

INITIAL STATEMENT OF REASONS
SAFER CONSUMER PRODUCTS REGULATIONS – LISTING CHILDREN’S FOAM-PADDED
SLEEPING PRODUCTS CONTAINING TDCPP OR TCEP
AS A PRIORITY PRODUCT
DECEMBER 2016

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Additions to the existing text are underlined in red and text deleted from the existing document is shown as ~~strikeout in red~~.

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I. SUMMARY OF PROPOSED ACTIONS AND REGULATORY PROGRAM ACTIVITIES AFFECTED

The Department of Toxic Substances Control (DTSC) proposes to add article 11, Priority Products list, and sections 69511 and 69511.1 to Chapter 55, Safer Consumer Products (SCP), Division 4.5 of Title 22, California Code of Regulations. The proposed action will establish a Priority Products list beginning with one Priority Product.

Per section 69503.5(a)(2) of the SCP regulations, the Priority Products list is being established through rulemaking under the Administrative Procedure Act.

II. DETAILED STATEMENT OF THE SPECIFIC PURPOSE AND RATIONALE

A. Statutory Intent and Requirements

The “Green Chemistry” statutes (Health and Safety Code [HSC] sections 25251-25257.1) are intended to significantly reduce adverse health and environmental impacts of chemicals used in commerce, as well as reduce the overall costs of those impacts to the state’s society by encouraging the redesign of consumer products, manufacturing processes, and approaches.

In 2013, DTSC adopted the SCP regulations to meet the statutory mandates in HSC sections 25252 and 25253. The SCP regulations:

- establish a process to identify and prioritize chemicals or chemical ingredients in consumer products. This process requires DTSC to consider the following factors:
 - (1) the volume of a chemical in commerce in California;
 - (2) the potential for exposure to a chemical in a consumer product; and
 - (3) the potential effects on sensitive subpopulations, including infants and children;
- establish a process for evaluating Chemicals of Concern in consumer products, and their potential alternatives, to determine approaches for limiting exposure or reducing the level of hazard posed by these chemicals;
- establish a process for evaluating the availability of potential alternatives and potential hazards posed by those alternatives, as well as evaluating critical exposure pathways. This process must include life cycle assessment tools that take into consideration thirteen (13) specified factors;
- specify the range of regulatory responses that DTSC may take following the completion of an Alternatives Analysis (AA); and

- allow the use of available information from other nations, governments, and authoritative organizations that have undertaken similar chemical prioritization processes.

In developing criteria by which chemicals and their alternatives may be evaluated, these criteria must include, at a minimum, the hazard traits and environmental and toxicological endpoints that the Office of Environmental Health Hazard Assessment (OEHHA) adopted under HSC section 25256.1, as Chapter 54, Green Chemistry Hazard Traits for California's Toxics Information Clearinghouse regulations.

B. Safer Consumer Products Regulations Overview

The SCP regulations (Title 22, California Code of Regulations (22 CCR) sections 69501-69510), adopted in October 2013, apply to all consumer products placed into the stream of commerce in California and establish science-based processes to identify Candidate Chemicals, identify product-chemical combinations as Priority Products that include Chemicals of Concern, and analyze alternatives for improving the safety of consumer products. DTSC must adopt each Priority Product in regulation in conformance with California's rulemaking law—the Administrative Procedure Act. Following the adoption of a Priority Product, responsible entities must do the following:

- notify DTSC that they manufacture the Priority Product; and
- remove or replace the Chemical(s) of Concern in their product; or
- remove their product from the California marketplace; or
- conduct an AA to determine if they can implement a safer alternative.

Following the completion of an AA, DTSC is authorized to identify and require implementation of one or more regulatory responses when DTSC determines such actions are necessary to protect public health or the environment. In selecting regulatory responses, DTSC will maximize the use of alternatives of least concern when they are functionally acceptable and technically and economically feasible.

Sections 69503 – 69503.7 of the SCP regulations specify the process for identifying product-chemical combinations as Priority Products that include Chemicals of Concern. Before proposing to list a product-chemical combination as a Priority Product, DTSC must ensure that the product-chemical combination meets the following criteria in section 69503.2(a):

- there must be potential human, environmental, or wildlife exposure to the Chemical(s) of Concern in the product through the use, handling, or disposal of the Priority Product; and

- there must be a potential for the exposure(s) to contribute to or cause significant or widespread adverse impacts to people or the environment.

C. Identifying Priority Products

DTSC selected the following product-chemical combinations for the initial proposed list of Priority Products based on an extensive review of the scientific literature; the product-chemical identification and prioritization factors listed in section 69503.2; and the adverse impact and exposure factors listed in section 69503.3:

- children’s foam-padded sleeping products containing tris(1,3-dichloro-2-propyl) phosphate (TDCPP) or tris(2-chloroethyl) phosphate (TCEP);
- paint and varnish strippers containing methylene chloride; and
- spray polyurethane foam systems containing methylene diphenyl diisocyanates.

As required by regulation, DTSC published this initial proposed list of Priority Products on March 13, 2014 and held public workshops throughout California to solicit stakeholder input before developing the text of the proposed regulations. These product-chemical combinations are distinctly different and pose potentially different hazard traits, exposure scenarios, and economic impacts for each group of product manufacturers and consumers. Therefore, DTSC will pursue separate rulemaking proposals to add each of these product-chemical combinations to the Priority Products list, beginning with this proposal to add children’s foam-padded sleeping products containing TDCPP or TCEP.

