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FROM: Karl Palmer
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CC: Nancy Ostrom
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DATE: December 24, 2020

SUBJECT: Request for External Scientific Peer Review of the Scientific Basis of the Proposed Adoption of Plant Fiber-Based Food Packaging Containing Perfluoroalkyl or Polyfluoroalkyl Substances as a Priority Product

Title of Proposal for Review

This request is regarding a proposed regulation to adopt the following product-chemical combination as a Priority Product:

Plant Fiber-Based Food Packaging Containing Perfluoroalkyl or Polyfluoroalkyl Substances

Safer Consumer Products staff requests that you initiate the process to identify external scientific peer reviewers for the proposal to adopt plant fiber-based food packaging containing perfluoroalkyl or polyfluoroalkyl substances as a Priority Product, per the requirements of California Health and Safety Code section 57004.

Purpose of Review

The California Safer Consumer Products (SCP) regulations, California Code of Regulations, Title 22, sections 69503 – 69503.7, require the Department of Toxic Substances Control (DTSC) to identify product-chemical combinations that pose risks to people or the environment and to adopt them as Priority Products in regulation. "Priority Products" are consumer products that a) contain chemicals included in DTSC's Candidate Chemicals List; b) may expose people or the environment to these chemical(s) through normal use; and c) have been adopted in regulation. Candidate Chemicals exhibit hazard traits or environmental or toxicological endpoints and are included on authoritative lists established by government agencies or scientific organizations (http://www.dtsc.ca.gov/SCP).

Prior to proposing a product-chemical combination for adoption as a Priority Product, DTSC must ensure that the product-chemical combination meets both of the following criteria: 1) there must be potential public and/or environmental exposure to the chemical(s) in the product; and 2) there must be potential for one or more exposures to contribute to or cause significant or widespread adverse impacts (22 CCR section 69503.2(a)).

In accordance with Health and Safety Code section 57004, DTSC requests external scientific peer review of the basis for proposing *plant fiber-based food packaging containing perfluoroalkyl or polyfluoroalkyl substances* as a Priority Product. As required by regulation, DTSC reviewed reliable scientific literature and concluded that this product-chemical combination meets the required regulatory criteria for listing as a Priority Product for the following reasons:

- Perfluoroalkyl and polyfluoroalkyl substances (PFASs) or their degradation products are extremely persistent and ubiquitous in the environment, leading to ubiquitous human and ecological exposures;

- Humans, including sensitive subpopulations such as infants and children, as well as other living organisms may be exposed to PFASs throughout the life cycle of plant fiber-based food packaging; and

- These human and ecological exposures to the PFASs associated with plant fiber-based food packaging have the potential to contribute to or cause significant and widespread adverse impacts due to the numerous hazard traits displayed by members of this class of chemicals (e.g., extreme environmental persistence, endocrine toxicity, developmental and neurodevelopmental toxicity, immunotoxicity).

This proposal shares many similarities with DTSC's 2019 proposal to adopt *Carpets and Rugs with Perfluoroalkyl or Polyfluoroalkyl Substances* as a Priority Product and its

2020 proposal to adopt *Treatments Containing Perfluoroalkyl or Polyfluoroalkyl Substances for Use on Converted Textiles or Leathers* as a Priority Product. It addresses the same chemical class and relies on much of the same research and findings. In fact, the technical documents are nearly identical. The only significant difference lies in the PFAS exposure pathways related to these products. From food packaging, PFASs can migrate directly into food leading to dietary exposures. Also, unlike the previous two product categories (carpets and rugs and treatments for converted textiles or leathers), plant fiber-based food packaging is sometimes composted, releasing PFASs into the compost stream. Because the basis for these three proposals is so similar, DTSC requests that this external scientific peer review be conducted as an addendum to the earlier reviews.

When References will be Available at the FTP Site

The documents are ready for review at any time.

Requested Review Period

We request that scientific peer review be accomplished within 30 days.

DTSC requests that documents submitted as part of this review are compliant with the Americans with Disabilities Act (ADA) Accessible formatting as specified in CA AB 434 (California Government Code section 11546.7).

Necessary Areas of Expertise for Reviewers

For this review, DTSC recommends that reviewers have expertise in the following areas, in order of importance:

- Hazard traits of PFASs, including human toxicology and ecotoxicology; this expertise is needed for Conclusion 2, as defined in the attachment.

- Human and ecological exposure assessment; this expertise is needed for Conclusion 1, as defined in the attachment.

- Physicochemical properties and environmental fate of PFASs; this expertise is needed for Conclusion 1, as defined in the attachment.

