FINAL STATEMENT OF REASONS

SAFER CONSUMER PRODUCTS REGULATIONS –

LISTING PAINT OR VARNISH STRIPPERS CONTAINING METHYLENE CHLORIDE AS A PRIORITY PRODUCT

July 2018

Department Reference Number: R-2016-05

Office of Administrative Law Notice File Number: Z-2017-1107-10

UPDATE OF INITIAL STATEMENT OF REASONS

As authorized by Government Code section 11346.9(d), the Department of Toxic Substances Control (DTSC) incorporates by reference the Initial Statement of Reasons prepared for this rulemaking.

This regulation was noticed one time for public review and comment.

45-day Public Review and Comment Period: The public notice and comment period for this rulemaking proposal began on November 17, 2017, and ended on January 8, 2018. The public hearing on the proposed regulations was held on January 8, 2018.

The regulatory text, first proposed in November of 2017, has undergone non-substantive changes. The first non-substantive change adds “containing methylene chloride” to the definition of “paint or varnish strippers containing methylene chloride” in §69511.3(a), where it was inadvertently left out. The entire rulemaking deals with paint or varnish strippers containing methylene chloride and it is understood by all that the regulation only applies to paint or varnish strippers containing methylene chloride and not any paint or varnish stripper product. An additional non-substantive change corrects an error in §69511(b)(1) in which strike-out text was inadvertently omitted.

In Section IV of the ISOR under the heading, Reports Relied On, one study was not relied upon and was removed from the record: “University of California-Santa Barbara (2015) Framework for Initial Life Cycle Screening in Alternatives Analysis.” In addition, the title of the report from the State of Washington contained a typographical error. The ISOR cites the title as “Alternative Assessment Guide for Small and Medium Businesses” but the citation title should read, “Washington State Alternatives Assessment Guide for Small and Medium Businesses.”

LOCAL MANDATE DETERMINATION

The proposed regulations do not impose any mandate on local agencies or school districts.

ALTERNATIVES DETERMINATION
DTSC determined that no reasonable alternative considered would be more effective in meeting the purpose for which the action is proposed, or as effective and less burdensome to affected private persons. Equally, none of the alternatives considered would be more cost-effective to affected private persons or as effective in implementing the statutory policy or other provision of law. DTSC did not receive any proposed alternatives that would lessen the impact on small businesses.

**Chosen alternative:** DTSC determined that listing paint or varnish removers containing methylene chloride as a Priority Product is the most effective and least burdensome approach to meeting the mandates specified in Health and Safety Code sections 25252, 25253, and 58012. This option was selected because it allows DTSC to effectively achieve the goal of reducing the potential for workers and consumers to be exposed to methylene chloride during the normal use of paint or varnish strippers. Methylene chloride is an acute toxin and inhalation exposure during the use of paint or varnish strippers can result in severe injury or death. DTSC estimates there are 24 or fewer manufacturers of paint or varnish strippers containing methylene chloride based in the United States, of which three are headquartered in California. DTSC estimates the cumulative cost for all affected manufacturers of paint or varnish strippers with methylene chloride to submit Priority Product Notifications and AA Reports, and to respond to DTSC’s review of these submittals, would be from $2,371,200 to $6,403,200.

**Considered and Rejected Alternatives:**

**Alternative 1:** DTSC considered waiting for U.S. EPA to regulate the use of paint strippers containing methylene chloride. U.S. EPA identified methylene chloride as a work plan chemical for assessment under the Toxic Substances Control Act (TSCA) in 2012, and proposed a rule to regulate certain uses of methylene chloride in paint strippers in January 2017. Although U.S. EPA announced in May of 2018 its intention to take action on methylene chloride, DTSC decided to move forward with its proposed rulemaking because the scope and timing of the U.S. EPA action remains unclear. DTSC's proposed rule will regulate methylene chloride under a regulatory framework that is fundamentally different from TSCA. For these reasons, and in light of recent deaths attributed to use of methylene chloride-based strippers, DTSC has chosen to move forward with its proposed rulemaking so workers and consumers can benefit from this innovative process.

**Alternative 2:** DTSC also considered listing paint or varnish strippers containing methylene chloride or N-methyl pyrrolidone (NMP, CAS number 872-50-4) as a Priority Product. NMP is a widely used chemical alternative to methylene chloride in paint strippers. NMP is a known reproductive and developmental toxicant and a skin and eye irritant. Moreover, NMP is on DTSC’s list of Candidate Chemicals due to reproductive and developmental toxicity. However, since NMP does not meet the condition specified in California Code of Regulations, title 22, section 69503.6(a), DTSC may not name paint or varnish strippers containing NMP as part of the initial Priority Products list. Paint or varnish strippers containing NMP may be designated a Priority Product in the future.

**ADVERSE ECONOMIC IMPACT ON SMALL BUSINESSES**

DTSC did not receive any proposed alternatives during the public comment period that would lessen any adverse economic impacts on small businesses.
SUMMARY AND RESPONSE TO COMMENTS

This section summarizes and responds to public comments submitted to DTSC about the proposed rulemaking, *Listing Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product*. DTSC appreciates the numerous comments provided by a variety of interested stakeholders, including manufacturers, businesses that use the Priority Product, government and non-governmental organizations, and individuals. This proposed regulation would formally list paint or varnish strippers containing methylene chloride as a Priority Product. Completing this listing supports our mission to promote the development of safer products through the evaluation of potential alternatives.

DTSC adopted the framework Safer Consumer Products (SCP) regulations in 2013. The SCP regulations established a new approach in the quest for safer consumer products by establishing a structure for identifying, listing, and analyzing products that contain harmful chemicals. The framework regulations rely on a series of basic tenets that inform the approach for developing safer products. They set in motion a precautionary strategy to reduce the use of toxic substances in products to create safer products that do not threaten human health or persist in the environment. This precautionary approach requires DTSC to make decisions even though there are gaps in the available data. Consistent with this, the criteria in the framework regulations for listing a product-chemical combination as a Priority Product focus on potential exposure to the Candidate Chemical in the product and the potential for such exposures to contribute to or cause adverse impacts, observed as health effects or environmental impacts.

Considerable research documents the potential adverse health impacts associated with exposure to methylene chloride, including cancer and death. DTSC determined that use of paint or varnish strippers containing methylene chloride produces measurable concentrations of airborne methylene chloride in the breathing zone, and any person involved in or near the application may experience inhalation exposure to methylene chloride, even when protective measures are used. DTSC finds that paint and varnish strippers with methylene chloride meet the criteria specified in section 69503.2(a) for listing as a Priority Product – that there is the potential for inhalation exposure to methylene chloride in paint or varnish strippers to cause or contribute to significant or widespread adverse health impacts.

DTSC understands that the SCP program entails novel processes that have not been undertaken by other state or federal chemical policy programs. To assess the validity of our rationale, we specifically asked independent peer reviewers whether DTSC had adequately supported the conclusion that there is potential for exposure to methylene chloride during use of paint or varnish strippers, and whether these exposures could potentially contribute to or cause significant or widespread adverse impacts to people. All three peer reviewers confirmed that DTSC had supported its conclusion.¹

¹ The External Scientific Peer Review (*External Peer Review for the Proposed Adoption of Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product*, June 6, 2016) is required by Health and Safety Code section 57004(b).
In addition to the peer review, DTSC conducted over three years of active engagement with interested stakeholders to further substantiate our determination that the criteria in the framework regulations have been met, and that the methods we used to analyze and apply the available data are sound. Since proposing this product, DTSC held workshops, issued draft documents, and met with individuals who wished to confer directly with DTSC. The in-depth engagement of stakeholders over this time-period culminated in the extensive and detailed comments we received for this proposed rulemaking.

During our review and evaluation of the submitted public comments, DTSC carefully considered all suggestions, reasons, contentions, and statements offered by commenters to improve or change the proposed regulation. After completing the review, DTSC concluded that none of the comments provided significant new information or compelling reasons to change or withdraw our proposed regulation.

However, DTSC recognizes that the variety and extent of the comments, as well as the common themes expressed therein, reflect stakeholders’ discomfort with the underlying tenets of the framework regulations. Many of the common themes of the comments address issues associated with making the Priority Product listing determination in the face of uncertainty or definitive causal data. We have listed the general comment themes below.

In summary, comments from other state agencies, environmental groups, and union organizations expressed support for the proposed listing of paint and varnish strippers containing methylene chloride as a Priority Product because current precautions are not protecting workers and consumers from exposure to methylene chloride, resulting in a potential for significant adverse health effects, including cancer and death. A number of private citizens affected by a recent methylene chloride fatality stressed that urgent action is needed to protect consumers. Comments from manufacturers and the associations that represent them centered around a common theme that provisions such as label warnings, the use of personal protective equipment, and the U.S. EPA proposal to regulate paint strippers with methylene chloride were adequate to protect consumers from the harmful effects of paint and varnish strippers with methylene chloride. The Department of Defense and defense contractors have a particular need for methylene chloride strippers for aeronautical applications, and expressed concern that these products will continue to be available for their use.

I. Technical topics – This group of comments addresses specific technical topics associated with the proposed regulation.

- **Definition of the Priority Product and basis for the listing** – comments related to the Priority Product definition and basis for listing.

- **Evidence of significant or widespread adverse impacts** – comments related to DTSC’s determination of potential impacts and the methods used to identify hazard and exposure potential of methylene chloride and alternatives.
II. Alternatives Analysis provisions in the framework regulations – This group of comments focuses on the requirement in the framework regulations to conduct an alternatives analysis.

- Example of an Alternatives Analysis – commenter provides an example of an Alternatives Analysis.
- Requirement and utility of an Alternatives Analysis – comments generally discuss the value of conducting an Alternatives Analysis.

III. Administrative and procedural issues – This group of comments apply generally to the authorities associated with adopting the proposed regulations:

- California Environmental Quality Act (CEQA) and the Administrative Procedures Act (APA) – comments regarding compliance with CEQA and the APA.
- Existing regulations – comments related to duplication with existing requirements and complementing existing requirements.
- Legal authority of Safer Consumer Products program – comments about DTSC’s regulatory authority related to other federal laws.