DTSC proposes to define “Children’s foam-padded sleeping products containing TDCPP or TCEP” as products designed for children, toddlers, babies, or infants to nap or sleep on that incorporate polyurethane foam mats, pads, or pillows that contain the chemical flame retardants TDCPP or TCEP. This proposed definition includes the following sub-products: nap mats, soft-sided portable cribs, play pens, play yards, infant travel beds, portable infant sleepers, bassinets, nap cots, infant sleep positioners, bedside sleepers, co-sleepers, and baby or toddler foam pillows. The identified sub-products are all used for sleeping and this common attribute is the basis for their inclusion in this Priority Product. Achieving a very clear definition of the Priority Product will improve compliance with this regulation.

D. Rationale for Listing Children’s Foam-Padded Sleeping Products Containing TDCPP or TCEP as a Priority Product

DTSC selected children’s foam-padded sleeping products containing TDCPP or TCEP as a Priority Product based on the potential risk of exposure to these Chemicals of Concern and potential for exposures to contribute to or cause widespread or significant adverse impacts to

people, particularly to children, families and workers, or wildlife, as required by sections 69503.2 and 69503.3 of the SCP regulations. This determination was based on a consideration of available, reliable scientific information pertinent to the regulatory criteria. Children spend many hours sleeping per day and they may spend that time on these sub-products. Close contact with products that contain flame retardants increases potential exposure through inhalation or dust ingestion. TDCPP and TCEP are semi-volatile compounds used as additive flame retardants that are not chemically bonded to polyurethane foam and are easily released from the foam to indoor and outdoor environments. Both TDCPP and TCEP have been detected worldwide, including in California, in dust sampled in indoor environments such as homes, offices, and day care centers. TDCPP and TCEP have been detected in waterways and wastewater treatment influent and effluent in the U.S. and other nations. Further, TDCPP and TCEP have been detected in wildlife such as fish, mussels, and birds.

Both TDCPP and TCEP are known to the State of California to cause cancer, and carcinogenicity has been demonstrated in animal studies for both TDCPP (e.g., liver, kidney, and testicular tumors) and TCEP (e.g., kidney and thyroid tumors). In addition to carcinogenicity, research studies suggest that exposures to these chemicals are associated with the additional hazard traits as described below:

- For TDCPP, these include, but are not limited to, genotoxicity (e.g., mutations, chromosomal aberrations, and cell transformation), developmental toxicity, reproductive toxicity, endocrine disruption (e.g., thyroid abnormalities), neurotoxicity, hepatotoxicity, nephrotoxicity, hematotoxicity, ocular toxicity, dermatotoxicity, and acute toxicity.
- For TCEP, these include, but are not limited to, genotoxicity (e.g., mutations, chromosomal aberrations, and cell transformation), reproductive toxicity, neurotoxicity, hepatotoxicity, and nephrotoxicity.

Human exposure to TDCPP has been demonstrated by detection in human breast milk, adipose tissue, and seminal plasma, as well as the detection of primary metabolites in urine samples collected from adults, including pregnant women, and children. Human exposure to TCEP has been demonstrated by detection in human breast milk, as well as detection of primary metabolites in adult urine samples. Further, TDCPP has been detected in hand wipe samples from adults and children and TCEP has been detected in hand wipe samples from children, demonstrating an important route for potential exposure to these chemical flame retardants.

There are no state or federal legal requirements to include chemical flame retardants in children's foam-padded sleeping products that are primarily marketed for use by children and

commonly used in homes and day care centers.¹ TDCPP and TCEP are harmful chemical flame retardants that are not necessary to the proper function or use of these products. Furthermore, flame retardant-free foam is a widely available, cost effective alternative to foam made with flame retardants. As discussed below, DTSC anticipates that manufacturers will be able to substitute flame retardant-free foam in their products without suffering adverse economic impacts.

DTSC determined that exposure to TDCPP or TCEP through the normal use of children's foam-padded sleeping products may contribute to or cause significant or widespread adverse health impacts with the greatest risks borne by sensitive subpopulations such as pregnant women, children, infants, and day care center and school employees. This determination is based on the widespread detection of TDCPP and TCEP in indoor and outdoor environments, the hazard traits associated with each compound, and the data showing widespread exposures to both TDCPP and TCEP in adults, children, and wildlife.

E. Summary of Technical Information for TDCPP²

TDCPP is a high production volume chemical that is commonly used as an additive flame retardant. TDCPP is a replacement for pentabromodiphenyl ether (pentaBDE) flame retardants in polyurethane foam. The pentaBDE mixture was banned in California in 2006 (California HSC section 108922) (OEHHA 2011b). Additive flame retardants are not chemically bonded to polyurethane foam and can migrate into indoor and outdoor environments (Marklund et al. 2003). TDCPP was removed from children's pajamas in the 1970s due to concerns regarding mutagenicity, but it is still used in baby and children's products containing polyurethane foam (Stapleton et al. 2011). Following the national phase-out of pentaBDE flame retardants and California's ban of pentaBDEs in 2006, the use of TDCPP grew significantly in flexible polyurethane foam. TDCPP is one of the most commonly used flame retardants found in baby products containing polyurethane foam (Stapleton et al. 2011). Exposure to TDCPP from polyurethane foam contained in consumer products may occur through dermal contact, inhalation, or ingestion of TDCPP-laden dust. Infant and toddler hand-to-mouth behavior plays a significant role in exposure to flame retardants in dust (ATSDR 2012; Stapleton et al. 2014). TDCPP is known to the State of California to cause cancer (OEHHA 2011a). Evidence of carcinogenicity includes increased incidence of liver and kidney tumors in male and female

¹ Child restraint systems used in vehicles and aircraft and standard crib mattresses are excluded from this proposed rulemaking because they are required to meet federal fire safety standards that may include the use of chemical flame retardants.

