SAFER CONSUMER PRODUCTS

CALIFORNIA DEPARTMENT OF TOXIC SUBSTANCES CONTROL

Work Plan Implementation:

Food Packaging with Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs)

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Introduction

The Safer Consumer Products regulations[*] define the process and criteria used by the Department of Toxic Substances Control (DTSC) to evaluate consumer products for possible designation as Priority Products. A Priority Product is a consumer product identified by DTSC that contains one or more chemicals – known as Candidate Chemicals – with a hazard trait that can harm people or the environment. As part of the process of evaluating consumer products, DTSC issues a Priority Product Work Plan (Work Plan) identifying the product categories to evaluate over a three-year period (Figure 1). DTSC then considers the product categories through the lens of the Work Plan's stated policy goals.

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 perfluoroalkyl and polyfluoroalkyl substances (PFASs) 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 PFASs as one or more Priority Products subject to the requirements of the Safer Consumer Products regulations.

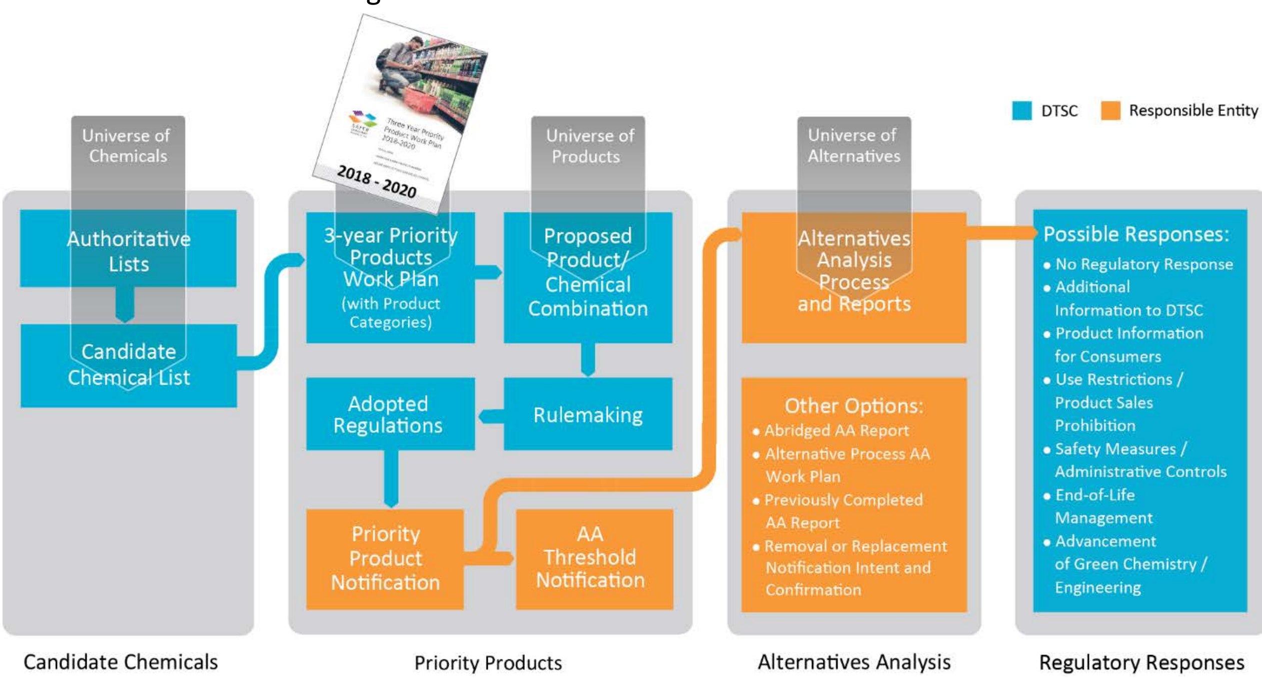

Figure 1. An overview of the Safer Consumer Products regulations.

[*] https://dtsc.ca.gov/what-are-the-safer-consumer-products-regulations/

Background

DTSC's 2018-2020 Priority Product Work Plan[1] adopted policy goals to guide DTSC in prioritizing Priority Products. In considering the product categories in the Work Plan and our policy goals, DTSC identified the class of PFASs as a Candidate Chemical that may warrant further research regarding its use in food packaging products. This research would address two of the policy goals outlined in the Work Plan:

- to protect children from exposure to harmful chemicals, especially carcinogens, mutagens, reproductive toxicants, neurotoxicants, developmental toxicants, and endocrine disruptors; and
- to protect Californians from chemicals that migrate into food from food packaging.

