

Economic and Fiscal Impact Analysis Attachment to STD 399

~~August 2021~~ May 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
Office of Administrative Law Reference Number: 2021-0921-06

This document details the background of the economic and fiscal impacts of the Department of Toxic Substances Control's (DTSC) proposal 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.

Note: This document only includes sections of the Form 399 for which an explanation could not fit in the space provided. As such, the section headings and titles are intentionally written to match the corresponding sections of the form and may not be in consecutive order.

Summary: The Department of Toxic Substances Control (DTSC) prepared this economic impact analysis to support the designation of Nail Products Containing Toluene as a Priority Product under the Safer Consumer Products (SCP) regulations (Chapter 55 of Division 4.5 of title 22 of the California Code of Regulations (commencing with sections 69501)). For the purposes of this regulation, DTSC defines "nail products containing toluene" as any nail coatings or nail polish thinners that contains toluene as an added ingredient, contaminant, or residual. Nail coatings include nail art paint, solvent-based nail coatings, and UV gel nail coatings.

Toluene is a clear, colorless, flammable volatile liquid that has a sweet and pungent odor. Toluene is produced in the process of making gasoline and other fuels from crude oil and in making coke from coal. Historically, toluene was used as a solvent in nail polish removers, but this use is now effectively banned by the California Air Resources Board (CARB) Consumer Products regulations. Moreover, exposure to toluene can cause or contribute to adverse nervous and immune system effects, and respiratory, liver, and kidney toxicity.

Findings: DTSC estimates that approximately ~~223~~ companies in the United States manufacture nail products containing intentionally added toluene. Approximately 11 of

those companies are based in California¹ and will be impacted by this proposed regulation. DTSC estimates that costs could range from \$13,486² ~~\$1,242,600~~ to ~~\$3,354,600~~ \$3,376,000 for California-based manufacturers to fulfill the SCP regulatory requirements ~~to submit a Priority Product Notifications and Alternatives Analyses (AA).~~

This economic impact assessment is 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 as this is the most fiscally conservative compliance pathway. Manufacturers of nail products containing toluene that do not submit AA Reports ~~must~~ may comply with the regulation in one of several ways. They may: 1) remove toluene from their nail products, 2) replace toluene with a different chemical that meets certain regulatory requirements for those products, or 3) stop selling nail products containing toluene in California.³ 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.

Nail product manufacturers may also submit Alternatives Analysis Threshold Notifications (AAT Notifications) in lieu of an Alternatives Analysis to certify that the concentration of toluene in their products does not exceed 100 ppm. At these concentrations, DTSC assumes that the toluene in the product was not added intentionally or entered the product as a contaminant. DTSC estimates that at most nine California-based manufacturers of nail products containing low levels of toluene will submit AAT Notifications. Total costs for all of these manufacturers to comply with the regulation by submitting AAT Notifications will range from \$13,486 to \$20,748.

Background: Following the designation of nail products containing toluene as a Priority Product, manufacturers must submit a Priority Product Notification and may conduct an AA to determine if there are any safer alternatives to the use of toluene in nail products. In lieu of submitting an AA Report, a manufacturer could also remove toluene from its nail products, replace toluene in its products, or stop selling their nail products containing toluene in California.

¹ 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.

² This lower bound estimate accounts for companies that submit an AAT in lieu of an AA.

³ See California Code of Regulations, title 22, section 69505.2.

In general, the AA is a two-stage process that takes into account many facets of product manufacturing, including process engineering, environmental management, financial analysis, and research and development. The AA also examines other product characteristics, such as use and end-of-life management. 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(s) 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 process, the manufacturer compares the Priority Product with possible alternatives using a more in-depth analysis and considers additional factors, including life cycle and economic impacts. This information is submitted to DTSC in the Final AA Report.

If a manufacturer determines that there are no functionally acceptable or technically feasible alternatives to use instead 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 manufacturers to document their screening of potential alternatives. Because the Abridged AA process allows for the continued sale and use of the Priority Product, Abridged AA Reports must include an implementation plan to carry out the following Regulatory Responses, which require:

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

If manufacturers of priority products cannot be identified or contacted in a reasonable manner, DTSC traces the supply chain to identify a responsible entity in the next tier of commerce. Other responsible entities include importers, assemblers, or retailers, in descending order of responsibility.⁴ ~~For instance, an importer or assembler of a priority product from an unreachable overseas manufacturer may be directed to cease sales of the product in California.~~

The completion of a draft AA report sets in motion a comprehensive and iterative review and discussion process. Following submission of an Abridged AA Report or Final AA

⁴ See California Code of Regulations, title 22, section 69501.2.