² The references noted in this section can be found in the DTSC report titled: *Summary of Technical Information and Scientific Conclusions for Designating Children's Foam-Padded Sleeping Products Containing Tris(1,3 dichloro-2-propyl) Phosphate (TDCPP) or Tris(2-chloroethyl) Phosphate (TCEP) as a Priority Product (2015)*. This report has been cited as a document relied upon for this proposed rulemaking.

rats and testicular tumors in male rats (ATSDR 2012; Bio/dynamics 1980; Freudenthal and Henrich 2000; OEHHA 2011b; OEHHA 2012; WHO 1998). TDCPP is metabolized in the body to several compounds that are also known to the State of California to cause cancer (OEHHA 2011b). TDCPP is associated with other adverse health effects including kidney, liver, and testicular abnormalities (ATSDR 2012; OEHHA 2011b). Research has also shown evidence of genotoxicity, developmental toxicity, reproductive toxicity, endocrine toxicity, and neurotoxicity related to TDCPP exposure.

In biomonitoring studies, TDCPP has been found in human fat, breast milk, and seminal fluid; and metabolites of TDCPP have been detected in urine (Butt et al. 2014; Hoffman et al. 2014; Hudec et al. 1981; LeBel and Williams 1983; LeBel and Williams 1986; LeBel et al. 1989; Sundkvist et al. 2010). TDCPP has also been detected in hand wipe samples taken from children and adults (Hoffman et al. 2015; Stapleton et al. 2014).

TDCPP has been detected in dust in homes, offices, automobiles, commercial airplanes, hospitals, and day care centers in California and other locations around the world. In an air and dust monitoring study of California early childhood education facilities,³ TDCPP was detected at higher concentrations in early childhood education facilities with foam-filled nap mats than those without (Bradman et al. 2014). The U.S. Environmental Protection Agency (U.S. EPA) estimates that children ingest on average approximately 60 mg dust/day. This is twice as much as adults, who on average ingest approximately 30 mg dust/day (U.S. EPA 2011). Further, children have a smaller body mass relative to adults, so their dosage in terms of mg dust/kg of body mass will be even greater compared to adults.

In a Consumer Product Safety Commission (CPSC) staff preliminary risk assessment report, it was calculated that adult and children's TDCPP exposures are above the acceptable daily intake (ADI) of 0.005 mg/kg/day for non-cancer health effects. It was estimated that TDCPP in furniture foam alone exposes adults to twice the ADI and exposes children to five times the ADI. Further, the cancer risk for a lifetime of exposure to TDCPP-treated foam-filled furniture was estimated to be 300 per million; a substance may be considered hazardous if the lifetime individual cancer risk exceeds one per million. In children, the estimated cancer risk from exposure to upholstered furniture during the first two years of life was 20 per million (Babich 2006).

³ Bradman's studies use the term "early childhood education facilities" which can include home-based childcare providers, private for-profit or non-profit preschools, and programs run by government agencies (e.g., preschools in school districts or Head Start) or religious institutions. For the purposes of this document, the term "early childhood education facility" is used when referring to Bradman's studies while the term "day care center" is used for all other study citations.

TDCPP contamination occurs in surface water, wastewater, and aquatic sediments. TDCPP has been detected in San Francisco Bay waters and sediment (Klosterhaus et al. 2012; SFEI 2013). TDCPP was detected in surface water in more than half of 139 freshwater streams tested across the U.S. including in California (Kolpin et al. 2002). TDCPP was measured in influents, effluents, and sludge of Swedish sewage facilities (Marklund et al. 2005b). TDCPP has also been detected in U.S. laundry wastewater samples from homes, as well as in the influents and effluents from the wastewater treatment plants associated with those homes thus indicating the release of TDCPP to waterways from wastewater effluents (Schreder and La Guardia 2014).

TDCPP has been detected in samples of fish, mussels, birds, and bird eggs (Evenset et al. 2009; Green et al. 2008; Leonards et al. 2011; Sundkvist et al. 2010; Takahashi et al. 2013).

Based on these factors, DTSC determined that potential exposure to TDCPP in children's foam-padded sleeping products may contribute to or cause significant and widespread adverse impacts to human health and the environment within California.

F. Summary of Technical Information for TCEP⁴

TCEP is an organophosphate chemical that is used as an additive flame retardant. TCEP is structurally similar to TDCPP (OEHHA 2011b). Like TDCPP, TCEP can migrate from foam products to indoor and outdoor environments (Marklund et al. 2003). Exposure to TCEP in consumer products containing polyurethane foam may occur through dermal absorption, inhalation, or ingestion of TCEP-laden dust. Infant and toddler hand-to-mouth behavior plays a significant role in exposure to flame retardants in dust (EC 2009; Stapleton et al. 2014). TCEP has been detected in polyurethane foam in several children's foam-padded products (Stapleton et al. 2011).