DTSC received thirty written letters during the comment period from November 17, 2017, through January 18, 2018, and nine oral comments at the public hearing held on January 8, 2018. We recorded the hearing and uploaded a transcript of the proceedings and testimony to the CalSAFER website. Table 1 provides a complete list of commenters, their affiliations, and the number DTSC assigned to their correspondence or oral comment. Most of the comment letters and testimony covered more than one theme. To organize the comments, DTSC numbered individual letters and public hearing comments, as shown in Table 1, then assigned a number to each individual comment. For example, the number “13-3” refers to the third comment in the letter numbered 13, and “PH2-2” refers to the second oral comment made by the second speaker at the public hearing. Finally, DTSC grouped and summarized the comments according to the listed themes, presenting summaries and responses in each section.
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<th>#</th>
<th>Commenter Name</th>
<th>Affiliation</th>
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<td>1</td>
<td>Lynda Ransley</td>
<td>Hazardous Waste Management Program, King County, Washington</td>
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<td>2</td>
<td>Sarah Rees</td>
<td>South Coast Air Quality Management District</td>
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<td>Gary Valasek</td>
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<td>Ben Brown</td>
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<td>Anonymous</td>
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<td>Bret Ashworth</td>
<td>Summit Consulting Group</td>
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<td>Ken Zarker</td>
<td>State of Washington Department of Ecology</td>
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<td>Kathryn Ostapuk</td>
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<td>Burke Rafter</td>
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<td>Sanjeev Rastogi</td>
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<td>22</td>
<td>Raleigh Davis</td>
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<td>Avinash Kar</td>
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<td>Anthony Samson</td>
<td>Arnold &amp; Porter Kaye Scholer LLP</td>
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<td>27</td>
<td>Jennifer McPartland</td>
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<td>28</td>
<td>Nancy Buermeyer</td>
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<td>29</td>
<td>Michael Wilson</td>
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<td>30</td>
<td>Catherine Houston</td>
<td>United Steelworkers, District 12</td>
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<td>PH1</td>
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COMMENTS REGARDING THE DEFINITION OF THE PRIORITY PRODUCT AND BASIS FOR THE LISTING

Comment Summary:

The CAS registry number for methylene chloride (79-09-02) should be included in the final published regulation because it provides a clear way to identify a chemical substance.

Comment: 3-1

DTSC Response:

DTSC agrees with the commenter that CAS numbers, when available for a specific chemical, can provide needed clarity on the identity of a regulated chemical. The CAS number for methylene chloride is indicated in section 69511.3 in the proposed regulation text where the Candidate Chemical is identified.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment Summary:

An important factor for DTSC to consider when listing a Priority Product is whether there is a safer alternative that is functionally acceptable, technically feasible, and economically feasible. DTSC did not address this in the ISOR, although it’s clear that no such alternative exists.

Comment: 26-24

DTSC Response:

Although section 69503.2(b)(3) of the SCP framework regulations states that DTSC may consider, prior to listing, whether there is a readily available safer alternative that is functionally acceptable, technically feasible, and economically feasible, it is not required to do so. DTSC is aware of a number of currently available paint and varnish strippers that do not contain methylene chloride, but has not made a determination regarding the viability of these alternatives. This type of evaluation should be conducted by the responsible entity and included in the Alternatives Analysis. During the Alternatives Analysis, the responsible entity compares the Priority Product with possible safer alternatives using appropriate relevant factors. This information is then submitted to DTSC in the Final Alternatives Analysis Report.

No changes were made to the proposed regulation or supporting documents based on this comment.
Comment Summary:

The chemical industry plays a major role in the lives of nearly all Californians, with nearly 4.8 pounds of chemical products used every day by California residents. Because the chemical industry is so influential, it should provide well-informed technical recommendations for safer alternatives, rather than resisting efforts to improve worker and consumer safety. The American Chemistry Council (ACC) represents the chemical industry and has stated a commitment to improve environmental, health, safety and security performance throughout the industry. When the European Union restricted the use of methylene chloride years ago, manufacturers developed less toxic and effective alternatives for that market. U.S. manufacturers of paint or varnish strippers containing methylene chloride have a duty to protect the health of Californians.

Listing paint or varnish strippers with methylene chloride as a Priority Product is fully warranted and necessary and the chemical industry should work with DTSC towards achieving the health and safety goals stated by the ACC.

Comments: 28-4, 29-4, PH9-3

DTSC Response:

DTSC agrees that listing paint and varnish strippers with methylene chloride as a Priority Product is fully warranted and necessary, and appreciates support from Breast Cancer Prevention Partners.

No changes were made to the proposed regulation or supporting documents based on these comments.
COMMENTS REGARDING POTENTIAL FOR SIGNIFICANT OR WIDESPREAD IMPACTS

Comment Summary:

The serious adverse health effects from exposure to methylene chloride, including cancer and death, are well-documented. DTSC’s Technical Report summarized findings from over 50 authoritative sources, which included a report of over 337 calls to poison control centers about methylene chloride poisoning in one year. Reports about worker and consumer deaths associated with the use of paint or varnish strippers containing methylene chloride span decades, even as regulatory programs aimed at improving the safety profile of these products were expanded. Since the mid-1980s, over 40 workers in the U.S. have died as a result of methylene chloride exposure from using paint or varnish strippers. Besides workers, children, pregnant women and chronically ill people are also vulnerable to exposures to methylene chloride from paint or varnish strippers. Methylene chloride is classified as a Hazardous Air Pollutant by the U.S. EPA and as a Toxic Air Contaminant by the State of California.

U.S. EPA extensively reviewed the health and safety of methylene chloride in paint and coating removal products, finding that such products present “an unreasonable risk of injury to health or the environment.” Methylene chloride is highly volatile and is a high production volume chemical, with between 250-500 million pounds produced or imported into the U.S. in 2015. Using monitoring data and validated exposure modeling, U.S. EPA estimated up to 1.3 million consumers and 32,000 workers are currently exposed to methylene chloride each year during paint and coating removal activities, with potentially significant acute and chronic adverse health effects. Because exposure to methylene chloride causes victims to lose consciousness and stop breathing, it’s possible that deaths attributed to heart attacks could be related to exposure to methylene chloride. Exposure to methylene chloride can lead to solvent-induced narcosis and death, even when victims are hospitalized. Due to continuing deaths from the use of paint or varnish strippers containing methylene chloride, the California Department of Public Health (CDPH) stated that methylene chloride is “too hazardous to be used outside of engineered industrial environments.”

Paint or varnish strippers containing methylene chloride are widely available and used by consumers, as evidenced by the amount that is turned into household hazardous waste collection sites. Paint strippers containing 100% methylene chloride are available in most hardware stores. Shops using methylene chloride present concerns for residents located nearby. Paint or varnish strippers containing methylene chloride are considered hazardous because of the environmental persistence and toxicity of methylene chloride, leading to increased costs to businesses to properly dispose of these materials.

DTSC has clearly met its evidentiary responsibilities to list paint or varnish strippers containing methylene chloride as a Priority Product based on its potential to contribute to or cause significant or widespread adverse impacts to health or the environment.

DTSC Response:
DTSC agrees with the comments. No changes were made to the proposed regulation or supporting documents based on these comments.

Comment Quotation:
“We understand that DTSC’s initial reason for pursuing listing of DCM-based paint strippers was primarily concern about reported fatalities from bathtub refinishing. This is a legitimate concern, but there are much more targeted ways to address it.”

Comment: 19-1

DTSC Response:
The wide availability and use of paint or varnish strippers containing methylene chloride, in conjunction with the potential for significant adverse health effects, including fatalities, from inhalation exposure to methylene chloride while using such products, are the reasons DTSC is pursuing the Priority Product listing. The health hazards associated with inhalation exposure to methylene chloride have been well-documented over decades and can affect workers and consumers who use paint or varnish strippers in a wide variety of applications. The Technical Summary summarizes results from over 50 scientific studies that thoroughly document the health risks from exposure to methylene chloride. U.S. EPA estimated nearly 32,000 workers and 1.3 million consumers are exposed to methylene chloride in paint or varnish strippers each year during use of paint or varnish strippers.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment Summary:
DTSC failed to meet the regulatory criteria for listing paint or varnish strippers containing methylene chloride as a Priority Product because it has not been shown that methylene chloride has the potential to contribute to or cause significant or widespread adverse impacts. The best available science, existing regulatory programs, and industry practices demonstrate that paint or varnish strippers containing methylene chloride do not present the potential for widespread or significant adverse impacts and do not meet the criteria for listing as a Priority Product.

Comments: 26-1, 26-13

DTSC Response:
The pattern of fatalities associated with the use of the Priority Product constitutes a significant adverse impact. The key prioritization principles for identifying and listing paint or varnish strippers containing methylene chloride as a Priority Product have been
met through documentation of the wide availability and use of paint or varnish strippers containing methylene chloride and the potential for widespread or significant adverse impacts, including death, from inhalation exposure to methylene chloride while using such products. The Technical Summary summarizes results from over 50 scientific studies that thoroughly document the potentially significant adverse health effects from exposure to methylene chloride. U.S. EPA estimated nearly 32,000 workers and 1.3 million consumers are exposed to methylene chloride in paint or varnish strippers each year during use of paint or varnish strippers, indicating potential for widespread exposure leading to adverse health effects.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comment Summary:
Some commenters suggest that DTSC is overstating the risk to workers and looking at worst case scenarios. We do need to consider why people who wear PPE still die on the job after exposure to methylene chloride.

Comment: PH7-3

DTSC Response:
As suggested by the comment, personal protective equipment (PPE) has proven inadequate in protecting users of the Priority Product. A recent study of calculated ventilation requirements shows that paint strippers containing methylene chloride require impractically large ventilation rates. For indoor paint stripping activities involving more than a minimal area, “adequate ventilation” cannot be achieved and such activities should require pressure demand respiratory protection, a form of PPE not typically available to most consumers.

Occupational exposures to harmful substances such as methylene chloride in paint or varnish strippers are typically addressed via hazard control methodology widely accepted by the industrial hygiene profession and safety organizations, including Cal/OSHA and federal OSHA. Following this approach, hazards are controlled via a “hierarchy” of potential solutions. This hierarchy, in order of preference, is: 1) elimination of the hazard; 2) substitution with a different chemical; 3) engineering controls, including processes and systems such as exhaust ventilation, which are designed to remove the hazard at the source, before it comes in contact with the worker; 4) administrative controls, including the implementation of policies, procedures, and employee training; and 5) the use of PPE. Currently, exposures to methylene chloride while using paint or varnish strippers are controlled primarily by solutions 3, 4 and 5.

Per the hierarchy, eliminating methylene chloride entirely, or substituting a less hazardous chemical, is the most effective means of minimizing potential occupational exposures to workers. The use of administrative controls and PPE, alone or in combination, are the least desirable approaches to controlling occupational exposure to methylene chloride because their effectiveness depends almost entirely on employees’ ability to comply and employers’ ability to supervise. Lack of training, experience, or supervision, as well as a range of physical and environmental variables, can significantly decrease the effectiveness of these methods. Because the methylene chloride is still present in the workplace, when employees fail to follow administrative controls or to use PPE properly, they risk exposure to methylene chloride that can lead to injuries, illnesses, or death. In 2012, the Centers for Disease Control reported that injuries and deaths from methylene chloride exposure are under-reported due a lack of reporting by self-employed workers and because deaths can be misidentified as caused by heart disease. Because of the well-characterized hazard traits of methylene chloride and the potential for exposure during use of paint and varnish strippers, DTSC is pursuing the Priority Product listing to move manufacturers to find safer alternatives that protect human health.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment Summary:

DTSC used a retail survey of California stores that found that paint or varnish strippers containing methylene chloride were the most commonly purchased paint strippers to show that the product could potentially have widespread adverse impacts. That such products are commonly purchased does not indicate that methylene chloride in the product will adversely impact the buyer. DTSC is overstating the potential for methylene chloride to contribute to significant or widespread adverse impacts.