We estimate that three reviewers will be adequate to cover all the necessary areas of expertise. As described above, this proposal shares many similarities with DTSC's 2019 proposal to adopt *Carpets and Rugs with Perfluoroalkyl or Polyfluoroalkyl Substances* as a Priority Product and its 2020 proposal to adopt *Treatments Containing Perfluoroalkyl or Polyfluoroalkyl Substances for Use on Converted Textiles or Leathers*. The two proposals address the same chemical class and most of the content in these technical documents is identical. The attachment further highlights the similarities within

the requested areas of expertise including, but not limited, to hazard traits, human exposure, and environmental fate of PFASs. Because the requested areas of expertise are identical to those in the previous proposals, we are requesting this review to be conducted as an addendum to the earlier reviews.

Refer to Attachment 2 for more details.

Contact Information

Please direct inquiries regarding this request to Nancy Ostrom, of my staff, at nancy.ostrom@dtsc.ca.gov or 916-445-3077.

Attachments

Attached please find:

1. Attachment 1: Plain English Summary.
2. Attachment 2: Scientific Assumptions, Findings, and Conclusions to Review.
3. Attachment 3: Individuals who Participated in the Development of the Proposal.
4. Attachment 4: References Cited.

Attachment 1: Plain English Summary

Brief Statement of Conclusions

DTSC has determined that plant fiber-based food packaging products containing any member of the class of PFASs meet the key prioritization criteria (California Code of Regulations, title 22, section 69503.2(a)) for listing a Priority Product:

> (1) There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and
>
> (2) There must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

The PFASs approved by FDA for use in food-contact paper, paperboard, and molded fiber products are environmentally persistent, but can eventually degrade into nonpolymeric PFASs, with PFAAs as the final degradation products. Also, according to documents submitted by manufacturers to FDA, these polymeric formulations contain nonpolymeric PFASs as impurities. Nonpolymeric PFASs display one or more hazard traits as defined by the California Code of Regulations.

Nonpolymeric PFASs migrate from the food packaging into food, resulting in dietary exposures. Migration efficiency increases with decreasing PFAS chain length. Also, at the end-of-life of the treated food packaging products, persistent PFASs or other hazardous compounds are released into compost and environmental media.

While FDA regulates the use of chemicals in food packaging, it does not consider all cumulative effects, aggregate effects, or end-of-life impacts, and therefore does not address all potential exposures and adverse impacts associated with the use of PFASs in food packaging.

Further studies may help inform DTSC's future decision-making. Despite these data gaps, DTSC has sufficient information regarding potential exposures and adverse impacts from plant fiber-based food packaging containing any member of the class of PFASs to designate this as a Priority Product.

Overview of the Safer Consumer Products Regulatory Program

The SCP regulations, implemented on October 1, 2013, specify the process for identifying consumer products that contain hazardous chemicals, evaluating safer alternatives to those chemicals, and eliminating or reducing potential exposures to and adverse impacts from these products. The regulations intentionally use a narrative standard for identifying and prioritizing product-chemical combinations, rather than a traditional risk-assessment-driven decision-making standard. This approach provides DTSC with a flexible process that allows the SCP program make decisions based on a

reasonable amount of reliable information and the potential for exposure and adverse impacts. The SCP regulations also use the hazard traits, toxicological and environmental endpoints, and other relevant data contained in Chapter 54 of the California Code of Regulations, Title 22.

To adopt a Priority Product listing, DTSC must follow the procedure described in the SCP regulations and adopt the listings through a rulemaking procedure. CCR section 69503.2 *et seq* uses the following prioritization factors for listing Priority Products:

- There must be potential public and/or aquatic, avian, or terrestrial animal or plant organism exposure to the Candidate Chemical(s) in the product; and

- 22 CCR sections 69503.2 and 69503.3 specify that there must be the potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

"Potential" is defined as reasonably foreseeable, based on reliable information (CCR section 69503.1(a)(51)). The potential for exposure is evaluated by considering one or more of the following factors: market presence of the product, the occurrence or potential occurrence of exposures to the Candidate Chemical in the product, the household and workplace presence of the product, potential exposure to the Candidate Chemical in the product during the product's life cycle (CCR section 69503.3(b)).

