disease Control and Prevention's *Fourth National Report on Human Exposure to Environmental Chemicals and Updated Tables.*
- Identified with non-cancer endpoints and listed with an inhalation or oral Reference Exposure Level by the California OEHHA under Health and Safety Code section 44360(b)(2).
- Identified as a chemical known to cause cancer and/or reproductive toxicity that is listed under Health and Safety Code section 25249.8 of the California Safe Drinking Water and Toxic Enforcement Act of 1986.
- Identified as a chemical for which a Primary Maximum Contaminant Levels has been established and adopted under section 64431 or section 64444 of Chapter 15 of title 22 of the California Code of Regulations.
- Identified as a priority pollutant in California Water Quality Control Plans under section 303(c) of the federal Clean Water Act and in section 131.38 of title 40 of the Code of Federal Regulations or identified as a pollutant by California or the U.S. EPA for one or more water bodies in California under section 303(d) of the federal Clean Water Act and section 130.7 of title 40 of the Code of Federal Regulations.
- Identified as a neurotoxicant that is identified in the Agency for Toxic Substances and Disease Registry's Toxic Substances Portal, Health Effects of Toxic Substances and Carcinogens, Nervous System.
- Identified as a chemical for which a reference dose or reference concentration has been developed based on neurotoxicity in the U.S. EPA's Integrated Risk Information System.

This section is necessary to clearly identify to responsible entities and the public that toluene is the Candidate Chemical that is the basis for listing nail products containing toluene as a Priority Product. This section also satisfies the provisions of Health and Safety Code section 25252 that require DTSC to reference and use available information from other nations, governments, and authoritative bodies. Clearly identifying the Candidate Chemical allows responsible entities and the public to understand the basis for listing nail products containing toluene as a Priority Product.

Add Section 69511.6(c).

Purpose. This section indicates the hazard traits associated with toluene. 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 toluene in nail products has the potential to harm Californians. Consistent with 22 CCR section 69503.6(a) of the SCP regulations, DTSC identified toluene as a Candidate Chemical, because toluene is included on certain authoritative lists or have been identified as a certain type of chemical.

Exposure to toluene is associated with the following hazard traits:

- Neurotoxicity,
- Developmental toxicity,
- Neurodevelopmental toxicity,
- Respiratory toxicity,
- Nephrotoxicity,
- Dermatotoxicity,
- Immunotoxicity,
- Ocular toxicity, and
- Ototoxicity.

In the human body, toluene is metabolized to the major metabolite hippuric acid and the minor metabolites ortho-cresol (o-cresol), meta-cresol (m-cresol), para-cresol (p-cresol), and benzaldehyde. DTSC lists ortho-, meta- and para-cresol as Candidate Chemicals, and CARB identifies ortho-, meta-, and para-cresol, as well as mixed cresols, as toxic air contaminants. The U.S. EPA Integrated Risk Information System (IRIS) also lists o-cresol and m-cresol as neurotoxicants. DTSC also lists the family of cresols, or mixed cresols, as Candidate Chemicals, and Agency for Toxic Substances and Disease Registry (ATSDR) and Office of Environmental Health Hazard Assessment (OEHHA)

consider mixed cresols neurotoxicants. Toluene distributes widely in the body and preferentially to the brain, liver, and kidney; it is capable of crossing the blood-brain barrier and the placenta, exposing the developing fetus to toluene.

This section is necessary because it identifies why exposure to toluene from nail products may contribute to or cause adverse impacts to Californians, including sensitive subpopulations such as nail salon workers, pregnant women and their fetuses, infants, children, and adolescents. This section also satisfies the provisions of Health and Safety Code section 25252 that require DTSC to develop and use criteria by which chemicals and their alternatives may be evaluated, including hazard traits, physicochemical characteristics, and toxicological endpoints. Clearly describing the hazard traits of the Candidate Chemical allows responsible entities and the public to understand the basis for listing nail products containing toluene as a Priority Product.

Add Section 69511.6(d).

Purpose. This section indicates toxicological endpoints associated with exposure to toluene, in accordance with section 69503.5(b)(2)(A). These toxicological endpoints include dizziness, fatigue, headache, decreased manual dexterity, and chronic degenerative brain disorder; decreased birth weight or retarded skeletal development; impaired cognitive function; respiratory tract irritation; increased kidney weight or metabolic acidosis; skin irritation; decreased thymus weight or dose-dependent effects on suppression of antibody response; vision effects or optic nerve damage; and hearing loss.