Comment: 26-20

DTSC Response:

In evaluating a product-chemical combination for listing as a Priority Product, DTSC must assess the potential for exposures to the Candidate Chemical in the product, and, whether one or more of those exposures could contribute to or cause significant or widespread adverse impacts (California Code of Regulations, title 22, section 69503.2(a)). In making this determination, DTSC considers a variety of factors including market presence, statewide sales by volume, and the intended uses of the proposed Priority Product. The retail survey was one source of information documenting the wide availability of paint or varnish strippers containing methylene chloride.

No changes were made to the proposed regulation or supporting documents based on this comment.
Comment Summary:

The information provided by DTSC in the Technical Summary misrepresents the number of people who have died from methylene chloride, does not accurately characterize its carcinogenicity or account for the fact that most people use methylene chloride outdoors. Therefore, DTSC has not adequately characterized the “potential”, which is defined in the SCP regulations as meaning “the phenomenon described is reasonably foreseeable based on reliable information,” for methylene chloride to cause or contribute to significant or widespread adverse impacts.

Comment: 26-14

DTSC Response:

The Technical Summary summarizes results from over 50 scientific studies that thoroughly document the health risks from exposure to methylene chloride, including cancer and death. U.S. EPA estimated nearly 32,000 workers and 1.3 million consumers are exposed to methylene chloride in paint or varnish strippers each year during use of paint or varnish strippers. Although fatalities associated with the Priority Product continue to be reported, deaths from methylene chloride exposure also are likely under-reported as workers and consumers with heart disease may experience a heart attack from methylene chloride exposure, resulting in “heart attack” being listed as the cause of death. There are no reliable sources of information that indicate most people use methylene chloride outdoors under conditions that eliminate the exposure potential.

The key prioritization principles for identifying and listing paint or varnish strippers containing methylene chloride as a Priority Product have been met through documentation of the wide availability and use of paint or varnish strippers containing methylene chloride and the potential for significant adverse health impacts, including cancer and death, from inhalation exposure to methylene chloride while using such products. The most recent death of a Californian from exposure to methylene chloride occurred on June 23, 2017, while he was refinishing a bathtub. His employer reported that use of methylene chloride-based strippers was a common practice in that small family-run business, yet the employee was not wearing any respiratory protection. If consumers and workers are not adequately protected from exposure to methylene chloride while using paint or varnish strippers, DTSC maintains that it is reasonably foreseeable that they could experience life-threatening adverse impacts.

No changes were made to the proposed regulation or supporting documents based on this comment.
Comment Summary:
Methylene chloride has been designated a probable carcinogen by IARC and the U.S. National Toxicology Program has concluded that it is reasonably anticipated to be a carcinogen. It is also included on California’s Prop 65 list of carcinogens. Scientific evidence links methylene chloride exposure to several forms of cancer.

Comment: 28-1

DTSC Response:
DTSC agrees that evidence links methylene chloride exposure to several forms of cancer. Consistent with section 69502.2(a)(1) of the SCP regulations, DTSC identified methylene chloride as a potential carcinogen because it is included on certain authoritative lists. The authoritative lists associated with carcinogenicity indicate that:

- Methylene chloride is known to the State of California to cause cancer (under the Safe Drinking Water and Toxic Enforcement Act of 1986).
- Methylene chloride is classified as “possibly carcinogenic to humans” (i.e., a group 2B carcinogen) by the International Agency for Research on Cancer (IARC).
- Methylene chloride is classified as “reasonably anticipated to be a human carcinogen” in the Twelfth Edition of the Report on Carcinogens published by the U.S. Department of Health and Human Services, National Toxicology Program.
- Methylene chloride is classified as “likely to be carcinogenic to humans” in the U.S. EPA’s Integrated Risk Information System.

Based on a careful review of the research literature and information from authoritative sources, DTSC has determined that evidence links methylene chloride exposure to several forms of cancer.

No changes were made to the proposed regulation or supporting documents based on this comment.

Comment Summary:
DTSC lists carcinogenicity as a hazard trait for methylene chloride based on EPA’s Integrated Risk Information System (IRIS) assessment and its IARC classification. The Technical Review that DTSC relied upon doesn’t discuss concerns that were raised to U.S. EPA about the draft IRIS assessment. DTSC should conduct a weight of evidence evaluation on the mechanisms by which exposure to methylene chloride causes tumor development and reevaluate evidence that methylene chloride is a probable/potential human carcinogen.

DTSC’s assertion that methylene chloride can cause brain, liver and biliary cancer is supported by referencing the IRIS assessment of methylene chloride and the IARC classification. These references do not address several studies that show no association between worker exposure to methylene chloride and increased cancer
incidence, including a review of studies by Dell et al. (1999) that concluded there is no substantive cancer risk associated with exposure to methylene chloride. The Technical Summary includes a report citing an IARC review of epidemiological studies on methylene chloride and concluded that “the evidence for carcinogenicity was too inconsistent to support a causal interpretation.” Large cohort studies at Eastman Kodak facility also found no long-term cancer risk from methylene chloride exposure. The proposal relies on flawed risk assessment and lacks scientific support.

Comments: 19-5, 19-7, 19-8, 19-9, 22-4, 26-17, 26-19

DTSC Response:
Consistent with section 69503.6(a) of the SCP regulations, DTSC identified methylene chloride as a potential carcinogen because it is included on certain authoritative lists. Those authoritative lists and chemical types are specified in section 69502.2(a)(1) and (2), respectively, and for methylene chloride they include:

- Methylene chloride is known to the State of California to cause cancer (under the Safe Drinking Water and Toxic Enforcement Act of 1986).
- Methylene chloride is classified as “possibly carcinogenic to humans” (i.e., a group 2B carcinogen) by the International Agency for Research on Cancer (IARC).
- Methylene chloride is classified as “reasonably anticipated to be a human carcinogen” in the Twelfth Edition of the Report on Carcinogens published by the U.S. Department of Health and Human Services, National Toxicology Program.
- Methylene chloride is classified as “likely to be carcinogenic to humans” in the U.S. EPA’s Integrated Risk Information System.

These standards rely on a rigorous examination of available information and are widely accepted as valid. Based on a careful review of the research literature and information from authoritative sources, DTSC has determined that evidence links methylene chloride exposure to several forms of cancer.

When considering hazard traits and toxicological endpoints associated with exposure to specific Candidate Chemicals, including methylene chloride, DTSC does not engage in chemical ranking or conduct weight of evidence evaluations on mechanisms of action by which chemicals exert a toxic effect. We rely on the expertise of toxicologists and cancer researchers to conduct this evaluation, which is reflected in the authoritative lists that constitute the Candidate Chemical Database.

DTSC does not agree that its evaluation of methylene chloride carcinogenicity relied on a flawed assessment or that it lacks scientific support. The IARC and IRIS lists are authoritative lists described in the SCP framework regulations. Also, in 2011, U.S. EPA published a comprehensive toxicological review of methylene chloride that is cited in DTSC’s Technical Summary. U.S. EPA presented comprehensive study data in support of the conclusion that methylene chloride is likely to be carcinogenic in humans. U.S. EPA also reviewed studies that failed to identify any cancer risk associated with methylene chloride exposure and identified significant limitations in some studies. U.S.
EPA concluded that the available epidemiologic evidence does suggest an association between methylene chloride and brain cancer, liver cancer, and specific hematopoietic cancers. Results from well-controlled laboratory studies in animals also provide additional evidence for the carcinogenicity of methylene chloride. Other authoritative bodies also recognize methylene chloride as a likely, probable, or possible human carcinogen.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comment Summary:

DTSC should conduct risk assessments under “normal use” exposure scenarios, including the use of industry standard practices and precautions. The CPSC agrees that label statements on paint or varnish strippers containing methylene chloride meet FHSA requirements to ensure safe use. DTSC should not further regulate methylene chloride.

Comment: 22-14

DTSC Response:

The Safer Consumer Products program does not conduct or rely upon risk assessments to determine whether a product-chemical Combination should be proposed as a Priority Product. DTSC does not specify a prescriptive quantitative process with thresholds for each chemical, but uses a narrative approach that allows DTSC to use the best available scientific information and practices to identify Candidate Chemicals and prioritize product-chemical combinations.

In response to concern about injuries and deaths from the use of paint or varnish strippers containing methylene chloride, regulatory agencies have initiated actions to minimize or eliminate human exposures to methylene chloride. The Halogenated Solvents Industry Alliance (HSIA) has responded to these regulatory actions by proposing changes to the label of paint or varnish strippers containing methylene chloride to clearly state that inhalation exposure to methylene chloride could be “extremely harmful.” In 2016, HSIA requested that the Consumer Product Safety Commission (CPSC) comment on the sufficiency of its proposed modified label for methylene chloride-containing paint stripper products. CPSC staff reviewed the petition submitted by HSIA and while the CPSC updated its labelling guidance for certain household products containing methylene chloride, the CPSC stated updating the guidance does “not suggest that labeling will address all hazards EPA identified in its proposed rulemaking.” The CPSC has not agreed that current labels ensure safe use. Rather, the CPSC states “providing warning information does not prevent consumer exposure to hazards.”

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3 83 FR 12255.
4 83 FR 12256.
No changes were made to the proposed regulation or supporting documents based on this comment.
COMMENTS REGARDING EXPOSURE OR USE OF PERSONAL PROTECTIVE EQUIPMENT

Comment Summary:

The Department of Ecology for the State of Washington recognizes the critical need of safer alternatives to methylene chloride, as it has been associated with numerous cases of serious illnesses and deaths. Data from the Washington State Poison Control Center showed multiple cases of exposure to methylene chloride in 2015.

Comments: 1-4, 11-2

Comment Summary:

United Steel Workers working in a paint can manufacturing plant experienced respiratory symptoms and dizziness. Once the workers were provided appropriate PPE and a new ventilation system was installed, the health issues were mitigated. Still, the danger to workers and consumers is likely more prevalent than has been reported. The Center for Public Integrity identified at least 56 deaths in the U.S. linked to exposure to methylene chloride since 1980. Methylene chloride poses an inherent danger to health.

Comments: 30-1, 30-3, PH8-2

Comment Summary:

The South Coast Air Quality Management District approved a management plan in 2016 to reduce health hazards to workers, consumers, and nearby residents from exposure to methylene chloride use in stripping operations.

Comment: 2-3

Comment Summary:

Drew Wynne died suddenly from the effects of Goof-Off, which contains 60-80% methylene chloride, as he was refinishing a floor. The autopsy report states his death was a result of blood methylene chloride concentrations. There are reports of up to 80 other people who have died while using products containing methylene chloride.

U.S. EPA estimates that approximately 32,000 workers and 1.3 million consumers are exposed to methylene chloride each year while using paint or varnish strippers containing methylene chloride. EPA also concluded that exposure levels in workers and consumers are “significant,” based on monitoring data and exposure modeling.

Comments: 7-3, 29-3
Comment Quotation:
“Simply put, this product kills people. My nephew died from the fumes two months ago while wearing a ventilating mask and gloves.”