22 CCR sections 69503.2 and 69503.3 relay that the potential to contribute to or cause adverse impacts is evaluated by considering reasonably available information about one or more of the following factors: hazard traits, endpoints, aggregate effects, cumulative effects, physicochemical properties, environmental fate, affected populations or organisms, potential for the Candidate Chemical(s) to degrade, form reaction products, or metabolize into another chemical that exhibits hazard traits or endpoints. DTSC shall give special consideration to the potential for adverse impacts to sensitive subpopulations, environmentally sensitive habitat, endangered and threatened species, and impaired environments. DTSC may also evaluate and consider adverse impacts associated with structurally or mechanistically similar chemicals with known toxicity profiles.

Once DTSC adopts a Priority Product listing, DTSC requires product manufacturers to submit a Priority Product notification per CCR section 69503.7 and conduct one of several types of Alternatives Analyses to determine if safer alternatives exist per CCR section 69505.1 *et seq*. Alternatively, product manufacturers may elect to:

- Remove or replace the chemical of concern in the product with a safer alternative; or

- Remove the product from the California marketplace.

If the product manufacturers do not comply, DTSC is authorized to, among others, require importers, assemblers, or retailers to stop selling the product in California.

Overview of the Proposal to Adopt Plant Fiber-Based Food Packaging Containing Perfluoroalkyl or Polyfluoroalkyl Substances

This proposal addresses plant fiber-based food packaging products treated with PFASs for grease, oil, or water resistance, which can expose humans and biota to PFASs during their manufacturing, use, and end-of-life. PFASs can migrate from food packaging into the packaged food, with migration rates dependent on the carbon chain length, temperature, acidity, storage time, and fat content of the food. Used PFAS-treated paper, paperboard, and molded fiber food packaging products are sometimes composted, releasing PFASs into the compost, which may then be used in agricultural applications. When used food packaging is sent to a landfill, the PFASs can migrate into landfill leachate, contaminating surface waters and the surrounding environment. When applied to soil as fertilizers, biosolids from wastewater treatment plants that treat PFAS-contaminated landfill leachate can contaminate drinking water sources with PFASs, as well as crops such as potatoes, grains, and leafy vegetables. Recycled products made from PFAS-treated paper, paperboard, and molded fiber food packaging can also be a source of PFAS exposure. Harmful PFAS combustion products may also be released when these products are incinerated.

The proposed regulation defines “perfluoroalkyl and polyfluoroalkyl substances (PFASs)” as fluorinated organic chemicals containing at least one fully fluorinated carbon atom, as defined by Biomonitoring California in “Biomonitoring California Priority Chemicals,” February 2019. PFASs vary in chain length, i.e., the number of carbon atoms forming the backbone of their molecule, from a chain of two carbons to large molecular weight polymers.

DTSC is taking a class approach to PFASs because:

- PFASs are a wide and varied group of chemicals used in many applications. All PFASs share one common trait – highly stable carbon-fluorine (C-F) bonds that make them or their final degradation products highly persistent in the environment.

- Persistence is a hazard trait identified in the Office of Environmental Health Hazard Assessment (OEHHA) Green Chemistry Hazard Traits regulations 69405.3: “Persistence of a chemical in the environment promotes sustained exposure and contributes to accumulation in the environment.”

- Within the overall PFAS class, perfluoroalkyl acids (PFAAs) are the most problematic subclass. They are the most widely and thoroughly characterized subclass and are associated with several different health hazards, including endocrine disruption, developmental and reproductive toxicity, and immune

dysregulation.

- In the case of PFAAs, their ubiquity in combination with their persistence results in continuous exposure from multiple sources, including contaminated drinking water sources and the food supply. They can accumulate in meat, plants and drinking water, and ultimately in humans and wildlife.

- The vast majority of PFASs degrade into PFAAs, which typically increases their mobility in the environment, making containment or removal a challenge.

- While persistence alone warrants enough concern to include any member of the PFAS class in product prioritization, the health hazards associated with exposure to PFAAs are additionally concerning and underlie our listing.

As required by regulation, DTSC considered several factors including the hazard traits, toxicological endpoints, and environmental fates associated with PFASs, as well as potential adverse impacts to sensitive subpopulations including infants, children, pregnant women, and workers. After reviewing the scientific literature and obtaining stakeholder input during several public workshops, DTSC has determined that:

1. Plant fiber-based food packaging products are sources of significant and widespread human and ecological PFAS exposures; and

2. Human and ecological exposures to PFASs associated with plant fiber-based food packaging use may lead to significant or widespread adverse impacts, especially to sensitive subpopulations. Fetuses, infants, toddlers, and young children experience higher relative exposure levels and are more vulnerable to the effects of toxicants. Individuals with certain preexisting conditions (e.g., elevated cholesterol, high blood pressure, poor kidney function) may be especially sensitive to PFASs. Pregnant women’s exposure to PFASs is of concern due to transplacental and lactational transfer to the offspring. Environmentally sensitive habitats and endangered and threatened species are vulnerable to contamination of waterways and food webs with PFASs from with plant fiber-based food packaging.