PFASs are a class of nearly 5,000 chemicals characterized by highly stable carbon-fluorine bonds and used in many applications.[2,3] PFASs are commonly added to food packaging made of paper, paperboard, and molded fiber in order to make these materials resistant to oil, grease, and water. They are also used in the manufacturing of molded fiber food packaging to help release the products from the formation mold. The U.S. Food and Drug Administration (FDA) has approved 19 distinct polymeric PFAS formulations for use in food packaging. However, the number of unique PFASs that may be present in food packaging is higher because the approved polymers can break down into non-polymeric PFASs[4] and may contain non-polymeric PFAS impurities.[5,6] These non-polymeric PFASs are extremely persistent in the environment[7] and have been associated with a number of health hazards, including endocrine disruption, developmental and reproductive toxicity, and immunotoxicity.[†] Therefore, DTSC is concerned about potential human and ecological exposures to PFASs from the use, landfilling, composting, and recycling of PFAS-treated food packaging.

DTSC is requesting additional information from stakeholders about the current uses of PFASs in food packaging products, the availability of alternatives, and the life cycle impacts of these products. DTSC is also interested in learning how manufacturers are meeting the new Biodegradable Products Institute compostability standard, which specifies that PFASs should not be intentionally added to biodegradable packaging and limits the total fluorine content to 100 parts per million. Please see the **Questions to Stakeholders** section below.

[†] See Appendix 3 in the Product-Chemical Profile for Perfluoroalkyl and Polyfluoroalkyl (PFASs) in Carpets and Rugs https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/10/Product-Chemical-Profile-PFAS-Carpets-and-Rugs.pdf

Preliminary Screening Results

Presence in Products

PFASs are used to impart water, stain, and grease resistance to a wide variety of food packaging products made of paper, paperboard, and molded fiber.[8] They also often serve as mold-releasing agents in the production of molded fiber packaging. Recent testing found PFASs in approximately half of paper and paperboard products tested – including bakery bags, deli wrappers, microwave popcorn bags, french fry boxes, takeout containers, and pizza boxes.[9,6] In other recent studies, PFASs were found in all molded fiber food packaging products tested – including bowls, soup containers, clamshells, plates, and food trays.[8,10]

The FDA regulates chemicals for use in food packaging that come in contact with food. There are several ways in which this occurs, including: Chemicals may be listed in the Code of Federal Regulations Title 21, Chapter 1; they may meet FDA's criteria for substances Generally Recognized as Safe; or they may be approved through the Food Contact Notification (FCN) process.[6] There are currently 31 PFAS-related FCNs and indirect food additive petitions approved by FDA for use in food contact surfaces. The indirect food additive petitions were approved under the Code of Federal Regulations Title 21, Section 176.170.[6] These FCNs and food additive petitions include a total of 19 distinct PFAS compositions, submitted by six chemical manufacturers.[11] One of the manufacturers, Chemours, has recently announced its decision to stop manufacturing PFASs for food packaging uses and has asked the FDA to withdraw its three approved FCNs.[12] This will reduce the number of approved FCNs to 28, and the number of distinct PFAS compositions to 17.

Hazard Traits

PFASs are either extremely persistent in the environment or they degrade into other extremely persistent PFASs.[13,14] Most PFASs are mobile in environmental media, which makes them widespread in the environment and in living organisms.[15] Several PFASs bioaccumulate significantly in animals or plants, including those consumed by humans as food.[7]

The FDA prohibits the use of certain PFASs in food contact materials because of their potential to cause adverse human health impacts. These effects are well established in animal and human studies, including kidney and testicular cancers, thyroid disease, reduced immune response, and pregnancy-induced hypertension.[16–19] However, evidence from animal, *in vitro*, and modeling studies also links the degradation products of the PFASs approved by the FDA with similar toxicological hazard traits, including developmental toxicity,[20,21] endocrine toxicity,[22–24] hepatotoxicity,[25] neurodevelopmental toxicity,[26] and reproductive and developmental toxicity.[20]

Figure 2. An overview of the exposure pathways to PFASs used in food packaging.

The intermediate degradation products of approved PFASs may be even more persistent in the body, and potentially more toxic than the PFASs prohibited by FDA.[4] A number of studies have also demonstrated the potential of some PFASs to impair the reproduction and development of aquatic organisms and birds.[‡]

Exposure

Humans are exposed to PFASs through a wide variety of sources and pathways. As a result, PFASs have been detected in the blood serum of over 98 percent of Americans.[27] Estimates vary, but it is thought that the primary sources of human exposure to PFASs are through dietary intake (accounting for up to half of total exposure) and inhalation and ingestion of contaminated indoor air and dust.[28] Human exposure to PFASs through dietary intake can occur via contaminated food and drinking water.

Once in the human body, PFASs accumulate in protein-rich tissues and typically have serum half-lives ranging from days to years, depending on their carbon chain lengths.[7,29,30] Many studies have shown that PFASs are capable of transfer from pregnant mothers to their fetuses via the placenta during gestation, as well as transfer from nursing mothers to their infants via

‡ See Appendix 3 in the Product-Chemical Profile for Perfluoroalkyl and Polyfluoroalkyl (PFASs) in Carpets and Rugs https://dtsc.ca.gov/wp-content/uploads/sites/31/2018/10/Product-Chemical-Profile-PFAS-Carpets-and-Rugs.pdf

breastfeeding.[31–36] These scenarios represent significant periods of PFAS exposure for developing fetuses and children, which may lead to adverse health outcomes.