Necessity. This section is necessary to identify toxicological endpoints associated with exposure to toluene. This section also satisfies the provisions of Health and Safety Code section 25252 that require DTSC to develop and use criteria by which chemicals and their alternatives may be evaluated, including hazard traits, physicochemical characteristics, and toxicological endpoints.

Exposure to toluene is associated with the following endpoints:

- Dizziness, fatigue, headache, decreased manual dexterity, and chronic degenerative brain disorder,
- Decreased birth weight or retarded skeletal development,
- Impaired cognitive function,
- Respiratory tract irritation,
- Increased kidney weight or metabolic acidosis,
- Skin irritation,
- Decreased thymus weight or dose-dependent effects on suppression of antibody response,

- Vision effects or optic nerve damage, and
- Hearing loss.

Clearly describing the toxicological endpoints of the Candidate Chemical associated with exposure to toluene by manufacturers, nail salon workers, and consumers of nail products containing toluene allows those who could be exposed to be aware of potential adverse impacts that could occur with normal use.

Add Section 69511.6(e).

Purpose. This section designates the Candidate Chemical, toluene, 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 toluene is the Chemical of Concern in nail products containing toluene 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 69511.6(f).

Purpose. This section provides responsible entities with a due date for submission of the Priority Product Notification and the Preliminary ~~Alternatives~~ Analysis ~~(~~AA~~)~~ Report. Further, this section makes it clear that a manufacturer submitting an AAT Notification to request an exemption from the AA requirements must do so no later than the due date for the Preliminary AA Report, as indicated in section 69505.3(a).

Necessity. This section is necessary to comply with sections 69505.3(a) and 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. Identifying the due date for submission of the Preliminary ~~Alternatives Analysis~~ ~~(~~AA~~)~~ Report or the AAT Notification clarifies the compliance expectations for responsible entities.

Add Section 69511.6(g).

Purpose. This section indicates that an AAT is being set at 100 ppm for toluene in nail products.

Necessity. Toluene may be present in nail products either as an intentionally added ingredient or as a contaminant or residual. The default AAT for a contaminant is the

Practical Quantitation Limit (PQL), which is defined in section 69501.1(a)(52) as “the lowest concentration of a chemical that can be reliably measured within specified limits of precision and accuracy using routine laboratory operating procedures.” DTSC may also set the AAT at a higher level, pursuant to section 69503.5(c). DTSC was informed that, when toluene is present as a contaminant in nail products, the concentration is generally 100 ppm or lower. Further, as noted earlier, several other states with chemical ingredient disclosure laws for children’s products have established a reporting threshold for toluene of 100 ppm. Based on these factors, DTSC has chosen to set the AAT for nail products at 100 ppm.

If the concentration of toluene in a product does not exceed the AAT, the manufacturer of that product may submit an AAT Notification instead of an AA Report. The AAT Notification may be submitted concurrently with the Priority Product Notification or afterwards, but not later than the due date for the Preliminary AA Report. If the manufacturer submits an AAT Notification, the manufacturer must also certify that it meets and will continue to meet the criteria and conditions that are the basis for the AA exemption.

Add Section 69511.6(h).

Purpose. This section specifies the reporting requirements for a manufacturer submitting an AAT to demonstrate and certify that the concentration of toluene in a product does not exceed the AAT.

This section also provides the sample preparation, analytical methods, instrumentation, calibration, and quality control criteria that a testing laboratory must follow if a manufacturer chooses to submit laboratory testing results of the formulated Priority Product.

Necessity. This section is necessary to ensure that manufacturers who assert that they are exempt from AA requirements understand the reporting requirements. To this end, this section specifies that a manufacturer may submit certificates of analyses from ingredient suppliers along with calculations of the concentration of toluene in the formulated Priority Product or they may submit laboratory testing results that demonstrate the concentration of toluene in the Priority Product. This section also specifies the laboratory criteria that must be met for measuring toluene in each Priority Product as well as the data submittal requirements. This section provides the specific quality control requirements and documentation to be submitted with an AAT Notification.

ENVIRONMENTAL JUSTICE

Government Code section 65040.12(e) defines “environmental justice” as “the fair treatment and meaningful involvement of people of all races, cultures, and incomes with respect to the development, adoption, implementation, and enforcement of environmental laws, regulations, and policies.” DTSC is committed to making environmental justice an integral part of its activities by promoting equity throughout its policies, programs, and decision-making; reducing the environmental and health burden of hazardous exposures on disadvantaged and vulnerable communities and California Native American Tribes; and leveraging funding and workforce development opportunities to redress those burdens. These policies apply to all communities in California, but DTSC recognizes that environmental justice issues have been raised more in the context of disadvantaged and vulnerable communities.