Comment: 9-1

Comment Summary:
Children and women of child-bearing age may be particularly vulnerable to effects from methylene chloride because chemical exposures during specific developmental periods can increase children’s risk for adverse health impacts, including cancer.

Comment: 28-2

DTSC Response:
DTSC evaluated the potential for human exposure to methylene chloride during product use. Following an extensive review of the scientific literature and analysis of the known hazard traits of methylene chloride, DTSC concluded that there is a potential for workers and consumers to be exposed to methylene chloride during normal use of paint or varnish strippers. These exposures could potentially contribute to or cause significant adverse health impacts, including cancer and death. Children and women of childbearing age are vulnerable population subgroups that are highly susceptible to adverse impacts from chemical exposures.

There have been numerous worker and consumer deaths associated with the use of paint or varnish strippers containing methylene chloride in enclosed spaces or without adequate ventilation, such as those documented in these comments. In 2012, the European Parliament concluded that the potential human health threat from using paint or varnish strippers containing methylene chloride was of sufficient concern that the sale of paint strippers containing methylene chloride to general consumers in the European Union was prohibited. In contrast, methylene chloride-based paint or varnish strippers are still widely available in the United States. Recognition of health hazards associated with inhalation exposure to methylene chloride prompted the U.S. Consumer Product Safety Commission in 1987 to require warning labels on paint or varnish strippers, but clearly this strategy has not eliminated the potential for adverse health effects from use of such products.

Eliminating the chemical hazard entirely, or substituting a less hazardous chemical, is the most effective means of minimizing potential occupational or consumer exposures to methylene chloride while using paint or varnish strippers. This proposed regulation is an important supplement to current state and federal standards and supports the ongoing effort to protect human health by preventing worker and consumer injuries.

No changes were made to the proposed regulation or supporting documents based on these comments.
Comment Summary:

Industrial paint stripping operations on flight hardware are carried out under strictly controlled conditions, with workers using supplied air respirators and full skin protection using a chemical-resistant suit. Worker exposure to methylene chloride is significantly reduced or eliminated.

The Department of Defense conducts air monitoring to assess employee exposure to methylene chloride. Employees are trained in the proper use of hazardous materials, such as methylene chloride, and protected from chemical exposures by use of appropriate PPE and engineering controls. Employees also undergo medical surveillance.

Comments: 12-2, 13-4, 13-8

DTSC Response:

DTSC appreciates that the Department of Defense (DoD) and related industries recognize the potential health risks faced by workers exposed to methylene chloride during use of paint or varnish strippers and take steps to reduce and monitor such exposures.

As recommended by Cal/OSHA and federal OSHA, occupational exposures to harmful substances such as methylene chloride in paint or varnish strippers are typically addressed via hazard control methodology widely accepted by the industrial hygiene profession. Following this approach, eliminating methylene chloride entirely, or substituting a less hazardous chemical, is the most effective means of minimizing potential occupational exposures to workers. Engineering controls and use of appropriate PPE, as used by the DoD and related industries, can be effective at reducing potential exposures when implemented in combination with appropriate administrative controls. Reportedly, there are many workplaces that do not follow such stringent protocols, leading to increased potential for exposure to methylene chloride and subsequent adverse health effects in workers. Because of the well-characterized hazard traits of methylene chloride and the potential for exposure during use of paint and varnish strippers, DTSC is pursuing the Priority Product listing to move manufacturers to find safer alternatives.

Listing paint and varnish strippers with methylene chloride as a Priority Product will not restrict DoD’s access to paint strippers with methylene chloride at this time. As manufacturers undertake the Alternatives Analysis required by the listing, the DoD and related industries may elect to participate in the process, ensuring their concerns are considered in the outcome.

No changes were made to the proposed regulation or supporting documents based on these comments.
Comment Summary:

DTSC cites studies that discuss adverse impacts when methylene chloride is used in situations without adequate ventilation. A study of consumers who used methylene chloride paint strippers was conducted by Riley et al. (2001) and showed that most respondents were aware of health effects from poor ventilation and either use the products outside (60%) or take steps to increase ventilation when used indoors. DTSC is over-estimating exposure and the potential for widespread adverse impacts by ignoring the facts that methylene chloride is usually used outdoors and most people understand the risks from working in poorly ventilated areas.

In its supporting documents, DTSC also cites U.S. EPA’s Toxicological Review of Dichloromethane, which summarized outdated exposure data and over-stated the risk to consumers from using paint removers containing methylene chloride by analyzing worst case scenarios and using default assumptions that over-estimated risk. W.M. Barr conducted a study that showed significantly lower exposure in users than was described by U.S. EPA and DTSC. DTSC needs to re-evaluate the potential risks for consumers.

Over exposure to methylene chloride has significantly declined over the last 10 years, as evidenced by the reduction in incidents reported to poison control centers, but is not from a decreased use of methylene chloride. Serious events have occurred during occupational use or from intentional misuse of products containing methylene chloride. DTSC should carefully evaluate data about risks and exposures to methylene chloride and consider a regulatory approach based on improved labelling and consumer education.

Comments: 22-5, 22-10, 22-12, 26-21, PH1-3, PH1-5

DTSC Response:

The study by Riley et al. (2001) sought to assess how consumers might change behavior depending on how well they understood the relationship between their actions and exposure to methylene chloride during use of paint strippers. In the study, 20 people were questioned as they were shopping in a home improvement store. Of the 20 study participants, one person reported wearing an appropriate respirator during the use of paint stripping products containing methylene chloride, while 18 people reported wearing gloves, although they were not chemically resistant gloves. The author noted that “although agencies such as OSHA continue to recommend specific gloves as protection against dermal exposure to methylene chloride, it appears that their stipulation of agency-approved material is not being followed by all consumers.” The author concludes that, for consumers, “there are not many important messages regarding exposure risk that most users know well enough to assume that they will take the associated precautions.” This conclusion contradicts the assertion that most consumers are aware of the health risks from using paint or varnish strippers containing methylene chloride.

DTSC considered the extent and quality of information available to substantiate the existence or absence of potential adverse impacts and potential exposures. In evaluating the quality of the available information, DTSC considered factors specified in...
section 69503.2(b)(1)(C) of the SCP regulations. Based on these criteria, U.S. EPA’s Toxicological Review of Dichloromethane is an authoritative source of information. Although W.M. Barr reports conducting a study that contradicts the findings of U.S. EPA, it is unclear whether the study meets the same criteria. If this study were made available to DTSC, we would consider the information if it does meet the necessary criteria. Regardless, DTSC does not depend on quantitative risk assessments to determine whether potential exists for exposure to a Candidate Chemical in a product to contribute to or cause significant or widespread adverse impacts. Rather, the criteria for listing are a narrative standard.

Poison control centers continue to report incidents of over-exposure to methylene chloride and deaths from use of paint or varnish strippers containing methylene chloride continue to be reported. DTSC carefully monitors data on illnesses and deaths attributed to methylene chloride exposure and has proposed this Priority Product listing to accelerate the quest for safer paint or varnish strippers.

No changes were made to the proposed regulation or supporting documents based on these comments.
COMMENTS REGARDING THE ECONOMIC IMPACT OF PROPOSED REGULATIONS

Comment Summary:

The Alternatives Analysis must reflect costs and benefits of any risk management or regulatory alternatives, as well as potential costs to businesses associated with discontinuing product lines, reformulating products, collecting and disposing of stranded products, and making label changes. Costs associated with the time required to complete these activities must also be factored in. The Alternatives Analysis must also assess the costs to consumers to buy and use alternatives to paint or varnish strippers containing methylene chloride.

Comment: 22-8

DTSC Response:

According to Section 69505.6(a)(3) of the SCP regulations, “if the responsible entity’s alternative selection decision is to retain the Priority Product based in whole or in part on internal cost impacts…the final Alternatives Analysis Report must include a quantified comparison of the internal cost impacts of the Priority Product and the alternatives, including manufacturing, marketing, materials and equipment acquisition, and resource consumption costs.” Thus, the costs enumerated by the commenter are to be captured in the Alternatives Analysis. The responsible entity must also evaluate, monetize, and compare public health and environmental costs. DTSC concurs with the commenter that private and public costs of alternatives should be considered in the Alternatives Analysis.

DTSC made no changes to the proposed regulation or supporting documents in response to this comment.

Comment Summary:

The Economic Impact Statement (EIS) violates the APA because it underestimates costs to businesses to comply with the regulation. DTSC estimates that Stage 2 of an Alternatives Analysis will cost manufacturers from $27,000 to $192,000. The manufacturer W.M. Barr estimates that Part 2 of an Alternatives Analysis would cost from $455,000 to $680,000. Because the costs associated with the regulation are much higher than DTSC estimated, the EIS is “legally deficient.”

DTSC presumes manufacturers will comply with the regulation by submitting a Priority Product Notification and Alternatives Analysis Reports, yet provides no justification for this assumption. Manufacturers may submit a Product-Chemical Replacement Intent and Confirmation Notification instead of conducting an Alternatives Analysis. These costs could be significant and should also be estimated. W.M. Barr requests that DTSC reevaluate the costs associated with the proposed regulation.

Comments: 26-9, 26-10, PH4-3
DTSC Response:

DTSC prepared an economic impact assessment for a non-major regulation and provided all required information in the Economic and Fiscal Impact Statement (EFIS), included as a background document with the rulemaking package. The actual costs and benefits associated with the regulations will depend on future choices made by manufacturers.

Since there are no previously conducted Alternatives Analyses to use as guides, DTSC relied on other data sources to estimate the cost of conducting an Alternatives Analysis. DTSC surveyed a variety of authoritative sources to fill this data gap: relying on estimates from Alternatives Analysis pilot studies and guides from other agencies, surveying manufacturers of paint or varnish strippers, including W.M. Barr, and manufacturers of other proposed Priority Products, and soliciting input from industry trade groups. DTSC included a range of estimates in its Economic Impact Analysis to reflect the uncertainty associated with this cost. The “high” estimate in the Economic Impact Analysis represents the largest estimate that DTSC obtained across the many data sources it surveyed. It is DTSC’s intent to refine these estimates as the SCP program matures. Once Alternatives Analyses are completed and approved by SCP, DTSC will have the opportunity to collect historical data on the true cost of conducting an Alternatives Analysis.

DTSC’s assumption that manufacturers will comply with the regulation by submitting Priority Product Notifications and Alternatives Analysis Reports is based in part on discussions with industry. As stated in the attachment to the Economic Impact Analysis, “manufacturers and an industry alliance representative indicated that at least four manufacturers plan on forming a consortium and submitting a combined Alternatives Analysis.” DTSC has not received indications from industry that manufacturers would submit a Product-Chemical Replacement Intent and Confirmation Notification. Similarly, these commenters do not provide evidence that manufacturers intend to submit a Product-Chemical Replacement Intent and Confirmation Notification.

No changes were made to the proposed regulation or supporting documents based on these comments.

