



Work Plan Implementation:
**Phthalates in
Food Packaging**

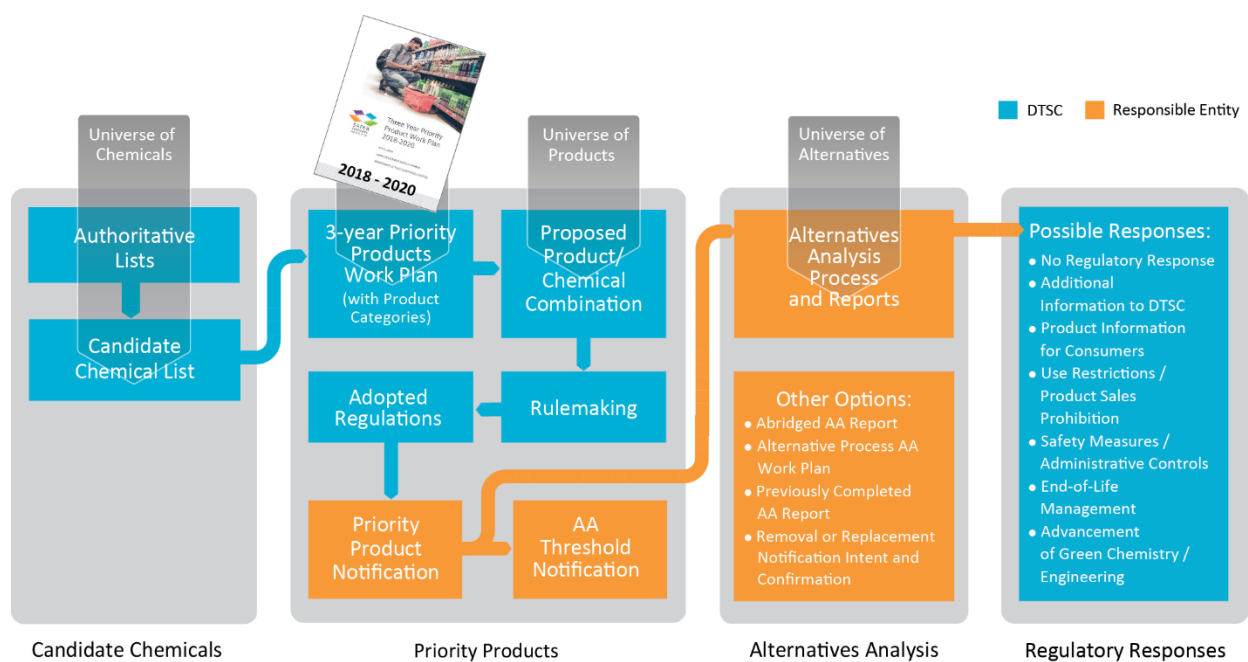
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Introduction

The [Safer Consumer Products regulations](#)¹ define the process and criteria used by the Department of Toxic Substances Control (DTSC) to evaluate consumer products for possible designation as Priority Products. In that process, DTSC issues a Priority Product Work Plan (Work Plan) identifying the product categories to evaluate over a three-year period. DTSC then considers the product categories through the lens of the Work Plan’s stated policy goals (Figure 1).

Since issuing the 2018-2020 Work Plan,¹ DTSC has conducted a review of product categories, chemicals, and chemical classes that align with our policy goals. This document summarizes our preliminary findings on food packaging containing ortho-phthalates (OPs) and their alternatives, and describes our concerns. Publication of this document signals the beginning of a dialogue with interested stakeholders, including manufacturers, nonprofit organizations, governments, and academia, to inform DTSC on the potential listing of specific consumer products containing BPA and its alternatives as one or more Priority Products subject to the requirements of the Safer Consumer Products regulations.



¹ DTSC webpage: [What are the Safer Consumer Products Regulations?](#)

Background

Food packaging is one of the product categories identified in DTSC's 2018-2020 DTSC Priority Product Work Plan. Ortho-phthalates (OPs) are dialkyl or alkyl esters of 1,2-benzenedicarboxylic acid and are all captured, as a group, on DTSC's Candidate Chemical List, whether or not the individual chemicals are specifically listed. One of the major uses of OPs is as plasticizers that impart flexibility and durability to products made of polyvinyl chloride (PVC), including some food packaging products. It has been estimated that 95 percent of all OPs produced globally are used as PVC plasticizers.

Foods packaged in PVC have been shown to contain OPs, and diet is considered a major source of human exposure to this class of chemicals (Rodgers, Rudel, and Just 2017). Biomonitoring data shows that human exposure to OPs is ubiquitous (Rodgers, Rudel, and Just 2017). OPs are potential endocrine disruptors that have a significant potential to adversely affect human reproductive development, especially in males (Rodgers, Rudel, and Just 2017). Although robust hazard data is publicly available for only a subset of OPs, emerging data suggests that many OPs may share similar hazard traits. Various authoritative bodies have recognized members of the OP group as potential reproductive and developmental toxicants, which is the basis for listing OPs on DTSC's Candidate Chemical list.