TCEP is a carcinogen and reproductive toxicant and is also associated with other potential adverse health effects. TCEP is known to the State of California to cause cancer and is classified by the European Commission as a reproductive toxicant (ECHA 2012; OEHHA 2011a). Evidence of carcinogenicity includes increased incidence of kidney tumors in male and female rats, while follicular thyroid cancer was increased in rats but not clearly related to chemical exposure (Matthews et al. 1993; NTP 1991). Evidence of reproductive toxicity in mice includes decreased number of pups per litter and number of litters per breeding pair, as well as

⁴ The references noted in this section can be found in the DTSC report titled: *Summary of Technical Information and Scientific Conclusions for Designating Children's Foam-Padded Sleeping Products Containing Tris(1,3 dichloro-2-propyl) Phosphate (TDCPP) or Tris(2-chloroethyl) Phosphate (TCEP) as a Priority Product (2015)*. This report has been cited as a document relied upon for this proposed rulemaking.

decreased sperm parameters in exposed male mice (Gulati et al. 1991). Research has also shown evidence of kidney toxicity, liver toxicity, and neurotoxicity related to TCEP exposure (EC 2009; Gulati et al. 1991; Matthews et al. 1990; Matthews et al. 1993; NTP 1991). In biomonitoring studies, TCEP has been detected in human breast milk (Kim et al. 2014; Sundkvist et al. 2010) and metabolites have been found in human urine samples (Hoffman et al. 2014; Schindler et al. 2009). TCEP has also been detected in baby products containing polyurethane foam (Stapleton et al. 2011) and in hand wipe samples taken from children (Stapleton et al. 2014). TCEP has been detected in dust in various indoor environments including homes, offices, and day care centers worldwide.

TCEP contamination in the environment has been documented in multiple studies. TCEP has been detected worldwide in rivers and streams, wildlife, sediment, and Antarctic ice. In California, TCEP has been detected in both drinking and surface waters.

TCEP has been detected in samples of fish, mussels, crabs, birds, and bird eggs (Green et al. 2008; Leonards et al. 2011; Sundkvist et al. 2010).

Based on consideration of these factors, DTSC has determined that there is potential exposure to TCEP from children's foam-padded sleeping products that may contribute to or cause significant or widespread adverse impacts to human health and the environment within California.

G. Additions to Chapter 55. The Safer Consumer Products Regulations

Add article 11. This new article, in its entirety, establishes the Priority Products list as part of Chapter 55, Safer Consumer Products, to Division 4.5 of Title 22, CCR. As specified by section 69503.5 (and 69503.6 for the Initial Priority Products list) of the SCP Regulations, DTSC is establishing the Priority Products list through the rulemaking process and is following the process and requirements described therein.

Add section 69511. General. This section describes the scope and purpose of article 11 and establishes a Priority Products list. ~~This section specifies that as part of this process, DTSC evaluated information from the public domain and other sources to identify product-chemical combinations and prioritize them as Priority Products.~~

Add section 69511(a). This section describes the scope and purpose of article 11 and establishes a Priority Products list. This section specifies that as part of this process, DTSC evaluated information from the public domain and other sources to identify product-chemical combinations and prioritize them as Priority Products.

Add section 69511(b). This section displays the names of the product-chemical combinations listed as Priority Products. The purpose of this section is to meet the requirements of section 69503.5 and to provide an easy reference. This section also adds subsection (b)(1) to identify Children’s Foam-Padded Sleeping Products Containing Tris(1,3-dichloro-2-propyl) Phosphate (TDCPP) or Tris(2-chloroethyl) Phosphate (TCEP).

Add section 69511.1. Children’s Foam-Padded Sleeping Products Containing Tris(1,3-dichloro-2-propyl) Phosphate (TDCPP) or Tris(2-chloroethyl) Phosphate (TCEP). This section establishes the product-chemical combination of children’s foam-padded sleeping products containing TDCPP or TCEP as a Priority Product. This section is necessary to inform responsible entities and the public what product-chemical combination is being listed as a Priority Product.

Add section 69511.1(a)(1). This section provides a description of the product-chemical combination “children’s foam-padded sleeping products containing TDCPP or TCEP” and lists twelve sub-products used for sleeping by children ~~, toddlers, babies or infants~~ 12 years of age or younger. This description and the list of sub-products are both necessary because enumeration of the sub-products more clearly defines the product and enables a responsible entity to easily determine if their product is a Priority Product, as required by section 69503.5(b)(1)(A). The identified sub-products are all used for sleeping, and this common attribute is the basis for their inclusion in this Priority Product. Children spend many hours sleeping per day and they may spend that time on these sub-products. Close contact with products that contain flame retardants increases potential exposure through inhalation or dust ingestion. Achieving a very clear definition of the Priority Product will improve compliance with this regulation.

Add section 69511.1(a)(2). This section indicates exclusions to the product-chemical combination. This section is necessary to clearly illustrate to responsible entities what is not considered a “children’s foam-padded sleeping product containing TDCPP or TCEP” for this Priority Product listing.

The principle federal law related to flame retardant standards for sleeping products is administered by the U.S. Consumer Product Safety Commission (CPSC). This law regulates mattresses and mattress pads under Title 16 Code of Federal Regulations Part 1632 and Part 1633 (16 CFR 1632 and 1633). Part 1632 is the standard for the flammability of mattresses and mattress pads, while Part 1633 contains the standard for flammability (open flame) for mattress sets. Bed mattresses, including mattresses for hard-sided cribs, are covered by 16 CFR 1632 and 1633. The requirements of 16 CFR Parts 1632 and 1633 are performance-based. The regulation does not specify the use of flame retardant chemicals to meet the requirements. The regulation allows manufacturers to choose the means of complying with the

regulation, which may include the use of inherently flame resistant materials, or barriers, or flame retardant chemicals, while requiring that mattresses meet strict performance requirements.

CPSC does not regulate juvenile product pads and provides examples of the exempt category in 16 CFR 1632.1(a)(2). Exempt products include “car bed pads, carriage pads, basket pads, infant carrier and lounge pads, dressing table pads, stroller pads, crib bumpers, and playpen pads”. Each of these “juvenile product pads” is further defined in 16 CFR 1632.8. Mattresses in portable cribs with mesh or soft sides are not regulated under 16 CFR 1632.