The use of nail products in salons and at home has the potential to expose nail technicians, other salon workers, patrons, and nail product consumers to toluene. Toluene has been detected in salon indoor air at levels above California regulatory standards, and nail technicians (also known as manicurists) have an especially high potential for exposure. Nail salon workers may have daily exposure to toluene. Moreover, nail technicians often have longer workdays and workweeks compared to employees in other sectors. Nail technicians may be exposed to toluene due to its frequent use in the workplace and some nail technicians work while pregnant; thus, their fetuses are also at risk of toluene exposure.

Nail technicians’ exposure to chemicals is an environmental justice issue in California, as a large majority of nail technicians are people of color and lower socioeconomic status. California’s nail industry workforce is composed of approximately 130,000 licensed nail technicians. According to the U.S. Census Bureau, out of over 9,000 nail salons in California, 90 percent of the salons in California are minority-owned, and 68 percent of salons are owned by ethnic Vietnamese. Approximately 59 to 80 percent of California nail salon workers are women of Vietnamese descent, many of whom face workplace safety challenges due to language barriers, limited education on chemical exposure from products, limited availability and use of personal protective equipment (PPE), and lack of appropriate ventilation at their workplace.

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 nail products market data, 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 Analysis is also based on the assumption that manufacturers of nail products containing toluene 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 nail products containing toluene that do not submit AA Reports must: 1) remove the toluene from their nail products; 2) replace the toluene with a different chemical that meets certain regulatory requirements for those products; or 3) stop selling nail products containing toluene in California. If a manufacturer fails to comply with the regulation and DTSC provides notice of this noncompliance, the requirements 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 not result in a total economic impact on the state's businesses of more than $10 million. Therefore, 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 nail products containing toluene to submit Priority Product Notifications, AA Reports, and to respond to DTSC's reviews of these submittals to be from $13,486 ~~$1,243,000~~ to $3,376,000 ~~$3,355,000~~. DTSC estimates there are a maximum of 11 manufacturers of nail products containing toluene that make and sell their products in California. However, all manufacturers of nail products containing toluene that also sell their product in California would be required to comply with this regulation. All of these types of manufacturers, 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 nail products containing toluene. 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 estimates that each manufacturer submitting an AAT Notification will invest a maximum of three hours at $42/hour to complete the notification and respond to

questions from DTSC. Each manufacturer may develop AAT Notifications for up to, at most, 20 percent of their products. Some of the larger manufacturers possess product ingredient laboratory results produced and gathered onsite, while most manufacturers will obtain and transmit ingredient certification specifications from their suppliers.

DTSC estimates the cumulative cost for all affected California manufacturers of nail products containing toluene to submit AAT Notifications and to respond to DTSC's reviews of these submittals to be between $13,486 to $20,748.

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 estimate of costs that individual manufacturers may absorb, 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.

In addition, DTSC has surveyed manufacturers of ~~paint or varnish strippers containing methylene chloride in a~~ previous Priority Products, who estimated ~~DTSC regulatory action for their expected costs of submitting an AA. Those interviewed indicated that they expect~~ the cost to prepare and submit the first stage of an AA ~~to cost their businesses~~ to range 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.~~ In the same survey, ~~M~~manufacturers ~~of these other products~~ estimated the cost to prepare ~~they would incur~~ an Abridged AA Report ~~costs~~ to range from $50,000 to $150,000~~ to prepare an Abridged AA Report~~ and the cost to prepare a two-stage AA Report to range from ~~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 in manufacturer costs 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 in response to a ~~separate~~ previous Priority Product listing 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 to submit a combined AA Report, overall costs could be lower. Collaborative approaches have been used to author AA reports for previously listed Priority Products.

DTSC estimates the maximum combined total costs to manufacturers for engaging in the development of Priority Product Notifications, AAs, and AAT Notifications will not exceed $3,376,000.