DTSC is concerned about the potential adverse impacts to human health posed by exposures to OPs from food packaging, especially in children. One of the policy goals stated in SCP's 2018-2020 Priority Product Work Plan is to protect children from exposures to harmful chemicals from consumer products. The American Academy of Pediatrics' 2018 policy statement on food additives and child health designates phthalates as one of five chemical classes of emerging concern with respect to children's health (Trasande et al. 2018). Emerging concerns over the potential adverse impacts of OPs have also prompted the U.S. Environmental Protection Agency to identify certain OPs (currently authorized for use in food packaging by the FDA) as candidates for designation as high priority chemicals under the Toxic Substances Control Act (U.S. EPA 2019). And concerns over OP exposure have compelled the U.S. Consumer Product Safety Commission (CPSC) and other authoritative bodies to ban the use of some OPs in certain children's and consumer products (Consumer Product Safety Commission 2017)(European Commission 2018). However, the use of some OPs in food packaging is still allowed. FDA has recently proposed a rule that would rescind the authorization for specific uses of OPs in food packaging, but this rule would not affect the previously authorized uses of certain OPs as plasticizers in food packaging (FDA 2018).

DTSC is considering whether to propose one or more food packaging products containing OPs as a potential Priority Product. To help reach a final decision, DTSC is requesting additional

information from stakeholders in order to learn more about the current uses of OPs in food packaging products.

PRELIMINARY SCREENING RESULTS

Some OPs have been recognized by various authoritative bodies as carcinogens, mutagens, or reproductive and developmental toxicants; these designations were the basis for listing OPs on DTSC's Candidate Chemical list. OPs appear to have a number of endocrine-disrupting properties on the developing human reproductive system. Recent epidemiological studies have demonstrated significant associations between maternal exposure to some OPs and adverse developmental impacts on the male fetus (Crinnion 2010). Prenatal exposures have also been related to adverse neurobehavioral outcomes in children such as increased aggression, attention deficits, depression, and impaired executive functioning and emotion control (Crinnion 2010)(Engel et al. 2009)(Colón et al. 2000). Epidemiological studies support an association between OP exposure and impaired testicular function in adult men (Serrano et al. 2014). OPs have been associated with increased weight, insulin resistance, asthma and allergies, uterine fibroids, and breast cancer(Crinnion 2010)(Stahlhut et al. 2007) . Some OPs appear to act as metabolic disruptors or obesogens, and increases in waist circumference and body mass index have been linked to OP exposures in men and in adolescent and adult females (Hatch et al. 2008)(Serrano et al. 2014).

Biomonitoring studies have consistently demonstrated widespread human exposures to OPs, although it has been reported that exposures to OPs in the U.S. population appear to be decreasing in recent years based on trends in the available biomonitoring data. It is unclear if this decrease in OP exposure is associated with the replacement of products that previously contained OPs with new products that do not have them, the use of alternatives in products that previously contained OPs, or both.

Next Steps

Recent studies have demonstrated that OPs are being used in some food packaging products (Carlos, de Jager, and Begley 2018). However, the available data is limited in scope, and it is unclear what types of food packaging still contains OPs. The supply chain of OP's manufacturing and use are also unclear to DTSC, especially within the food packaging sector. Finally, it is unclear what chemical alternatives for OPs are currently available and being used in specific food packaging applications. SCP hopes to resolve a number of these data gaps in an upcoming workshop.

Public Engagement

DTSC is asking stakeholders to address the questions listed in Themes 1-3 below. Written comments can be submitted via the online information management system [CalSAFER](#). The comment period will close on December 19, 2019, at 11:59 p.m. In addition, DTSC will hold a

public workshop with stakeholders and invited participants on November 19, 2019 in Sacramento, California. Further details about this workshop will be available on our [Workshops and Events Webpage](#). This stakeholder engagement process will help inform additional research that may result in the proposal of one or more Priority Products. Please monitor our [Priority Products Work Plan Implementation webpage](#) for updates on this topic.

QUESTIONS TO STAKEHOLDERS

Theme 1. Manufacturing

- Who manufactures food packaging in the United States?
- Who manufactures food packaging that contains OPs?
- Are there any food packaging manufacturers in California that make products with OPs?
- Which OPs are currently used in food packaging and what products are they used in?
- What alternatives to OPs are being used as plasticizers in food packaging?

Theme 2. Market Presence

- Who are the consumers of food packaging, generally; who in California purchases and uses packaging that may contain OPs to package foods?
- How much food packaging containing OPs, and what types, are on the market in California and Nationally?
- Who makes bottle caps and gaskets sold in California that contain OPs?
- Do you have any specific data on the market presence of food packaging containing OPs and the supply chain?

Theme 3. Supply chain

- Who manufactures and supplies the OPs or OP-containing starting materials (e.g., plastisol) to food packaging manufacturers?
- Are there intermediaries (converters) involved who take materials (e.g., PVC film) and assemble them into a more final food package product. and who are they?

- Are there manufacturers of food packaging that contains OPs located outside the United States, and if so who are they, and where are they located?

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