Part 571 Federal Motor Vehicle Safety Standards, Standard No 302 specifies the flame retardant requirements for interior materials of motor vehicles including child restraint systems (i.e., car seats). Car seats have been exempted from the definition of children’s foam-padded sleeping products; therefore, there is no conflict with this standard.

Add section 69511.1(b). This section ~~indicates~~ designates the TDCPP or TCEP as the Candidate Chemicals that are the basis for the product-chemical combination being listed as a Priority Product. This section is needed to clearly indicate the ~~Chemicals of Concern~~ Candidate Chemicals identified as the basis for listing children’s foam-padded sleeping products associated with this as a Priority Product, as required by section 69503.5(b)(2)(A).

Add section 69511.1(c). This section indicates the hazard traits ~~or environmental or toxicological endpoints~~ associated with TDCPP. Section 69503.5(b)(2)(A) specifies that DTSC evaluate, at a minimum, the hazard traits of the Candidate Chemicals that are the basis for the product-chemical combination being listed as a Priority Product following the identification and prioritization criteria and process specified in sections 69503.2 and 69503.3. The statutory requirements state that chemicals must be evaluated, at a minimum, based on their associated hazard traits and endpoints. The hazard traits associated with TDCPP include carcinogenicity, genotoxicity, developmental toxicity, reproductive toxicity, endocrine disruption, neurotoxicity, hepatotoxicity, nephrotoxicity, hematotoxicity, ocular toxicity, dermatotoxicity, and acute toxicity. This section is necessary because it identifies why exposure to TDCPP from the use of children’s foam-padded sleeping products has the potential to harm children, California workers, and consumers. This section is necessary because the hazard traits associated with a product-chemical combination must be provided in the Priority Products list, as specified by section 69503.5(b)(2)(A).

Add section 69511.1(d). This section indicates the toxicological endpoints associated with TDCPP. These toxicological endpoints include liver, kidney, and testicular tumors, mutations, chromosomal aberrations, and cell transformation, and thyroid abnormalities. It is necessary to identify toxicological endpoints associated with exposure to TDCPP so that

manufacturers and users of children’s foam-padded sleeping products are aware of potential adverse impacts that could occur with normal use of children’s foam-padded sleeping product containing TDCPP.

Add section 69511.1(de). This section indicates the hazard traits ~~or environmental or toxicological endpoints~~ associated with TCEP. Section 69503.5(b)(2)(A) specifies that DTSC evaluate, at a minimum, the hazard traits of the Candidate Chemicals that are the basis for the product-chemical combination being listed as a Priority Product following the identification and prioritization criteria and process specified in sections 69503.2 and 69503.3. The hazard traits associated with TCEP include carcinogenicity, genotoxicity, reproductive toxicity, neurotoxicity, hepatotoxicity, and nephrotoxicity. This section is necessary because it identifies why exposure to TCEP from the use of children’s foam-padded sleeping products has the potential to harm children, California workers, and consumers. The statutory requirements state that chemicals must be evaluated, at a minimum, based on their associated hazard traits and endpoints. This section is necessary because the hazard traits associated with a product-chemical combination must be provided in the Priority Products list, as specified by section 69503.5(b)(2)(A).

Add section 69511.1(e). ~~This section indicates exclusions to the product-chemical combination. This section is necessary to clearly illustrate to responsible entities what is not considered a “children’s foam-padded sleeping product containing TDCPP or TCEP” for this Priority Product listing.~~

Add section 69511.1(f). This section indicates the toxicological endpoints associated with TCEP. These toxicological endpoints include kidney and thyroid tumors, and mutations, chromosomal aberrations, and cell transformation. It is necessary to identify toxicological endpoints associated with exposure to TCEP so that manufacturers and users of children’s foam-padded sleeping products are aware of potential adverse impacts that could occur with normal use of children’s foam-padded sleeping product containing TCEP.

Add section 69511.1(g). This section designates the Candidate Chemicals TDCPP and TCEP as the Chemicals of Concern for the Priority Product. Section 69503.5(b)(2)(B) states that any Candidate Chemical that has been identified as the basis for a product being listed as a Priority Product is then designated as the Chemical of Concern for that product. This section is necessary to clearly identify to responsible entities and the public that TDCPP (CAS RN 13674-87-8) and TCEP (CAS RN 115-96-8) are the Chemicals of Concern in children’s foam-padded sleeping products affected by this proposed regulation. Clearly identifying the Chemicals of Concern in a Priority Product ensures that responsible entities understand DTSC’s concerns with their product and take the appropriate steps to comply with the notification and reporting requirements included in the SCP regulations.

Add section 6911.1(fh). This section provides responsible entities a due date for submission of the Preliminary AA Report, as indicated by section 69503.5(b)(3)(B). This section is necessary to comply with section 69503.5(b)(3)(B) and to provide responsible entities with a time frame for complying with the notification and reporting requirements included in the SCP regulations.

III. ECONOMIC IMPACT ANALYSIS

As required by Government Code section 11346.2(b)(2) and (5), DTSC completed an economic impact assessment⁵ and determined that the proposed regulation will not have a significant adverse economic impact on business.

A. Creation or Elimination of Jobs within California

This regulation will not result in the creation or elimination of jobs in the children's products or polyurethane foam manufacturing industries within California.

Manufacturers and assemblers of children's foam-padded sleeping products who choose to use flame retardant-free foam will not need to change their manufacturing processes because flame retardant-free foam has the same functional use as foam with flame retardants. It is also less expensive than foam treated with flame retardants and, because manufacturers are not likely to pass these savings to their consumers, they may realize some cost savings. Therefore, this regulation will not result in the creation or elimination of jobs in the children's products manufacturing industry.