5 Halogenated Solvents Industry Alliance, Inc. (HSIA), whose members include W.M. Barr & Co.
COMMENTS REGARDING EXTERNAL SCIENTIFIC PEER REVIEW

Comment Summary:

Dr. Jim Bruckner, in his peer review of DTSC’s Technical Summary, stated that the association between exposure to methylene chloride and specific tumors in humans is not strong, even in studies of high inhalation exposures in industry and incidence of cancer.

Dr. Raymond Yang, another ESPR reviewer, said the use of the term “numerous” to describe the number of deaths from methylene chloride exposure made him feel “very uncomfortable” because it over-stated the issue. The sources cited by DTSC indicate about 15 deaths since 2000, most of which were worker deaths during bathtub refinishing. This low number does not indicate the potential for significant or widespread adverse impacts in California.

Comments: 19-6, 26-15, 26-18

DTSC Response:

An association between methylene chloride exposure and cancer is recognized by authoritative bodies including the U.S. EPA, the International Agency for Research on Cancer, the U.S. Department of Health and Human Services, and the federal OSHA. The State of California’s Office of Environmental Health Hazard Assessment has listed methylene chloride on its Proposition 65 list as a chemical known to the state to cause cancer. This designation by these authoritative bodies implies that one potential adverse health impact from methylene chloride exposure is cancer, regardless of the specific type of tumor that might result.

DTSC respectfully disagrees with Dr. Yang and has determined that the deaths represent significant evidence of potential adverse impacts and the finding of potential for significant or widespread harm is warranted. Evaluating the potential for significant adverse impacts also included consideration of methylene chloride’s toxicity, and potential impacts on sensitive subpopulations or sensitive environmental receptors. Similarly, the evaluation of the potential for widespread adverse impacts included consideration of how widely paint or varnish strippers containing methylene chloride are sold or used.

No changes were made to the proposed regulation or supporting documents based on these comments.
Comment Summary:

The ESPR reviewers were not given adequate information on how to properly evaluate DTSC’s conclusions that the criteria were met for listing paint or varnish strippers containing methylene chloride as a Priority Product. Without a clear explanation of the meaning of the word “potential” as used in the SCP regulations, ESPR reviewers applied their own understanding of the term, leading to flawed evaluations and faulty conclusions. As well, the term “reasonably foreseeable”, as defined in the ISOR, is not defined in the documents provided the ESPR reviewers.

The Technical Summary refers to “reliable information” but does not explain how that relates to the SCP regulations. The Technical Summary does state that reliable information can be from sources other than primary, peer-reviewed scientific literature. Without a clear definition of the term, ESPR reviewers lacked appropriate guidance on how to judge whether DTSC cited reliable information; therefore, could not accurately determine whether DTSC met the regulatory standards required to list paint or varnish strippers containing methylene chloride as a Priority Product.

Comments: 26-22, 26-23

DTSC Response:

The statutory mandate for external scientific peer review (Health and Safety Code section 57004) states that the reviewer’s responsibility is to determine whether the scientific portion of the proposed regulation is based on sound scientific knowledge, methods, and practices. Reviewers were given an opportunity to comment on all aspects of the scientific basis of the proposed regulation and were provided copies of referenced journal articles and other information sources for their own review. Reviewers were also instructed to request clarification of the review process or the documents, if needed, and they did not indicate any confusion about how to interpret the use of the terms “potential” or “reasonably foreseeable.” The framework regulations defines “potential” as reasonably foreseeable based on reliable information, further defining reliable information as peer reviewed literature and government reports. “Reasonably foreseeable” means that a reasonable person would be able to predict or expect ultimately harmful results. DTSC defines these terms in the framework regulations and its regulation package to provide clarity, but does not consider the definitions of these terms to be particularly unusual or unconventional. The reviewers did recommend additional primary, peer-reviewed scientific studies be included in the Technical Summary to further substantiate DTSC’s position. These comments were noted and additional references made to support DTSC’s conclusions.

No changes were made to the proposed regulation or the supporting documents based on these comments.
COMMENTS IN SUPPORT OF THE RULEMAKING

Comment Summary:

These comments express general support for the proposal to list Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product based on hazard traits, exposure potential and potential health effects.

Comments: 16-1, 17-1, 18-1, 27-1, 27-4, 28-6, PH5-1, PH6-1, PH6-3, PH7-1, PH9-1

Comment Quotation:

“The Local Hazardous Waste Management Program in King County strongly supports the California Department of Toxic Substances Control (DTSC) proposal to add paint or varnish strippers containing methylene chloride as a Priority Product. Thank you for taking much-needed leadership to address worker and consumer exposure to this hazardous chemical.”

Comment: 1-1

Comment Summary:

The South Coast Air Quality Management District staff support this proposal. “We agree that workers and consumers can be exposed to methylene chloride during normal use of paint or varnish strippers.”

Comment: 2-1

Comment Quotation:

“On behalf of the Hazardous Waste and Toxics Reduction (HWTR) Program at Washington State Department of Ecology, I am writing in support of the California Department of Toxic Substances Control (DTSC) proposal to add paint or varnish strippers containing methylene chloride as a Priority Product.”

Comment: 11-1

DTSC Response:

DTSC acknowledges the support offered by these comments. DTSC made no change to the proposed regulation or supporting documents in response to these comments.
Comment Summary:
Drew Wynne died recently after using a methylene chloride paint stripper. I'm very troubled these dangerous products are available to the public.

Comments: 4-1, 6-1, 8-1, 15-1, 20-1, 21-1, 24-1

DTSC Response:
DTSC agrees that Mr. Wynne’s unfortunate death is precisely the outcome we hope to avoid in the future with this proposed regulation. No changes were made to the proposed regulation or supporting documents based on these comments.

Comment Summary:
Methylene chloride is deadly and should not be commercially available. This product should be banned from sale to the public.

Comments: 5-1, 7-1, 10-1, 14-1

DTSC Response:
DTSC proposed listing paint or varnish strippers containing methylene chloride as a Priority Product because of the well-established health hazards associated with exposure to methylene chloride. The proposed regulation triggers the requirements for notification and an Alternatives Analysis to identify safer alternatives. If the outcome of the Alternatives Analysis does not reveal safer alternatives, the SCP regulations provide a variety of regulatory responses in addition to possible sales prohibitions to address the adverse impacts associated with use of the Priority Product.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comment Summary:
DTSC has clearly met the key prioritization criteria listed in the California Code of Regulations for listing Paint or Varnish Strippers Containing Methylene Chloride as a Priority Product based on methylene chloride’s hazard traits, exposure potential and risks to sensitive subpopulations.

Comments: 28-3, 29-1

DTSC Response:
DTSC acknowledges the commenters’ agreement with the demonstration for the proposed listing for this Priority Product. No changes were made to the proposed regulation or supporting documents based on these comments.
COMMENT EXPRESSING GENERAL DISAGREEMENT WITH PROPOSAL

Comment Summary:

*The American Coatings Association (ACA) believes the risks and hazards associated with methylene chloride are inaccurate and overstated and the proposed designation of methylene chloride as a Priority Product is fundamentally flawed.*

Comment: 22-1

DTSC Response:

DTSC respectfully disagrees with the commenter’s assertions. DTSC’s Technical Summary and our conclusions are accurate and were validated through peer review. The risks, hazards, and potential for adverse impacts associated with methylene chloride are well-documented in the literature and by other authoritative bodies.

The Technical Summary summarizes results from over 50 scientific studies that thoroughly document the health risks from exposure to methylene chloride, including cancer and death. U.S. EPA estimated nearly 32,000 workers and 1.3 million consumers are exposed to methylene chloride in paint or varnish strippers each year during use of paint or varnish strippers. The key prioritization principles for identifying and listing paint or varnish strippers containing methylene chloride as a Priority Product have been met through documentation of the wide availability and use of paint or varnish strippers containing methylene chloride and the potential for significant adverse health impacts, including cancer and death, from inhalation exposure to methylene chloride while using such products.

The overall intent of the Priority Product listing is to move manufacturers to perform an Alternatives Analysis in the quest for safer alternatives. DTSC does not presume what potential outcome may result from the Alternatives Analysis and each manufacturer’s decision-making process. The purpose of this proposed regulation is to protect the health of workers and consumers and identify safer options to the use of methylene chloride in paint or varnish strippers.

No changes were made to the proposed regulation or the supporting documents based on this comment.
EXAMPLE OF ALTERNATIVES ANALYSIS

Comment Summary:

BizNGO has provided an example of one approach to conducting an Alternatives Analysis (AA) of paint or varnish strippers containing methylene chloride in line with the requirements of the SCP regulations. The emphasis of the report is the scoping and hazard assessment step specified for the first stage of the two-stage AA.

Comment: 25

DTSC Response:

DTSC appreciates the example provided by BizNGO. Responsible Entities may wish to review the BizNGO report to help identify approaches that may be helpful in conducting an Alternatives Analysis. DTSC released version 1.0 of the Alternatives Analysis Guide to help responsible entities understand and complete an Alternatives Analysis that fulfills SCP regulatory requirements. It provides useful approaches, methods, resources, tools, and brief examples. The Alternatives Analysis Guide is available on the SCP website at: http://dtsc.ca.gov/SCP/AlternativesAnalysisGuidance.cfm.

No changes were made to the proposed regulation or supporting documents based on this comment.
COMMENTS REGARDING THE REQUIREMENT AND UTILITY OF AN ALTERNATIVES ANALYSIS

Comment Summary:

There are two general themes expressed in comments regarding the value of conducting an Alternatives Analysis for the use of methylene chloride in paint or varnish strippers: 1) the dangers of methylene chloride are so well-known that an Alternatives Analysis is imperative for finding a safer alternative and avoiding a potentially regrettable substitution; and 2) the requirement to conduct an Alternatives Analysis is unnecessary because the chemical industry has already evaluated chemical alternatives and knows there is no functionally acceptable, technically feasible and economically feasible alternative to the use of methylene chloride in paint or varnish strippers.

Comments: 1-3, 11-3, 22-2, 22-6, 26-25, 26-29, PH4-1

DTSC Response:

DTSC recognizes that paint or varnish strippers containing methylene chloride are used in a wide variety of distinct applications and that methylene chloride is an effective solvent for removing the broadest range of surface coatings. DTSC understands that some alternatives to the use of paint or varnish strippers containing methylene chloride have been assessed by some manufacturers. Alternative methods for removing paint or varnish from different surfaces have been implemented where deemed feasible by commercial entities. These alternative methods include physical/mechanical stripping, pyrolytic/thermal stripping, and chemical stripping. Although these alternatives may not possess the "all-in-one" surface coating removal capability of methylene chloride, they have utility in specific applications. In addition, researchers continue to develop new paint stripping product alternatives that are safer than methylene chloride and that work as effectively.6

The potential acute and chronic health hazards associated with exposure to methylene chloride while using paint or varnish strippers are well-established. The purpose of requiring an Alternatives Analysis by manufacturers of paint or varnish strippers containing methylene chloride is to advance the further development of safer alternatives to remove paint or varnish in a wide range of applications. DTSC cannot predict the outcome of an Alternatives Analysis, and for certain specific uses, there might not be a safer alternative. One intent of the SCP regulations is to spur innovation of safer alternatives.