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, two-stage AA Reports, and AAT Notifications in response to this proposed regulation 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 nail product 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. 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 manufacturers of nail products. DTSC anticipates zero ongoing costs associated with this proposed regulation. DTSC expects that the one-time costs associated with the Priority Product Notifications, AA Reports, and AAT Notifications 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 nail product manufacturers 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~~ whether any Regulatory Response will be proposed by DTSC after the AA process is complete. 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 the preparation of AA Reports ~~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 nail products 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 the SCP regulations is to protect public health by reducing exposures to potentially harmful chemicals. By listing nail products containing toluene as a Priority Product, DTSC sets in motion a strategy to reduce human exposure to toluene from the manufacturing, use, and end-of-life these products. A reduction in exposure to toluene could benefit the health of California's residents and wildlife. The development of and adoption 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.~~ DTSC anticipates benefits may result from the 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 could stimulate economic activity.

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 laboratories. Institutional and corporate financial support of chemical and material science programs focused on developing safer alternatives to toluene in nail products 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 nail products containing toluene, including nail coatings and nail polish thinner, as the Priority Product.

This option was selected because it allows DTSC to quickly and effectively reduce significant exposure to toluene from nail products.

Alternative 2: List nail products ~~polish remover~~ containing toluene, including nail coatings, nail polish thinner, as well as nail polish remover~~, among other products~~, as the Priority Product.

This option was dismissed because toluene is not used in nail polish removers in California. Historically, toluene was used as a solvent in nail polish removers, but this use is now effectively banned by the CARB Consumer Products regulations, which limit the total concentration of volatile organic compounds in polish removers to one percent by weight.

Alternative 3: List nail products containing all Candidate Chemicals that are volatile organic solvents (VOCs) used in nail products.

This was considered as an alternative but dismissed as an option due to differences in hazard traits and endpoints of various volatile organic solvents. Further, this alternative would significantly increase the scope and scale of the product-chemical combinations evaluated, greatly expand DTSC's workload, and include compounds in which their exposure does not cause or contribute to significant or widespread adverse impacts.

Small Business Alternatives

DTSC has not identified reasonable alternatives that would lessen any adverse impact on small business.

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 and whether there is a safer alternative, with the goal of protecting consumers and the environment from adverse effects associated with a product throughout its lifetime.

Nail products, as a cosmetic are regulated by the U.S. Food and Drug Administration (FDA), and toluene is regulated by the U.S. EPA, the U.S. Occupational Health and Safety Administration (OSHA), the California Division of Occupational Safety and Health (Cal/OSHA), and the California Department of Public Health (CDPH), California Safe Cosmetics Program. The proposed regulation does not duplicate or conflict with any of these regulations, which are discussed below.

U.S. Food and Drug Administration

The FDA is authorized by the Federal Food, Drug, and Cosmetic Act (FDCA) to oversee the safety of food, drugs, and cosmetics. The FDCA does not authorize the FDA to require safety testing of cosmetics, and there is no approval process for cosmetics products prior to sale in the U.S. (except for color additives). However, the FDA can and does inspect cosmetics manufacturing facilities to ensure that cosmetics are not adulterated.

While cosmetic product manufacturers are legally responsible for ensuring the safety of their products, neither the FDCA nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients, and manufacturers are not required to share their safety information with the FDA. However, the FDA can pursue enforcement action against products on the market that it determines are not in compliance with the FDCA or the Fair Packaging and Labeling Act (FPLA), or against firms or individuals who violate these laws.

Federal Food, Drug, and Cosmetic Act

The FDCA is a set of laws passed by Congress in 1938 giving authority to the FDA to oversee the safety of food, drugs, and cosmetics. The FDCA defines cosmetics as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance.” As noted above, the FDA does not pre-approve cosmetic products. However, cosmetic products must be properly labeled and

safe for consumers under labeled or typical conditions of use. The FDCA prohibits the marketing of adulterated or misbranded cosmetics in interstate commerce, and the FDA can remove cosmetics from the market that contain unsafe ingredients or that are mislabeled.

Fair Packaging and Labeling Act

The FPLA requires each package of household consumer products (including cosmetic products) to bear a label that includes a statement identifying the commodity (detergent, sponge, etc.); the name and place of business of the manufacturer, packer, or distributor; and the net quantity of contents in terms of weight, measure, or count (in both metric and English units). The FPLA is designed to facilitate value comparisons and to prevent unfair or deceptive packaging and labeling of many household consumer commodities.