Publicly available evidence suggests that PFASs associated with plant fiber-based food packaging display one or more hazard traits, including:

- Carcinogenicity;

- Cardiovascular toxicity;

- Developmental toxicity;

- Endocrine toxicity;
- Hepatotoxicity;
- Immunotoxicity;
- Nephrotoxicity;
- Ocular toxicity;
- Reproductive toxicity;
- Phytotoxicity;
- Wildlife developmental, reproductive, or survival impairment;
- Environmental persistence;
- Bioaccumulation;
- Mobility in environmental media; and
- Lactational and transplacental transfer.

DTSC identified several policy goals in its 2018-2020 Priority Product Work Plan, including “to protect Californians from chemicals that migrate into food from food packaging” and “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.” Addressing PFASs in food packaging aligns with these overarching goals.

Attachment 2: Scientific Conclusions to Review

Directions for Reviewers

The statutory mandate for external scientific peer review (California Health and Safety Code Section 57004) states that the reviewer’s responsibility is to determine whether “the scientific portion of the proposed rule is based upon sound scientific knowledge, methods, and practices.” Your task is to make this determination for the assumptions, findings, or conclusions below that the CalEPA External Scientific Peer Review Program has determined you can address the with confidence, based on expertise and experience. (If you decide to address other assumptions, findings, or conclusions,

identify the expertise and experience you are relying on to do so.) We also invite you to address these questions:

- Are there any scientific subjects that are part of the scientific basis of the proposal that are not described below?
- Taken as a whole, is the proposal based upon sound scientific knowledge, methods, and practices?

Reviewers should also note that some proposed regulatory actions might rely significantly on professional judgment where available scientific data are not as extensive as desired to support the statutory requirement for absolute scientific rigor. In these situations, the proposed course of action is favored over no action.

Reviewers should recognize that DTSC has a legal obligation to consider and respond to all feedback on the scientific portions of the proposed regulation. Because of this obligation, reviewers are encouraged to focus feedback on the scientific issues that are relevant to the central regulatory elements being proposed.

For further direction, please see the attachment, “Guidance for Reviewers,” on the FTP site and sent to you with the letter initiating your review.

Scientific Conclusions

Conclusion 1

Humans and biota may be exposed to members of the class of perfluoroalkyl and polyfluoroalkyl substances (PFASs), including perfluoroalkyl acids (PFAAs), through the manufacturing, normal use, and disposal of plant fiber-based food packaging products.

Conclusion 1 is supported by the following points:

- The PFAS treatments currently used in plant fiber-based food packaging products are side-chain fluorinated polymers and perfluoroether compounds. These PFASs can degrade to PFAAs or contain PFAA impurities.

- 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. 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. 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.

- The PFASs used in food packaging can degrade to PFAAs or contain PFAA impurities, which are taken up by plants grown in compost-treated soil. Compost samples collected from California and four other U.S. states that included food service packaging had significantly higher PFAA levels than compost that did not include these items, with the shorter-chain PFAAs (PFBA, PFPeA, and PFHxA) being most prevalent. In a recent study, 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, including food crops.

- Many studies have shown that PFASs are capable of transferring from pregnant mothers to their fetuses via the placenta during gestation, as well as transferring from nursing mothers to their infants via breastfeeding. These scenarios represent significant periods of PFAS exposure for developing fetuses and children, which may lead to adverse health outcomes.

- In general, fetuses, infants, toddlers, and young children experience higher relative PFAS exposure levels and are more vulnerable to the effects of environmental toxicants. The American Academy of Pediatrics released a policy statement in 2018 about 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, a joint 2013 report from the World Health Organization and United Nations Environment Program, and a statement from the International Federation of Gynecology and Obstetrics in 2015, indicating broad consensus on protecting children's health from environmental contaminants, including the PFASs used in food packaging.

- Once released to the environment during product manufacture, use, or disposal, PFASs become part of a virtually closed cycle leading to chronic, lifelong human and ecological exposures.

- PFASs are found ubiquitously in the environment (including indoor air and dust, surface water and groundwater, wastewater treatment plant effluent, sewage sludge and biosolids, sediments, and soil), plants, animals, and humans. However, most of the PFASs that contribute to total organic fluorine in the environment, wildlife, and human blood samples remain unidentified. The full extent of the contamination, despite extensive research, remains poorly understood.