No changes were made to the proposed regulation or supporting documents based on these comments.

**Comment Summary:**

*Information generated by the Alternatives Analyses conducted by manufacturers could be used by regulatory agencies in other states to inform new regulations and drive market changes.*

**Comments:** 1-7, 11-4

**DTSC Response:**

The Safer Consumer Products regulations were adopted to establish a process to evaluate Chemicals of Concern in consumer products placed into the stream of commerce in the state of California, and their potential alternatives. While the primary purpose of an Alternatives Analysis is to determine how best to limit exposure or reduce the level of hazard posed by a Chemical of Concern, the analyses will be publicly available and will likely be added to the body of knowledge regarding these products and inform a wide range of decision-making beyond California.

No changes were made to the proposed regulation or supporting documents based on these comments.

**Comment Summary:**

*Paint and varnish strippers containing methylene chloride are necessary for use in specific aircraft and space manufacturing practices and many of the alternatives cannot be used because they do not meet customer specifications. Manufacturers of paint or varnish strippers containing methylene chloride that are used by the U.S. military should not be required to conduct an Alternatives Analysis because these products are not used by the common consumer.*

**Comments:** 12-1, 13-2

**DTSC Response:**

DTSC recognizes that methylene chloride is used for aviation and space applications where currently known alternatives cannot be used due to specific material requirements and customer specifications. DTSC acknowledges that the DoD has reduced methylene chloride use and already implemented alternatives to methylene chloride-based paint strippers for many applications. While we recognize the importance of the remaining uses of methylene chloride in DoD operations, these formulations are not unique and are indistinguishable from the other formulations that are included in the Priority Product listing. Because the requirements applicable to a product-chemical combination focuses on the Priority Product itself, operationally, it is not possible to exclude a specific type of use or user of otherwise identical Priority Products from the provisions of the regulations, including the requirement to conduct an Alternatives Analysis.
The proposed rule defines the Priority Product as a product-chemical combination, describing the potential adverse impacts and exposures, as required by the framework regulations (22 CCR 69503 et seq). The definition of the Priority Product includes the Candidate Chemical, methylene chloride in this case, and a description of the product, namely, paint and varnish strippers. The framework regulations do not provide exclusions for specific uses of the product. The formulations used by the DoD are not unique formulations. They meet the definition of the Priority Product in the proposed regulations and are produced by the same manufacturers who produce paint and varnish strippers containing methylene chloride for the commercial market.

Rather than excluding the DoD and defense contractors’ uses of the Priority Product from the Alternatives Analysis, those who have evaluated alternatives to the Priority Product and determined that such alternatives cannot be used should provide their data to the manufacturers of the Priority Product. Manufacturers may welcome this information and use it to inform their Alternatives Analyses. While the outcome of an Alternatives Analysis cannot be predetermined, it may include a recommendation that specific uses continue due to lack of alternatives. Such information is also appropriately considered during the development of any regulatory response at the conclusion of the Alternatives Analysis.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comment Summary:

The Department of Defense has already tested and implemented safer alternatives to the use of paint or varnish strippers containing methylene chloride and reduced the overall use of dichloromethane by 97% at Fleet Readiness Center Southwest. By applying alternatives assessment principles, the Navy concluded that the use of paint or varnish strippers containing methylene chloride is still required or may be required in the future for some mission critical or maintenance applications.

Although the Department of Defense has determined that there is no functionally acceptable and technically feasible alternative to the use of paint or varnish strippers containing methylene chloride for all applications, the Department of Defense is not a Responsible Entity as defined in the Safer Consumer Products regulations, and does not have the legal duty to submit an Alternatives Analysis Report, which puts the Department of Defense at a disadvantage. The Department of Defense is prohibited from making its impacts analysis arguments to a third party, which limits the Department’s ability to advocate for the exclusion of specific paint or varnish strippers containing methylene chloride.

The Department of Defense urges DTSC to exempt specific paint or varnish strippers containing methylene chloride that are used in applications that are essential to military aviation and space applications. DTSC. DTSC has the legal authority to grant an exemption for military aviation applications and should distinguish between industrial users with well-developed OSHA programs and consumers who shouldn’t use these products at home.
Comments:  12-3, 13-1, 13-3, 13-6, 13-7, 13-9, 13-10

DTSC Response:
DTSC commends Fleet Readiness Center Southwest for its ongoing efforts to reduce its use of methylene chloride. While we recognize the importance of the remaining uses for methylene chloride-based paint strippers for certain applications, DTSC cannot carve out these applications from our proposed Priority Product listing. The listing must clearly identify a product-chemical combination in such a manner that the manufacturer of the product would know it is being regulated. Although it is possible to define the Priority Product to exclude clearly unique products from the listing, the paint stripper with methylene chloride used at DoD facilities is not a unique product.

Once a Priority Product is listed, manufacturers are required to perform an Alternatives Analysis within a specified period to ascertain whether there are ways to make the product safer. The Alternatives Analysis process accommodates different specific end user requirements; therefore, Fleet Readiness Center Southwest’s mission critical requirements may be considered and addressed by the entity performing the Alternatives Analysis. While DTSC cannot provide a specific exemption for military applications, we encourage the DoD to engage with manufacturers in the Alternatives Analysis process to ensure its concerns are considered. Additionally, it can publicly comment on any submitted Alternatives Analyses.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comment Summary:
Industry claims that the use of methylene chloride is declining, indicating there are alternatives available that perform the same function and that this regulation will not devastate an industry. We have the opportunity in California to innovate and find safer alternatives. It’s not the label on the product that’s the problem, it’s the dangerous chemical in it.

Comment:  PH7-5

DTSC Response:
DTSC is aware that some major stakeholders, including the DoD, do report that use of methylene chloride is declining and alternatives are being utilized where applicable. We agree that the regulatory intent of the SCP program is to spur innovation to develop safer products for use in applications where the Priority Product is considered the only acceptable method of removing paint or varnish.

No changes were made to the proposed regulation or the supporting documents based on this comment.
Comment Summary:

An Alternatives Analysis of the solvent function of methylene chloride in paint or varnish strippers can include chemicals that strip paint via other functions. Technologies have been developed that can be used in combination with safer chemicals to create alternatives that perform equal to or better than methylene chloride, are cost-effective, non-flammable, and are safer for workers. When assessing the hazards of a chemical and whether it appears from a market perspective to be both economically viable and technically feasible, it is apparent that alternatives to the use of methylene chloride in paint strippers are available. If a goal of requiring Responsible Entities to conduct an Alternatives Analysis is to avoid regrettable substitutions, it is important that a hazard assessment be performed on other chemicals in the reformulation and not just the solvent replacement. Also, better soy-based alternatives are available (Soy Technologies in Kentucky).

Comments: 9-2, 18-2

DTSC Response:

DTSC agrees that a number of alternatives to paint strippers with methylene chloride are available and recognizes that there are three general categories of paint or varnish stripping methods, including physical/mechanical stripping, pyrolytic/thermal stripping, and chemical stripping. Chemical stripping utilizes organic solvents or alkaline or acidic chemicals to dissolve paint or varnish. The purpose of the Alternatives Analysis is to identify safer alternatives to the use of methylene chloride in paint or varnish strippers, which may include chemical substitution, reformulation, or integration of a technological application with the use of a safer chemical. The Alternatives Analysis process includes a comparative evaluation of alternatives using a wide range of relevant factors, including, but not limited to, exposure, hazard, economic and market viability, and technical feasibility.\(^7\)

No changes were made to the proposed regulation or the supporting documents based on these comments.

Comment Summary:

Paint or varnish strippers containing methylene chloride are the most efficient and cost-effective paint remover products available to consumers and small businesses. Marketplace experience has shown that customers are disappointed by the performance of products that do not contain methylene chloride, negatively affecting the economic viability of the brand and causing economic harm to the industry.

There are also potential health and environmental risks from using alternatives to methylene chloride in paint or varnish strippers. Because paint or varnish strippers that do not contain methylene chloride are less effective, consumers and workers need to use more of these products, thereby increasing the risk of exposure and risk of potential release to the environment. Other chemical solvents can also be more flammable than methylene chloride and increase the fire risk from using these. As well, other solvents can result in increased ozone formation and ground level smog. Alternatives that have not been proven to benefit health could present increased health risks. If consumers and workers use mechanical methods to remove paint or varnish, they can be exposed to dust and lead-based paint during removal.

Although listing paint and varnish strippers with methylene chloride as a Priority Product does not impose risk management actions, the American Coatings Association is concerned that the listing will lead to risk management efforts.

The SCP regulations permit Responsible Entities to avoid performing an Alternatives Analysis by reformulating the product and replacing the Chemical of Concern with a chemical not on the Candidate Chemical list. These chemical substitutes could also have a negative environmental impact; for example, the substitution of methylene chloride with benzyl alcohol. DTSC must conduct a higher level of environmental review when Responsible Entities do not provide an Alternatives Analysis Report but simply indicate a reformulation has occurred using a chemical that is not on the Candidate Chemical list.

Comments: 19-10, 19-11, 22-7, 26-12, 26-26, 26-27, 26-28, PH1-1, PH2-1, PH2-2

DTSC Response:

DTSC recognizes that paint or varnish strippers containing methylene chloride are used in a wide variety of distinct applications and that methylene chloride is the most effective solvent for removing a broad range of surface coatings. In some cases, alternative methods for removing paint or varnish from different surfaces have already been implemented where deemed feasible by commercial entities.

The proposed regulation lists a Priority Product, which in turn triggers requirements to notify DTSC and perform an Alternatives Analysis to identify safer alternatives for the listed Priority Product. The Alternatives Analysis includes identification and consideration of possible adverse impacts to human health or the environment, including impacts such as ozone depletion and global warming potential, waste and end-of-life impacts of potential replacement chemicals. These are to be taken into consideration when selecting the preferred alternative. If the outcome of the Alternatives Analysis does not reveal preferable alternatives, the framework regulations provide a
variety of regulatory responses to address the environmental or public health impacts associated with the Priority Product. DTSC cannot predict the outcome of an Alternatives Analysis. However, one intent of the SCP regulations is to spur innovation of safer alternatives.

While it is true that a responsible entity may avoid an Alternatives Analysis by replacing the Chemical of Concern with a substitute chemical not on the Candidate Chemicals list, the Candidate Chemicals list is a comprehensive list compiled from established authoritative lists and updated quarterly. In addition such a reformulation would still require notification. Namely, if a responsible entity decides to substitute methylene chloride with another chemical that is not on the Candidate Chemicals list, the manufacturer must submit to DTSC a Product-Chemical Replacement Intent and Confirmation Notification. This document includes the name of the replacement chemical, the concentration of each replacement chemical in the reformulated product, and the hazard traits and environmental or toxicological endpoints known to be associated with the replacement chemical. Even though a replacement chemical may not currently be on the Candidate Chemical list, if the SCP program deems the replacement to possess undesirable hazard traits or toxicological endpoints, DTSC may revise the Candidate Chemicals list using factors specified in section 69502.2(b). If DTSC also determines the substitute chemical poses sufficient potential for exposure and adverse impacts, it may propose a Priority Product listing for the new chemical-product combination.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comment Summary:

In January 2017, U.S. EPA published a notice of proposed rulemaking on the use of methylene chloride in paint and coating removers, but DTSC decided to move forward with its own listing. This will require manufacturers to undertake a costly Alternatives Analysis (AA), even when DTSC may be preempted by TSCA.