Report, DTSC will invite the public to comment on the report. Manufacturers are required to address all public comments identified by DTSC. DTSC will then initiate a departmental review of the AA Report. DTSC must evaluate each report on its own merit, taking into consideration each manufacturer's unique conclusions and proposals. Because the information provided by manufacturers in the AA Reports and any proposed Regulatory Responses they may include would address the manufacturers' 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~~ whether any Regulatory Response will be proposed by DTSC after the AA process is complete. ~~Despite uncertainty surrounding individual AA Reports, DTSC's response to these submissions will maximize the use of alternatives of least concern and give preference to Regulatory Responses that provide the greatest level of inherent protection to people and the environment.~~

I. ECONOMIC IMPACT STATEMENT

The following information supplements statements in the Economic and Fiscal Impact Statement (STD 399) for the rulemaking proposal titled "Safer Consumer Products Regulations – Listing Nail Products Containing Toluene." The section headings and numbers shown below correspond to sections in the Economic Impact Statement portion of the STD 399 that require additional information.

A) Estimated Private Sector Cost Impacts

3. Total Number of Businesses Impacted

Through internet research and consultation with industry representatives, DTSC estimates there are at most 11 California-based manufacturers of nail products containing toluene that would be required to comply with this regulation. All of these types of manufacturers must submit Notifications and AA reports. At most, nine California-based manufacturers will submit AAT Notifications. 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.

Types of Businesses

These businesses are manufacturers of nail products containing toluene that make and sell their products in California.

Number or Percentage of Total Businesses Impacted that are Small Businesses

Under California Rulemaking Law, Government Code section 11342.610, a small business is defined as being both independently owned and operated and not dominant in its field of operation. California Government Code 11346.3(b)(4) adds an additional criterion to the small business definition: a small business must have fewer than 100 employees. Many of the potentially impacted manufacturers are non-public companies and do not publish information about employment size, ownership, or management of their organizations. DTSC relied on the United States Census Bureau and D & B Hoovers databases to provide estimates of employment size for each potentially impacted manufacturer. Based on this information and the limited information that is available on company websites, DTSC estimates that 8 of the 11 potentially impacted manufacturers of nail products containing toluene at levels higher than 100 ppm are small businesses.

4. Number of Businesses Created and Eliminated

DTSC determined that this proposal is unlikely to result in the elimination of any manufacturers of nail products containing toluene. 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, 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 safer 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 nail products containing toluene 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 this proposed regulation could potentially lead to increased business opportunities in consulting services, chemical and material science research and support, product research and design and marketing.

6. Number of Jobs Created and Eliminated

Statewide job expansion could occur in consulting services, product research and design, chemical and material science research, and support and marketing.

B) Estimated Costs

DTSC estimates the costs to responsible entities to complete a Priority Product Notification, an Alternatives Analysis and Report to identify safer alternatives, and to respond to DTSC's Alternatives Analysis Report review, because these are the outcomes required by the proposed regulation.

Following the completion of the Alternatives Analysis, each responsible entity may elect to take one or more actions, which may include, but are not limited to, selecting an identified alternative to the Priority Product (for example, removing or replacing the Chemical of Concern in the Priority Product) or retaining the Priority Product. This decision may result in additional costs or cost savings to the responsible entity. The additional costs or cost savings associated with these decisions are not calculable because they are dependent on the specific factors relevant to each responsible entity's Alternatives Analysis. DTSC cannot pre-determine the outcome of any Alternatives Analysis or the subsequent actions of any responsible entity.

1.a. Small Business Costs

DTSC estimates that it will take each manufacturer a maximum of 16 hours at \$60/hour to complete a Priority Product Notification or a total of \$960. DTSC estimates that the cost to each manufacturer for the Priority Product Notification, AA report, and responding to DTSC's AA report review will be \$112,960 to \$182,960 for an Abridged AA (Table 1a) and \$139,960 to \$304,960 for a two-stage AA (Table 1b) regardless of manufacturer size. Feedback from the author of one AA submitted to DTSC confirms that this estimate remains reasonable.

DTSC expects costs to individual manufacturers to be lower if they form a consortium and submit a combined AA. Adopted Safer Consumer Product Regulations and those well into the development pipeline confirm the prevalence of collaborative approaches to authoring AAs. These are one-time notification and reporting requirements that manufacturers are expected to complete within one year of adoption of the proposed regulation; therefore, there are no ongoing costs. Eight out of the 11 impacted California businesses are small businesses; however, each business size will incur the same costs of regulatory compliance.