Like humans, wildlife is exposed to PFASs by consuming contaminated water or food. Within aquatic food webs, PFASs were found to increase in concentration from ambient water to plankton[37] and further up the food chain.

PFAS-treated food packaging contributes in several ways to these human and ecological exposures. PFASs can migrate out of food packaging directly into the food items they contain, with migration rates dependent on the temperature, acidity, storage time, and fat content of the packaged food.[5,38,39] After use, PFAS-treated paper, paperboard, and molded fiber products are sometimes composted, thus releasing and incorporating the PFASs into the compost.[40] In a recent study,[41] the majority of PFASs found in compost samples from commercial facilities that accept food packaging contained six or fewer fluorinated carbons in their molecules. These shorter-chain PFASs are extremely persistent in the environment, highly mobile in water, and preferentially taken up by plants,[42] thus accumulating up food chains. If the used food packaging is sent to landfills, the PFASs can migrate into landfill leachate, contaminating surface waters and the surrounding environment.[43,44] Biosolids from wastewater treatment plants that treat PFAS-contaminated landfill leachate, when applied to soils, can contaminate drinking water sources[45] and crops such as potatoes, grains, and leafy vegetables.[46–48] Recycling of PFAS-treated paper, paperboard, and molded fiber food packaging products may also be a significant source of exposure, including from products that contain these recycled materials.

Potential for Adverse Impacts

PFASs are extremely persistent and mobile in the environment, can accumulate in animals and plants (including those consumed by humans), and are transferred from mothers to offspring through the placenta and breastfeeding. Thus, the potential for chronic PFAS exposure in humans and wildlife is extremely high and has been validated by numerous monitoring studies. Due to their widespread presence and chronic exposure in humans and wildlife, PFASs have the potential to elicit adverse impacts that include the following hazard traits identified by DTSC: developmental toxicity, endocrine toxicity, hematotoxicity, immunotoxicity, neurodevelopmental toxicity, reproductive toxicity, respiratory toxicity, and ocular toxicity.

In general, fetuses, infants, toddlers, and young children experience higher relative exposure levels and are more vulnerable to the effects of environmental toxicants. This is true for PFASs, with children being most at risk of exposure and adverse effects. The American Academy of Pediatrics released a policy statement in 2018 on the risk that food additives pose to children's health, highlighting the potential adverse effects associated with PFASs in food packaging. This statement cites support from the Endocrine Society in 2009, a joint report from the World Health Organization and United Nations Environment Program in 2013, and a statement from the International Federation of Gynecology and Obstetrics in 2015, indicating broad consensus on this topic of protecting children's health from environmental contaminants such as the PFASs used in food packaging.[49]

DTSC identified several policy goals in its 2018-2020 Priority Product Work Plan, including "to protect children, women of childbearing age, and pregnant women from exposures to harmful chemicals, especially carcinogens, mutagens, reproductive toxicants, neurotoxicants, developmental toxicants, and endocrine disruptors."[1] Addressing PFASs in food packaging aligns with this overarching goal.

Next Steps

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 Tuesday, January 14, 2019, at 11:59 p.m. In addition, DTSC will hold a public workshop with stakeholders and invited participants on Tuesday, January 14, at the CalEPA Headquarters Building, 1001 I Street, 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.

Please also note that this workshop and public comment period will focus on the current uses of PFASs in food packaging, the availability and feasibility of alternatives, and life cycle impacts. DTSC has already established from past research and stakeholder engagement that the class of PFASs in consumer products is of concern. Therefore, this workshop is not intended to explore the hazard traits of PFASs or the basis for addressing them in consumer products as a class.

Questions to Stakeholders

Theme 1. Current uses of PFASs in food packaging

- Which food packaging products are currently treated with PFASs? What percent of the market do they represent? Who manufactures those products? Which PFASs do they use?

- Is PFAS performance needed in all the applications it is used in? What is the performance difference between a product treated with PFASs and one that is not?

Theme 2. Availability of alternatives to PFASs in food packaging

- What alternatives to PFASs are available for paper and paperboard products?
- Will manufacturers be able to comply with the new Biodegradable Products Institute standard? What is the status of manufacturers' efforts to find alternatives to the use of PFASs in molded fiber products?

Theme 3. Life cycle impacts

- What happens to food packaging after use? How much gets recycled, composted, and landfilled?
- Do PFASs or their alternatives impact the ability to recycle or compost food packaging?
- What happens to PFASs and their alternatives after food packaging is landfilled?
- What happens to PFASs and their alternatives if food packaging is composted?
- What happens to PFASs and their alternatives if food packaging is recycled?

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