Comment: 26-6

DTSC Response:

U.S. EPA issued a proposed rule pertaining to methylene chloride under TSCA in January 2017, but at the time of the public notice for this DTSC rulemaking proposal, U.S. EPA had not finalized this proposed ban. On May 10, 2018, U.S. EPA announced it intends to finalize the ban of the manufacture, processing, and distribution of methylene chloride for use in paint strippers. However, as of August 23, 2018, no final rule has been published in the Federal Register. Until U.S. EPA announces and publishes the final rule, DTSC cannot determine the effect of the federal regulation. If U.S. EPA adopts the proposed rule from January 19, 2017, without change, it is

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possible that some manufacturers would still be subject to the state requirements to perform an Alternatives Analysis due to extensions of the effective dates in the federal requirements. Furthermore, if the federal requirement is finalized as proposed, information gathered from the Alternatives Analysis can only benefit manufacturers who must necessarily seek alternatives to methylene chloride in paint strippers after the U.S. EPA ban becomes effective.

No changes were made to the proposed regulation or supporting documents based on this comment.

**Comment Summary:**

*The outcome of the Alternatives Analysis process is not a given because many decisions depend on what the regulated entity proposes. There’s no harm in assessing what can be done to improve worker and consumer safety while stripping paint from walls and tubs.*

**Comment:** PH7-4

**DTSC Response:**

DTSC agrees that the process of evaluating alternatives provides valuable information and no one can pre-determine the outcome from an Alternatives Analysis and individual manufacturer’s decision process. Similarly, DTSC does not presume that a Regulatory Response will be necessary.

No changes were made to the proposed regulation or supporting documents based on this comment.
COMMENTS REGARDING THE CALIFORNIA ENVIRONMENTAL QUALITY ACT (CEQA) AND THE ADMINISTRATIVE PROCEDURES ACT (APA)

Comment Summary:
DTSC claims the new regulation is exempt from CEQA based on the “common sense exception.” DTSC presumes there is no possibility that the activity may have a significant effect on the environment, but this has not been factually demonstrated by DTSC. Responsible Entities could avoid submitting an Alternatives Analysis Report by substituting methylene chloride with another chemical that would increase harmful air emissions. As such, the proposed regulation is not exempt from CEQA. In the past, air district regulations seeking to reduce VOCs in paint were overturned for failing to comply with CEQA after it was shown that lower quality products would result in a net increase in VOC emissions because more paint would have to be used to achieve a result equal to the initial product.

Comment: 26-11

DTSC Response:
DTSC determined in its draft CEQA document that listing paint or varnish strippers containing methylene chloride as a Priority Product would not result in significant environmental effects for CEQA purposes since the purpose of the regulations is to reduce the likelihood of adverse environmental and health impacts associated with the Priority Product. The proposed regulation lists a Priority Product, which in turn simply triggers the requirements to notify DTSC and perform an Alternatives Analysis to identify safer alternatives for the listed Priority Product. The Alternatives Analysis includes evaluation of possible economic, environmental, and public health impacts from alternatives, including adverse impacts on air quality. In contrast to the case cited in the comment, the proposed regulation listing paint and varnish strippers with methylene chloride as a Priority Product does not require any manufacturer or individual to use any particular alternative.

No changes were made to the proposed regulation or supporting documents based on this comment.
Comment Quotation:

“To comply with the APA, the Department must describe reasonable alternatives to the regulation and the Department’s reason for rejecting those alternatives. The Department has not adequately considered the alternatives or provided an appropriate basis to reject them.”

Comment: 26-4

DTSC Response:

The Administrative Procedure Act requires DTSC to consider alternatives that are proposed as being more effective, less burdensome and equally effective, or more cost effective and equally effective in accomplishing the purpose of the regulation. Any proposed alternative must be considered if it achieves the purpose of the regulation and is in full compliance with the authorizing statute. DTSC considered two alternatives: to wait for the U.S. EPA proposed regulations for paint strippers with methylene chloride to be adopted and to list paint and varnish strippers containing either methylene chloride or N-methyl pyrrolidone (NMP) as Priority Products. As described in this Final Statement of Reasons, DTSC determined that neither of these alternatives would be more effective in meeting the purpose for which the action is proposed, or as effective and less burdensome to affected private persons: DTSC determined there was too much uncertainty surrounding the scope and timing of the U.S. EPA proposal, and DTSC was unable to include NMP in its proposed regulation because NMP was not included in the initial Priority Products list. DTSC did not receive any proposed alternatives that meet these requirements and would be less burdensome.

Stakeholders have commented that DTSC should withdraw the proposed regulation and allow manufacturers of paint or varnish strippers containing methylene chloride to undertake voluntary actions, such as expanded labelling of such products to include more cautionary language. DTSC rejects any delay in the proposed regulation. The incidence of continued fatalities resulting from the use of this product reinforces the urgency of completing the listing for this Priority Product so that Alternatives Analyses can be commenced. In addition, suggesting cautionary language for the Priority Product is premature at this stage because it would be considered as a regulatory response only after an Alternatives Analysis has been complete. Finally, nothing in the proposed regulation would prevent manufacturers from undertaking voluntary mitigating actions at any point in time.

No changes were made to the proposed regulation or supporting documents based on this comment.

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COMMENTS REGARDING EXISTING U.S. REGULATIONS

Comment Summary:

The federal government has not protected Americans from these dangerous products, which should not be on the market. Although U.S. EPA issued a proposed rule under TSCA to ban methylene chloride for use in paint and coating removal, the agency is not moving forward to finalize this proposed ban. California should “step up” and ban paint or varnish strippers containing methylene chloride.

The EU already banned methylene chloride in paint or varnish strippers used by consumers and safer alternatives are available. There is more than enough evidence to support a ban on the use of methylene chloride in paint or varnish strippers. Since the federal government has abdicated its responsibility to protect public health by banning the use of methylene chloride in such products, it’s critical that California act now.

Paint or varnish strippers containing methylene chloride can cause immediate death but nowhere is that fact stated on the product label. There are warnings about long-term health risks, but no warning about the risk of sudden death. The warnings do not advise users on the depth of precautions necessary to prevent health effects.

U.S. EPA determined that current regulations concerned with the labeling of paint or varnish strippers containing methylene chloride are insufficient for protecting workers and consumers from the serious adverse health effects associated with exposure to methylene chloride, including death through inhalation exposure. A warning label is a grossly insufficient way of protecting people from a chemical exposure that could kill them.

The removal of methylene chloride from paint or varnish strippers is the only way to protect consumers and workers, particularly vulnerable workers such as day laborers and temporary workers, from adverse health effects from exposure to methylene chloride. This aligns with industry-wide experience applying the hierarchy of controls to address workplace chemical hazards. The substitution of safer alternatives for hazardous chemicals is widely recognized as the most effective approach for protecting workers and the public from lethal hazards. Labeling, PPE, product reformulation and engineering controls are not sufficient.

Comments:  4-2, 6-2, 7-2, 8-2, 14-2, 15-2, 20-2, 21-2, 23-2, 23-4, 24-2, 27-3, 28-5, 29-5, PH6-2, PH7-2, PH9-4

DTSC Response:

DTSC agrees that current laws applicable to methylene chloride in paint or varnish strippers do not provide adequate protection against potential exposures and adverse impacts. Data compiled by OSHA, CPSC, state records and publicly reported information led U.S. EPA to identify 49 fatalities in consumers and workers who were exposed to methylene chloride while using paint or varnish strippers. In 2012, the Centers for Disease Control reported that injuries and deaths from methylene chloride exposure are under-reported due a lack of reporting by self-employed workers and because deaths can be misidentified as caused by heart disease.
Eliminating the chemical hazard entirely, or substituting a less hazardous chemical, is the most effective means of minimizing potential occupational or consumer exposures to methylene chloride while using paint or varnish strippers. Although this proposed regulation does not ban the Priority Product, it is an important supplement to current state and federal standards. The proposed regulation supports the ongoing effort to protect human health by requiring manufacturers to evaluate safer alternatives.

No changes were made to the proposed regulation or supporting documents based on these comments.

Comment Summary:
Although even one death from exposure to methylene chloride is too many, it’s important to note that every death from using paint or varnish strippers containing methylene chloride “invokes misuse of the products.” The vast majority of consumers know about the risks of misusing paint or varnish strippers containing methylene chloride.

Comment: 26-16

DTSC Response:
DTSC disagrees that every fatality associated with the Priority Product is the result of product “misuse.” The commenter does not provide evidence that most consumers know that inhalation exposure to methylene chloride in paint or varnish strippers can cause death and that a dust mask and latex gloves provide inadequate protection. Theoretically, workers and consumers may take precautionary steps to safeguard their health when fully informed of specific steps to take to reduce the exposure risk, including highly specific instructions about necessary PPE and the impractically large level of ventilation needed for indoor use. However, in cases where the margin for error is very small and exposure can be lethal, the hierarchy of controls, which identifies elimination of the hazard as the preferred option, becomes even more relevant.

No changes were made to the proposed regulation or supporting documents based on this comment.
Comment Summary:

Product manufacturers and formulators can manage potential risks to reasonable levels by improving product labels, consumer education and training requirements for users. U.S. EPA wrongly concluded that labels and warnings are ineffective even though there is comprehensive industry guidance on effective labeling of paint strippers that references requirements of the Consumer Product Safety Commission (CPSC) and the Federal Hazardous Substances Act (FHSA). Recommended labeling for paint or varnish strippers containing methylene chloride has recently been updated and reviewed by the CPSC to include acute hazard warnings. These labels indicate precautions users should take for safe use, including precautions required for skin and inhalation hazards, and address risks from using methylene chloride to refinish bathtubs.

The safe use of methylene chloride by workers can be achieved through using PPE and engineering controls, which mitigate exposures and minimize risk of adverse impacts with a much lower economic impact to manufacturers. DTSC should accept these viable and effective alternatives to the regulation.

Comments: 22-11, 22-13, 26-8, PH1-4, PH3-1

DTSC Response:

U.S. EPA determined that a ban on the use of methylene chloride in paint or varnish strippers for certain applications was the only restriction that would adequately protect workers and consumers. U.S. EPA rejected label warnings and instructions because they are difficult to comprehend and are not uniformly read or followed, particularly in small business situations where there is high employee turnover. "Presenting information about methylene chloride on a product label would not adequately address the unreasonable risk presented by this use of this chemical because the nature of the information the user would need to read, understand, and act upon is extremely complex." The use of engineering and administrative controls was evaluated and found to be inadequate in sufficiently mitigating against potentially harmful exposures to methylene chloride in many situations.