Table 1a. Estimated Costs to Manufacturers – Abridged AA

Manufacturer AA-Related Tasks	Individual Manufacturer Cost Range	CA Industry-Wide Cost Range
Priority Product Notification	\$960 - \$960	\$10,560 - \$10,560
AA	\$100,000 - \$150,000	\$1,100,000 - \$1,650,000
Respond to Reviews of AA	\$12,000 - \$32,000	\$132,000 - \$352,000
Combined Tasks	\$112,960 - \$182,960	\$1,242,560 - \$2,012,560

Table 1b. Estimated Costs to Manufacturers – Two-stage AA

Manufacturer AA-Related Tasks	Individual Manufacturer Cost Range	CA Industry-Wide Cost Range
Priority Product Notification	\$960 - \$960	\$10,560 - \$10,560
AA	\$120,000 - \$250,000	\$1,320,000 - \$2,750,000
Respond to Reviews of AA	\$19,000 - \$54,000	\$209,000 - \$594,000
Combined Tasks	\$139,960 - \$304,960	\$1,539,560 - \$3,354,560

The costs incurred in developing and submitting AAT Notifications will primarily include administrative activities. DTSC estimates that each manufacturer will invest a maximum of three hours at \$42/hour to complete an AAT 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 certificates of analyses from their suppliers.

Table 1c. Estimated Costs to Manufacturers – AAT Notifications

<u>Manufacturer AAT Notification-Related Tasks</u>	<u>Individual Manufacturer Cost Range</u>	<u>CA Industry-Wide Cost Range</u>
<u>Gathering and Transmitting Data</u>	<u>\$528 - \$1,507</u>	<u>\$8,818 - \$13,566</u>
<u>Respond to Reviews of AAT Notifications</u>	<u>\$279 - \$798</u>	<u>\$4,668 - \$7,182</u>
<u>Combined Tasks</u>	<u>\$807 - \$2,305</u>	<u>\$13,486 - \$20,748</u>

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.

1.b. Typical Business Costs

See section ‘1.a.’, which immediately precedes this section. DTSC estimates that costs for each business will be the same regardless of size.

1.c. Individual Costs

There are no anticipated costs to individuals.

3. Reporting Requirement Costs

There are no annual ongoing reporting costs because Priority Product Notifications, Abridged AA Reports, ~~and~~ two-stage AA Reports, and AAT Notifications are one-time reporting requirements.

5. Federal Regulations

The SCP program established a unique approach to regulating Chemicals of Concern in consumer products that allows DTSC to take a precautionary approach to protecting people and the environment when other regulatory programs or protective standards are lacking. 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. This proposed regulation is an important effort to protect the health of California workers and consumers from harmful exposures to nail products containing toluene. Furthermore, this proposed regulation is an important supplement to current research, legislation, and regulatory activities related to toluene at the federal level and in other states.

C) Estimated Benefits

A reduction in exposure to toluene could benefit the health of California's residents. The development of safer alternatives benefits California workers, consumers, employers, and the environment. A full description of the potential adverse impacts of toluene and factors related to potential exposure to toluene is presented in DTSC (2020) Product-Chemical *Profile for Nail Products Containing Toluene*, a reference listed in the Initial Statement of Reasons.

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's process encourages the use of ~~DTSC will maximize the use of~~ alternatives of least concern and prefers ~~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 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 nail

product ingredients 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.

D) Alternatives to the Regulation

DTSC's analysis found that no reasonable alternative to the selected alternative (the proposed regulation) would be either more effective in carrying out the purpose for which the action is proposed or would be less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.

D.1. Alternatives Considered

DTSC considered the following alternatives to the proposed regulation:

Regulation: 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 achieve the goal of significantly reducing exposure to toluene in nail products.

- 1) Alternative 1: List nail products ~~polish remover~~ containing toluene, including nail coatings, nail polish thinner, and nail polish remover, ~~among other products~~, as the Priority Product.

This option was dismissed since 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 California Air Resources Board (CARB) Consumer Products regulations, which limit the total concentration of volatile organic compounds in polish removers to one percent by weight.

- 2) Alternative 2: List nail products containing all Candidate Chemicals which 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.

D.2. Costs of Alternatives

DTSC did not attempt to quantify costs associated with any of the Alternatives because none of the Alternatives would have yielded health and environmental benefits approximating the health and environmental benefits provided by including nail products containing toluene, including nail coatings and polish thinners, in the Priority Product designation. CARB effectively addressed the goal of Alternative 1. The broad scope of Alternative 2 would cast too wide of a regulatory net as to make implementation and enforcement unworkable.

E) Major Regulations

DTSC estimates that regulatory costs to manufacturers of nail products containing toluene will be less than the threshold amounts for a "major" regulation cited in Section 11346 of the Government Code and Section 57005 of the Health and Safety Code. Accordingly, DTSC is not required to prepare, and submit for approval, a "Standardized Regulatory Impact Assessment" because the estimated costs incurred by manufacturers of nail products containing toluene will be less than \$50 million in the first year. Consequently, DTSC is not required to conduct macro-economic modeling for the proposed rulemaking pursuant to Section 11346 of the Government Code. Similarly, the estimated additional costs for the proposed regulation will be less than the \$10 million CalEPA-specific threshold pursuant to Section 57005 of the Health and Safety Code.