There is an increasing demand for products made with flame retardant-free foam due to changes in other states' laws,⁶ growing consumer awareness, and the prevalence of lawsuits. It is also easier and cheaper to manufacture flame retardant-free polyurethane foam. Based on consultation with major trade organizations representing manufacturers of the proposed Priority Products, DTSC believes that many manufacturers already use flame retardant-free foam instead of foam treated with TDCPP or TCEP in their children's products. Given these manufacturing considerations and the resultant increasingly abundant flame retardant-free

⁵ [Std. 399 Economic and Fiscal Impact Assessment](#) for the proposal to list children's foam-padded sleeping products as a Priority Product.

⁶ *Maryland* - Bans use of TCEP or TDCPP greater than 0.1% in specified products intended for children under age three, including baby products, toys, car seats, nursing pillows, crib mattresses and strollers (effective October 2014). *Minnesota* - By July 1, 2018, manufacturers must stop selling children's products and upholstered residential furniture containing TDCPP and TCEP greater than 1,000 ppm in Minnesota. *New York* - First in the nation ban on children's products containing the flame retardant TCEP (effective December 1, 2013). The Tris-free Children and Babies Act was expanded to include TDCPP (effective December 1, 2015). *Vermont* - Bans the manufacturing of children's products and furniture containing 1,000 ppm (0.1%) TCEP and TDCPP on Jan. 1, 2014. After July, 2014, the sale in or into Vermont of any such products will be prohibited.

foam, manufacturers may benefit from this change and this regulation will not negatively impact jobs in the foam manufacturing sector.

In addition, due to DTSC's CalSAFER online information management system and streamlined reporting requirements, there will be no need for extra workers to comply with the regulatory reporting requirements.

B. Creation of New Businesses or Elimination of Existing Businesses within California

This regulation will not result in the creation or elimination of children's products or polyurethane foam manufacturing businesses within California.

Many children's products manufacturers already use flame retardant-free foam in their children's products. Those that do not will be able to switch to flame retardant-free foam without changing their manufacturing processes because it has the same functional use as foam with flame retardants. Since flame retardant-free foam is widely available and less expensive, children's product manufacturers that adopt the use of this foam may be positively impacted and may experience some cost savings. Opportunities for the creation of new consulting businesses are also likely to be limited.

There is an increasing demand for products made with flame retardant-free foam due to changes in other states' laws, growing consumer awareness, and the prevalence of lawsuits. In addition, it is cheaper to manufacture flame retardant-free polyurethane foam. Therefore, the foam manufacturing industry is not expected to lose business or face increased production costs and may see some benefits as a result of this proposed regulation.

Due to DTSC's CalSAFER online information management system and streamlined reporting requirements, there will be no need for companies to hire consultants to meet regularly reporting requirements.

C. Expansion of Current California Businesses

This regulation will not result in the expansion of children's products manufacturing businesses currently within California. As noted above, DTSC believes that many manufacturers already use flame retardant-free foam in their children's products. Children's sleeping products manufacturers that do not use flame retardant-free foam will be able to easily adopt its use without changing their manufacturing processes. The potential cost savings associated with the use of flame retardant-free foam are not likely large enough to spur expansion of existing businesses.

Flame retardant-free polyurethane foam is already widely available in California; therefore, DTSC does not anticipate significant expansion of current foam manufacturing business in California as a result of this regulation.

D. Cost Impacts on Representative Private Persons or Businesses

In developing this regulatory proposal, DTSC evaluated the potential economic impacts on representative private persons or businesses. DTSC determined that representative private persons or businesses would incur costs for reasonable compliance with the proposed action. DTSC estimates that there are 35-50 manufacturers of children’s foam-padded sleeping products worldwide, who make or sell their products in California, who may be affected by this proposed regulation, and these manufacturers could collectively spend \$1,750 to \$40,000 to comply with the notification and reporting requirements. The low-end of the range represents businesses with few products and the high-end represents very large businesses with numerous products. Industry leaders report that many manufacturers no longer use chemical flame retardants in their children’s products; therefore, these costs are likely overestimated. If 80% of the manufacturers are exempt from notification and reporting requirements because they already use flame retardant-free polyurethane foam in their products, then industry-wide compliance costs could be as low as \$350 to \$8,000 [see *Economic Analysis*]. Assuming that only 20% of children’s foam-padded sleeping product manufacturers still use foam containing TDCPP or TCEP, then there may only be 7 to 10 manufacturers impacted by these proposed regulations.

Table 1. Estimated costs to manufacturers.

Total Hours	Total Manufacturers	
	35	50
1	\$1,750	\$2,500
16	\$28,000	\$40,000

Based on this analysis, DTSC determined that this action will not have a significant adverse economic impact on business.

E. Effect on Small Businesses

DTSC determined, pursuant to California Code of Regulations, Title 1, section 4, that the proposed regulatory action would affect small businesses because small businesses are regulated parties under the existing regulations. According to the JPMA, approximately 88% of their members are small to medium-sized businesses. Of the total manufacturers (Table 1) potentially affected by this proposed regulation, DTSC estimates that 30-44 of them are small to medium-sized businesses (Table 2). These small to medium-sized manufacturers could

collectively spend \$1,500 to \$35,000 to comply with the notification and reporting requirements. Industry leaders report that many manufacturers, including small to medium-sized businesses, no longer use chemical flame retardants in their children’s products; therefore, these costs are likely overestimated. If 80% of the small to medium-sized manufacturers are exempt from notification and reporting requirements because they use flame retardant-free polyurethane foam in their products, then industry-wide compliance costs for these businesses could be as low as \$300 to \$7,000.

Table 2. Estimated costs for small to medium-sized businesses.