The specific labeling requirements for cosmetic products are specified in regulation in Title 21 of the Code of Federal Regulations, parts 701 and 740. Cosmetic products produced or distributed for retail sale to consumers for their personal care are required to bear an ingredient declaration. Cosmetic products not typically distributed for retail sale (e.g., nail products used by professionals on customers at their places of work) are exempt from this requirement provided these products are not also sold to consumers at professional establishments or workplaces. However, the California Professional Cosmetics Labeling Law requires that all professional cosmetic products manufactured on or after July 1, 2020, and sold in California, must meet all labeling requirements for any other cosmetic pursuant to the federal Food, Drug, and Cosmetic Act and the federal Fair Packaging and Labeling Act.

U.S. Environmental Protection Agency

Toluene is listed under the Toxic Substances Control Act (TSCA) of 1976, which was enacted by Congress to test, regulate, and screen all chemicals produced in or imported into the United States. TSCA requires any chemical that reaches the consumer marketplace to be tested for possible toxic effect prior to commercial manufacture. Under Section 8, TSCA requires reporting and record keeping by persons who manufacture, import, process, and/or distribute chemical substances in commerce. Under Section 8(e), any person who manufactures (which includes importing), processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment should immediately inform EPA, except in situations where EPA has been adequately informed of such information.

Toluene is listed as a hazardous air pollutant under the Clean Air Act.

Toluene is listed as an organic hazardous air pollutant under Federal Code of Regulations 40 C.F.R., Section 63, Subpart F, National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry.

U.S. Occupational Safety and Health Administration

OSHA has set a permissible exposure limit (PEL) for workers of 200 parts per million (ppm) for toluene in air averaged over an eight-hour workday. OSHA acknowledges that many of its PELs are outdated and inadequate to ensure protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health Act in 1970 and have not been updated since then. The OSHA PEL for toluene was set in 1971. Nevertheless, changes to occupational exposure limits for a chemical are not among the regulatory response options that DTSC might eventually impose for toluene-containing nail products.

California Division of Occupational Safety and Health

In 2012, the California Division of Occupational Safety and Health (DOSH), also known as Cal/OSHA, set a PEL for workers of 10 ppm (37.6 mg/m^3) for toluene in air averaged over an eight-hour workday. If adopted, these Priority Product listing regulations would not affect existing occupational exposure limits like the PEL. DTSC may eventually impose one or more regulatory responses on manufacturers of toluene-containing nail products. However, regulatory responses must be selected from among seven options described in Article 6 of the SCP regulations; changes to occupational exposure limits for a chemical are not among these options.

California Department of Public Health, California Safe Cosmetics Program

CDPH created the California Safe Cosmetics Program (CSCP) in response to the passage of the California Safe Cosmetics Act. Beginning in 2009, cosmetic manufacturers with aggregate sales greater than $1 million must report to CSCP products they sell in California which have intentionally added chemical ingredients identified as known or suspected carcinogens or reproductive or developmental toxicants by authoritative bodies.

While the intention of the Safe Cosmetics Act is to improve access to information about potentially harmful ingredients in cosmetics and to influence the reformulation of some products toward safer alternatives, it does not duplicate the SCP regulations. The Safe Cosmetics Act requires manufacturers to report certain chemical ingredients in

products, but it does not require manufacturers to evaluate those products for safer chemical alternatives.

California Professional Cosmetics Labeling Law

The California Professional Cosmetics Labeling Law requires that all professional cosmetic products manufactured on or after July 1, 2020, and sold in California, must meet all labeling requirements for any other cosmetic pursuant to the federal Food, Drug, and Cosmetic Act and the federal Fair Packaging and Labeling Act.

California Board of Barbering and Cosmetology

The California Board of Barbering and Cosmetology (BBC) protects the public health, safety, and welfare by regulating the practices of the beauty industry (e.g., professional barbers, cosmetologists, estheticians, manicurists, and tanning salon workers). BBC qualifies and licenses individuals and businesses, establishes and enforces administrative rules and laws, and provides information for the public to make informed decisions. The BBC does not restrict or prohibit the use of toluene in nail products.

REFERENCES

Assembly Bill 1879 (Feuer, Chapter 559, Stats. 2008) and Senate Bill 509 (Simitian, Chapter 560, Stats. 2008) were signed into law on September 29, 2008, laying the critical foundation for the Green Chemistry Program. These bills provide the authority and mandate to adopt the proposed regulations.

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

DTSC. (2020) Product-Chemical Profile for Nail Products Containing Toluene.

DTSC. (2022) Revised Product-Chemical Profile for Nail Products Containing Toluene.

~~APPENDICES~~

~~A. Proposed Regulatory Text~~

~~B. Documents Relied On~~