II. FISCAL IMPACT STATEMENT

The following information supplements statements in the Economic and Fiscal Impact Statement (STD 399) for the rulemaking proposal titled "Safer Consumer Products Regulations – Listing Nail Products Containing Toluene." The section headings and numbers shown below correspond to sections in the Fiscal Impact Statement portion of the STD 399 that require additional information.

A) Fiscal Effect on Local Government

No fiscal impact exists.

B) Fiscal Effect on State Government

Safer Consumer Products (SCP) estimates that the state fiscal impact of adopting this regulation will range from \$1,375,864 ~~653,269~~ to \$4,928,500 ~~2,367,735~~ Toxic

~~Substances Control Account (TSCA)~~ in DTSC staff costs for reviewing all Notifications, Abridged Alternatives Analysis (AA) Reports, ~~and two-stage AA reports, and AAT Notifications~~ submitted by manufacturers that intentionally add or use find trace amounts of toluene in their products (Tables 2, 3 and 4). Resources will be drawn from the Toxic Substances Control Account. This calculation uses job classification rates from the State of California Civil Service Pay Scale. Moreover, the costs are dependent on the complexity of the type of AA report submitted.

Table 2. Estimated Fiscal Cost to State Government for AA Reviews

Number of Notifications and AAs	Low	High
Individual Notification and AA	\$33,547 <u>28,403</u>	\$120,490 <u>102,945</u>
Total (All Notifications and AAs)	\$738,034 <u>653,269</u>	\$2,650,780 <u>2,367,735</u>

DTSC estimates these one-time⁵ costs would be absorbed within DTSC’s existing budget. Existing DTSC staff and managers will perform the reviews, and no new personnel resources will be needed to complete these tasks. However, if actual workload exceeds expectations and the SCP Program’s capacity, the Program will initially issue Notices of Ongoing Review, as provided in the SCP regulations, to extend the AA review into subsequent fiscal years. Given substantial uncertainty as to the total number and breadth of AA submittals for this proposed regulation, Notices of Ongoing Review may only partially mitigate SCP’s resource shortfall. For instance, complex two-stage AAs may comprise the bulk of submittals. Should circumstances such as these dictate that SCP requires additional resources to complete required AA reviews, DTSC will pursue a staffing augmentation through the annual budget process.

The SCP Program anticipates that it is unlikely that all ~~223~~ responsible manufacturing entities will submit individual AAs; thus, fiscal impacts could be overstated. The Program’s experience with regulations for spray polyurethane foam containing methylene diphenyl diisocyanates and paint strippers containing methylene chloride provides evidence to support this assumption. Other responsible entities will simply fail to comply with AA requirements.⁶ These circumstances will drive down actual fiscal impacts.

⁵ These activities will likely fall within FY 2022-23, depending on the precise timing of regulatory milestones.

⁶ Failure to comply, of course, may result in an array of other difficult to estimate costs, such as legal enforcement.

Estimates include costs of review by a variety of technical staff including environmental scientists, toxicologists, engineers, economists, and attorneys. The primary sources of uncertainty in these estimates are as follows: the precise number of manufacturers of nail products with toluene; how many manufacturers will form a consortium to submit a combined AA Report; the number of hours it will take DTSC to review an individual Notification, Abridged AA, or two-stage AA report; and whether any of the 223 identified entities are not manufacturers but assemblers (which would only be required to submit a Priority Product Notification under SCP regulations in the absence of a manufacturer or importer submission). Similar technical staff at DTSC will review AAT Notifications. Table 3 lists these cost impacts, and Table 4 combines all the fiscal impacts of this regulation.

Table 3. Estimated Fiscal Cost to State Government for AAT Notification Reviews

<u>Number of AAT Notifications</u>	<u>Low</u>	<u>High</u>
<u>Individual AAT Notifications</u>	<u>\$1,865</u>	<u>\$6,660</u>
<u>Total (All AAT Notifications)</u>	<u>\$637,830</u>	<u>\$2,277,720</u>

Table 4. Estimated Total Combined Fiscal Cost of Reviews to State Government

<u>Number of AAs and AAT Notifications</u>	<u>Low</u>	<u>High</u>
<u>Total (All AAs)</u>	<u>\$738,034</u>	<u>\$2,650,780</u>
<u>Total (All AAT Notifications)</u>	<u>\$637,830</u>	<u>\$2,277,720</u>
<u>Total Fiscal Impact</u>	<u>\$1,375,864</u>	<u>\$4,928,500</u>

C) Fiscal Effect on Federal Funding of State Programs

No fiscal impact exists.