Total Hours	Total Manufacturers	
	30	44
1	\$1,500	\$2,200
16	\$24,000	\$35,000

Based on this analysis, DTSC determined that this action will not have a significant adverse economic impact on small business.

F. Anticipated Benefits of the Regulation

The broad objective of the SCP regulations, adopted in October 2013, is a comprehensive, state-level effort to find safer alternatives to hazardous chemicals. The use of fewer hazardous chemicals reduces the potential for adverse impacts to the people of California and the environment. By listing Priority Products that contain Chemicals of Concern in regulation, DTSC sets in motion a preemptive strategy to reduce the use of toxic substances in product design and industrial processes with the aim of creating safer, more sustainable products that do not threaten human health nor persist in the environment. The use of fewer hazardous substances means healthier air quality, cleaner drinking water, and safer homes, schools, day care centers, and workplaces.

The direct benefit of this amendment to the SCP regulations is decreased exposure to TDCPP or TCEP in children’s foam-padded sleeping products to children, families, and childcare providers. DTSC anticipates that children’s sleeping products manufacturers will switch to flame retardant-free foam because they are not required to meet flame retardant standards for these products and they can continue to use their current manufacturing processes. Since flame retardant foam is cheaper, they will also be able to lower their production costs to some degree and may also benefit from profit increases. Because there are no anticipated barriers to the use of flame retardant-free foam in these products, DTSC anticipates that manufacturers will switch to flame retardant-free foam rather than completing an AA.

Benefits to Consumers

Removing TDCPP and TCEP from children's foam-padded sleeping products will lead to decreased concentrations of these chemicals in homes, day care centers, and schools (Example 1). By reducing the potential for exposure to these flame retardants, particularly to children and employees of day care centers and schools, the potential for adverse health effects, such as cancer, reproductive toxicity, developmental toxicity, and neurotoxicity, will also be reduced. Because people are exposed to chemical flame retardants through the use of other common household products, including furniture and consumer electronics, DTSC is unable to quantify the potential health benefits. Nevertheless, it is reasonable to assume that public health benefits would accrue to children, families, and employees as a result of this regulation.

Play yards were selected in the examples below to demonstrate anticipated benefits to consumers and businesses because they have high annual sales and contain the largest amount of foam in any of the products listed in this proposed regulation. In Example 1, DTSC estimates that consumers could avoid introducing up to 28,000 pounds annually of TDCPP or TCEP into their homes and workplaces. Because DTSC cannot estimate the amount of foam used in the other sub-products, we cannot estimate the total amount of flame retardant exposure that could be avoided annually. While DTSC anticipates that consumers will benefit from lower levels of TDCPP or TCEP in their homes and workplaces, it is not possible to quantify these benefits due to uncertainties in these estimates.

Example 1 – Potential Decrease in the Amount of Chemical Flame Retardants in Play Yards

- approximately 2 million play yards were sold by JPMA member companies in the U.S. in 2012.⁷
- play yard dimensions: 3.08 ft. x 2.25 ft. x 0.17 ft.
- play yard foam density: Approximately 1.5 lbs./cubic ft.
- weight of foam in a play yard = play yard dimensions x foam density = approximately 1.35 lbs.
- estimated amount of chemical flame retardant in foam: 1-5% by weight

If all of the play yards sold in 2012 contained chemical flame retardants in the estimated percent range above, then the amount of flame retardants would range from 20,000 lbs. to 140,000 lbs. per 2 million play yards sold. If only 20% of manufacturers still use foam

⁷ JPMA 2013 Annual Industry Study – Final Report, Part 1 of 3 Manufacturer Data Summary.

containing flame retardants, then the estimated amount of flame retardant used in play yards could range from 4,000 to 28,000 lbs.

Benefits to Manufacturers

There will also likely be some cost savings, as well as potential profit increases, for manufacturers of children's foam-padded sleeping products who opt to purchase flame retardant-free foam, since flame retardant-free foam generally costs less than foam that includes flame retardants. Children's product manufacturers are able to order flame retardant-free foam from foam manufacturers or fabricators and will not need to change their manufacturing processes when they switch to flame retardant-free foam.⁸ As was discussed above, these savings are likely to be small since many of the largest children's product manufacturers do not request the addition of chemical flame retardants to the foam they purchase directly from foam manufacturers. Also, quantifying benefits that may accrue to children's product manufacturers is made more difficult due to uncertainties in the number of units sold for each sub-product covered by the proposed regulation, the type and costs of foam purchased by typical manufacturers, and the amount of foam used in each type of sub-product.

In the example shown below, DTSC estimated that play yard manufacturers could save approximately \$0.80 per play yard by purchasing flame retardant-free foam. By assuming that 20% of the manufacturers currently purchase foam containing flame retardants, DTSC estimates a potential benefit of approximately \$320,000 annually for play yard manufacturers that opt to switch to flame retardant-free foam to manufacture this product. Given the uncertainties noted above and the difficulties in applying these assumptions to the remaining sub-products covered by the proposed regulation, DTSC is unable to accurately quantify the total industry-wide benefit. According to an industry representative, consumers are unlikely to benefit from any cost savings achieved by manufacturers through the use of flame retardant-free foam.

Example 2 – Economic Benefits of Manufacturing Play Yards with Flame Retardant-Free Foam

- approximately 2 million play yards were sold in the U.S. in 2012 by manufacturers that were members of the JPMA.⁹
 - 1) cost per board foot (1" x 12" x 12") of flexible foam:¹⁰

⁸ The slabstock production method of foam is the technique typically used for children's foam-padded sleeping products. The mix is poured onto a moving conveyor with sides from 3 to 4 feet high, where it reacts and expands into a slab. The continuous slab is then cut, stored, and allowed to cure for up to 24 hours, and then undergoes fabrication into useful shapes for a wide range of applications. Because the addition of flame retardants increase the cost of the slabstock foam, only manufacturers that are required to comply with fire safety standards opt to add flame retardants.