A recent study of calculated ventilation requirements shows that paint strippers containing methylene chloride require impractically large ventilation rates and indoor activities may require pressure demand respiratory protection (Offerman and Nicas, 2018), a form of PPE not typically available to most consumers. Under the well-established “hierarchy of controls,” the use of engineering, work practice and administrative controls to minimize or eliminate exposure to methylene chloride are the least preferred worker protection methods and are only used when chemical substitution or elimination is not feasible.

No changes were made to the proposed regulation or supporting documents based on these comments.

11 82 FR 7474.
Comment Summary:

The Department of Defense (DoD) and chemical manufacturers comply with OSHA, the Clean Air Act and the Toxic Substances Control Act requirements. OSHA and Cal/OSHA have adequately regulated worker exposure to methylene chloride for many years and ensure workers are protected from adverse health effects via exposure monitoring, training and labeling requirements and permissible exposure limits. OSHA requirements are protective of workers who may be exposed to methylene chloride, and OSHA also provides guidance for bathtub refinishers on the safe use of paint strippers containing methylene chloride. DTSC has not shown that methylene chloride is being used in violation of OSHA/CalOSHA requirements.

Methylene chloride is a Hazardous Air Pollutant and is subject to the National Emission Standards for Organic Hazardous Air Pollutants for Paint Stripping and Miscellaneous Surface Coating Operations at Area Sources (“NESHAP”). These protective standards reduce the risk of worker exposure to methylene chloride and protect public health.

Methylene chloride is also regulated as a carcinogen under Proposition 65, and consumer products sold in California are labeled as such. As well, businesses in California must warn people before exposing them to methylene chloride.

California state and local air quality agencies also restrict the amount of methylene chloride that is permissible in paint strippers, which protects workers, consumer and the environment from exposure to VOCs. Requiring manufacturers to develop risk management protocols in response to the listing of paint or varnish strippers as a Priority Product will duplicate regulatory protections that are already in place.

Consumer health and safety is under the jurisdiction of the Consumer Product Safety Commission (CPSC) and the Federal Hazardous Substances Act (FHSA), with regulations that are being enhanced and would protect consumers from the same potential exposures and adverse impacts that SCP has highlighted. It is the responsibility of the CPSC to issue rules that eliminate or reduce unreasonable risks associated with use of a consumer product, including prohibiting the use of hazardous substances in consumer products. CPSC expanded labeling requirements to include both acute and chronic hazards, which will address the risk of improper use of paint stripping products to refinish bathtubs. It is not consistent with SCP regulations to remove a product from the marketplace because workers or consumers fail to comply with existing requirements.

Overall, DTSC has failed to address the extent to which regulations already adequately protect workers and consumers from adverse impacts and exposure pathways considered by this proposed regulation. This proposed regulation does not meet the criteria under the Safer Consumer Products regulations because it duplicates and conflicts with existing federal regulations.

Comments: 13-5, 19-2, 19-4, 22-3, 22-9, 26-3, 26-5, PH1-2, PH3-2, PH4-2
DTSC Response:

The SCP regulations establish a unique approach to regulating Chemicals of Concern in consumer products that meaningfully enhances protections through the Priority Product requirements. No equivalent state or federal regulations require product manufacturers to determine if the chemical in their product is necessary, determine if there is a safer alternative, and to take steps to protect human health and the environment from exposure to the chemical in the product.

OSHA regulations attempt to limit worker exposure to methylene chloride in occupational settings by setting provisions for exposure monitoring, engineering controls, work practice controls, medical monitoring, employee training, personal protective equipment, and recordkeeping. Unfortunately, many occupational settings where paint or varnish stripping activities occur are not monitored for OSHA compliance. U.S. EPA reviewed air monitoring data from occupational settings and concluded that air concentrations frequently exceeded OSHA standards for worker safety.

In addition, sole proprietors and consumers are not subject to OSHA regulations and are of particular concern to DTSC. These groups are exempt from state and federal worker protection standards and, as a result, are unlikely to invest in engineering controls and PPE, utilize industry-recommended administrative controls, or receive adequate safety guidance. Even when workers and consumers use PPE during use of paint or varnish strippers, improper use, imperfect fit, and malfunction of PPE can occur and result in exposure to methylene chloride.

As noted by the commenter, methylene chloride is designated as a hazardous air pollutant (HAP) under the Clean Air Act and U.S. EPA has issued NESHAPs for area sources engaged in paint stripping, surface coating of motor vehicles and mobile equipment, and miscellaneous surface coating operations. California state and local air quality agencies also regulate the methylene chloride content in paint strippers. The SCP listing regulations are not risk-based determinations of appropriate concentrations of methylene chloride in consumer products. The SCP regulations specify an Alternatives Analysis, which requires product manufacturers to determine if the chemical in their product is necessary, if there is a safer alternative, and to take steps to protect human health and the environment.

In response to recent regulatory actions to reduce or eliminate human exposures to methylene chloride, the Halogenated Solvents Industry Alliance proposed that labels for paint or varnish strippers containing methylene chloride be changed and explicitly state that inhalation exposure to methylene chloride could be “extremely harmful.” CPSC staff reviewed the HSIA petition and updated its labeling guidance. However, the CPSC also found that providing label warnings does not prevent consumer exposure to hazards. Upon a review of the efficacy of existing regulations in preventing harmful exposures to methylene chloride in paint or varnish strippers, U.S. EPA determined that a ban on the use of methylene chloride in such products was the only restriction that would adequately protect workers and consumers. U.S. EPA rejected label warnings and instructions because they are not uniformly read, comprehended or followed, particularly in small business situations where there is high employee turnover.
Eliminating the chemical hazard entirely, or substituting a less hazardous chemical, is the most effective means of minimizing potential occupational chemical exposures. This proposed regulation is an important supplement to current state and federal exposure standards and supports the ongoing effort to protect human health by requiring manufacturers to evaluate safer alternatives.

No changes were made to the proposed regulation or supporting documents based on these comments.
COMMENTS REGARDING LEGAL AUTHORITY OF SAFER CONSUMER PRODUCTS PROGRAM

Comment Summary:

The FHSA granted jurisdiction over household products, such as paint strippers containing methylene chloride, to the Consumer Product Safety Commission. Federal law pre-empts any state requirement that is not identical to the FHSA requirement, meaning that DTSC, as a state agency, cannot preempt the CPSC.

In response to concerns about deaths from use of paint strippers to refinish bathtubs, the CPSC voted in June 2017 to draft a policy statement about changing the labels on paint or varnish strippers containing methylene chloride to address acute health hazards. The new labels are expected to enhance user awareness and eliminate the use of methylene chloride to refinish bathtubs, which is the basis of DTSC’s concern about methylene chloride. Under FHSA, further regulation of methylene chloride is precluded unless the new cautionary language is shown to be ineffective. Because federal law pre-empts any state requirement that is not identical to the FHSA requirement, DTSC, as a state agency, cannot propose or enact a requirement that is designed to address the same health risk unless it is identical to the regulation of the CPSC or provides more protection. To comply with this requirement, DTSC must show that new requirements imposed on the use of methylene chloride in paint or varnish strippers are either identical to those issued by CPSC or provide greater protection. The proposed regulation is not identical to the requirements of the CPSC nor does it provide greater protection; for example, regarding flammability risk.

U.S. EPA published a notice of proposed rulemaking on methylene chloride in paint and coating removers. If EPA finalizes a rule on these products, the rule will preempt DTSC’s regulatory action. Instead of issuing its own regulation, DTSC should work with U.S. EPA.

DTSC’s proposed regulation would likely be preempted by these existing federal regulations and CPSC’s action on a proposal to enhance product labelling. This proposed regulation burdens commerce and is a contravention of federal requirements.

Comments: 19-3, 26-7

DTSC Response:

Under the Federal Hazardous Substances Act (FHSA), manufacturers of paint or varnish strippers containing methylene chloride are required to include precautionary labeling to address health and safety concerns associated with use of such products. The Act empowers the CPSC to ban hazardous household products when labeling does not sufficiently protect consumers.

In response to concern about injuries and deaths from the use of paint or varnish strippers containing methylene chloride, regulatory agencies have initiated actions to minimize or eliminate human exposures to methylene chloride. The Halogenated Solvents Industry Alliance (HSIA) has responded to these regulatory actions by proposing changes to the label of paint or varnish strippers containing methylene
chloride to clearly state that inhalation exposure to methylene chloride could be “extremely harmful.” CPSC staff reviewed the HSIA petition and, as described earlier in these responses, the CPSC updated its labeling guidance, and stated that labeling will not address all the hazards U.S. EPA identified in its proposed rule for methylene chloride paint strippers, and that warning labels do not prevent consumer exposure to hazards.

The FHSA requirement about product labeling is distinctly different from the proposed regulation to list paint or varnish strippers containing methylene chloride as a Priority Product and require manufacturers to conduct an Alternatives Analysis. The proposed DTSC regulation does not prescribe any requirements as to the performance, composition, contents, design, finish, construction, packaging or labeling of paint or varnish strippers containing methylene chloride and is therefore not subject to federal preemption under the Consumer Product Safety Act.

In January of 2017 U.S. EPA issued a proposed rule under TSCA to ban methylene chloride for use in paint removal. In May of 2018 U.S. EPA announced that it intends to implement the proposed ban on paint removers with methylene chloride. It is not yet clear whether U.S. EPA will adopt the proposed rule without changes. Until the final rule is made public, DTSC cannot determine the effect it will have on this proposed regulation.

No changes were made to the proposed regulation or supporting documents based on these comments.
Comment Quotation:

“The Department’s proposed regulation and accompanying documents and analyses are deficient under the California Administrative Procedures Act (“APA”), and the Department’s underlying environmental review violates the California Environmental Quality Act (“CEQA”). Accordingly, Barr requests that the Department withdraw its proposed regulation and instead direct its resources to product-chemical combinations that meet the statutory and regulatory criteria for listing as a Priority Product.”

Comment: 26-2

DTSC Response:

DTSC has fully complied with all procedural requirements of the regular rulemaking process as proscribed by the California APA, including the statutory requirements under CEQA. This has included engaging in preliminary rulemaking activities, such as the provision of multiple avenues for public participation.

In evaluating a product-chemical combination for listing as a Priority Product, the SCP regulations stipulate that DTSC must assess the potential for exposures to the Candidate Chemical in the product and whether one or more of those exposures could contribute to or cause significant or widespread adverse impacts (California Code of Regulations, title 22, section 69503.2(a)). The Technical Summary summarizes results from over 50 scientific studies that thoroughly document the health risks from exposure to methylene chloride, including cancer and death. U.S. EPA estimated nearly 32,000 workers and 1.3 million consumers are exposed to methylene chloride in paint or varnish strippers each year during use of paint or varnish strippers.

The key prioritization principles for identifying and listing paint or varnish strippers containing methylene chloride as a Priority Product have been met through documentation of the wide availability and use of paint or varnish strippers containing methylene chloride and the potential for significant adverse health impacts, including cancer and death, from inhalation exposure to methylene chloride while using such products.

No changes were made to the proposed regulation or the supporting documents based on this comment.
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