⁹ JPMA 2013 Annual Industry Study – Final Report, Part 1 of 3 Manufacturer Data Summary.

- flame retardant-free: \$0.42-\$0.44 per board foot
 - with flame retardants: \$0.49-\$0.50 per board foot (approximately 12-15% higher)
- 2) cost per 37" x 26" x 2" polyurethane foam pad for a play yard:
- flame retardant-free: \$5.60 - \$5.88
 - with flame retardants: \$6.54 - \$6.68
- cost savings:
 - based on this information, a flame retardant-free foam pad for a play yard would cost approximately \$0.80 less than a foam pad with chemical flame retardants.
 - if 2 million play yards are sold per year and it is assumed that only 20% of manufacturers of children's foam-padded sleeping products include chemical flame retardants, then 400,000 play yards are assumed to include flame retardants. If the manufacturers of these 400,000 play yards remove chemical flame retardants from their products, there would be a \$320,000 cost savings for these manufacturers.

IV. REPORTS RELIED ON

DTSC relied on the Economic Impact Assessment, per Government Code section 11346.3(b) in proposing this regulatory action.

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

DTSC, 2015. Summary of Technical Information and Scientific Conclusions for Designating Children's Foam-Padded Sleeping Products Containing Tris(1,3 dichloro-2-propyl) Phosphate (TDCPP) or Tris(2-chloroethyl) Phosphate (TCEP) as a Priority Product.

JPMA. 2013 Annual Industry Study – Final Report, Part 1 of 3 Manufacturer Data Summary.

Title 16, Code of Federal Regulations, Part 1632. Standard for the Flammability of Mattresses and Mattress Pads (FF 4-72, Amended). http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=2a2ff88d7_0b535b426f8603f16a6a076&r=PART&n=16y2.0.1.4.95 (accessed December 2013).

Title 16, Code of Federal Regulations, Part 1633. Standard for the Flammability (Open Flame) of Mattress Sets <http://www.ecfr.gov/cgi->

¹⁰ Information provided by the American Excelsior Company.

[bin/retrieveECFR?gp=&SID=2a2ff88d70b535b426f8603f16_a6a076&r=PART&n=16y2.0.1.4.96](http://www.ecfr.gov/binary/retrieveECFR?gp=&SID=2a2ff88d70b535b426f8603f16_a6a076&r=PART&n=16y2.0.1.4.96)
(accessed December 2013).

Consumer Product Safety Commission (CPSC) (2014) Questions and Answers, Standard for the Flammability (Open Flame) of Mattress Sets 16 CFR Part 1633. <http://www.cpsc.gov/PageFiles/113012/mattqa.pdf> (accessed January 30, 2014).

V. REASONABLE ALTERNATIVES CONSIDERED

DTSC considered the following alternatives to the proposed regulatory action:

- 1) **Selected Alternative:** List TDCPP or TCEP in children's foam-padded sleeping products as the Priority Product -
 - This option was selected because it allows DTSC to quickly and effectively achieve the goal of significantly reducing children's exposures to chemical flame retardants.
- 2) List TDCPP or TCEP in all flexible polyurethane foam as a Priority Product -
 - This was considered as an alternative but dismissed as an option due to potential conflicts with existing state or federal flame retardant standards for a wide variety of product types. The Priority Product was narrowed to focus on children's sleeping products because there are no regulatory requirements to include flame retardants in these products.
- 3) List TDCPP or TCEP in nap mats only -
 - This was considered as an alternative but dismissed, as it would not result in the reduction of flame retardant exposure nor improvements to children's safety that DTSC is working to achieve. The Priority Product was expanded to include a variety of children's foam-padded sleeping products to achieve greater impact.

VI. DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS

As discussed below, children's foam-padded sleeping products are not required to comply with any flame retardant standards; therefore, this regulation does not duplicate or conflict with federal regulations.

The principle federal law related to flame retardant standards for sleeping products is administered by the U.S. Consumer Product Safety Commission (CPSC). This law regulates mattresses and mattress pads under Title 16 Code of Federal Regulations Part 1632 and Part 1633 (16 CFR 1632 and 1633). Part 1632 is the standard for the flammability of mattresses and mattress pads, while Part 1633 contains the standard for flammability (open flame) for mattress sets. Bed mattresses, including mattresses for hard-sided cribs, are covered by 16

CFR 1632 and 1633. The requirements of 16 CFR Parts 1632 and 1633 are performance-based. The regulation does not specify the use of flame retardant chemicals to meet the requirements. The regulation allows manufacturers to choose the means of complying with the regulation, which may include the use of inherently flame resistant materials, or barriers, or flame retardant chemicals, while requiring that mattresses meet strict performance requirements.

CPSC does not regulate juvenile product pads and provides examples of the exempt category in 16 CFR 1632.1(a)(2). Exempt products include “car bed pads, carriage pads, basket pads, infant carrier and lounge pads, dressing table pads, stroller pads, crib bumpers, and playpen pads”. Each of these “juvenile product pads” is further defined in 16 CFR 1632.8. Mattresses in portable cribs with mesh or soft sides are not regulated under 16 CFR 1632.

Part 571 Federal Motor Vehicle Safety Standards, Standard No 302 specifies the flame retardant requirements for interior materials of motor vehicles including child restraint systems (i.e., car seats). Car seats have been exempted from the definition of children’s foam-padded sleeping products; therefore, there is no conflict with this standard.