- Because PFAAs and other persistent PFASs lack a natural degradation route,

their levels in the environment, humans, and biota may continue to rise for as long as PFASs are used in consumer products such as plant fiber-based food packaging.

The sections of the product-chemical profile (noted above) that pertain to Conclusion 1 include:

- Section 1 – Rationale for Product-Chemical Selection, pages 6– 8;
- Section 4 – Potential for Exposures to the Candidate Chemical in the Priority Product, pages 42 – 73;
- Section 5 – Potential for Significant or Widespread Adverse Impacts, pages 74 – 85; and
- Section 9 – Conclusions, page 100.

Conclusion 2

Exposure to any PFASs found in plant fiber-based food packaging products, or to their degradation products, during product manufacturing, use, or at its end-of-life, may contribute to or cause significant or widespread adverse impacts to humans or biota.

Conclusion 2 is supported by the evidence for widespread exposures identified in Conclusion 1, and by the following points:

- All PFASs have at least one hazard trait according to the Safer Consumer Products regulations. At a very minimum, PFASs are either extremely persistent (e.g., PFAAs), or have extremely persistent degradation products.
- The U.S. Food and Drug Administration (FDA) prohibits the use of certain longer-chain PFASs in food-contact materials because of their potential to cause adverse human health impacts. These effects, which are well established in animal and human studies, include kidney and testicular cancers, thyroid disease, reduced immune response, and pregnancy-induced hypertension. However, evidence from animal, *in vitro*, and modeling studies also links the degradation products of FDA-approved PFASs with multiple toxicological hazard traits, including developmental toxicity, endocrine toxicity, hepatotoxicity, neurodevelopmental toxicity, and reproductive and developmental toxicity.
- Shorter-chain PFAAs such as perfluorohexanoic acid (PFHxA), appear not to bioaccumulate in humans and animals, but bioaccumulate in plants, including those grown for agriculture, and are very mobile in environmental media, which is

another exposure potential hazard trait of concern under the Safer Consumer Product regulations.

- Recent studies show that the intermediate degradation products of the shorter-chain fluorotelomer-based PFASs currently used widely in plant fiber-based food packaging are more bioaccumulative and toxic than PFHxA, raising concerns for potential adverse impacts. As a result, FDA negotiated a three-year voluntary phase out with some of the manufacturers beginning January 1, 2021. However, as the history of regrettable substitutions illustrates, the PFASs that will continue to remain in use may not necessarily be safer, but just less well studied.

- PFAAs also display environmental hazard traits: phytotoxicity and wildlife developmental, reproductive, or survival impairment.

- PFAAs may have cumulative impacts with one another and with other hazardous chemicals. Some studies found that other PFAAs can cause adverse impacts when mixed with other toxicants, even at doses at which the individual PFAAs and the other toxicants produced no observed adverse impacts.

- The adverse impacts associated with PFAAs are relevant to the entire class of PFASs because most PFASs either:

    - degrade to PFAAs in humans, biota, or the environment (i.e., are PFAA precursors);

    - form PFAAs during combustion; or

    - are manufactured using PFAAs and contain them as impurities.

The sections of the product-chemical profile (noted above) that pertain to Conclusion 2 include:

- Section 1 – Rationale for Product-Chemical Selection, pages 6 – 8;

- Section 3 – Candidate Chemical Definition and Properties, pages 11 – 41;

- Section 5 – Potential for Significant or Widespread Adverse Impacts, pages 74 – 95;

- Section 9 – Conclusions, page 100; and

- Appendix C – PFAS Hazard Traits.

References included in these sections will be provided to the reviewers as part of this

request.

Attachment 3: Individuals who have Participated in the Development of the Proposal

Reviewers: in general, do not contact these individuals. For further direction, please see the attachment, "Guidance for Reviewers," on the FTP site and sent to you with the letter initiating your review.

Section A. California Department of Toxic Substances Control Personnel

Name	Title	Program
André Algazi	Senior Environmental Scientist	Safer Consumer Products Program
Simona A. Balan	Senior Environmental Scientist	Safer Consumer Products Program
Scott Braithwaite*	Senior Environmental Scientist	Safer Consumer Products Program
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Armeen Etemad	Hazardous Substances Engineer	Safer Consumer Products Program
Lynn Goldman	Attorney	Office of Legal Affairs
David Grealish	Graphic Designer III	Office of Communications
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Brian Taylor	Information Officer I	Office of Communications
Meredith Williams	Director	Department of Toxic Substances Control
Jeff Wong	Staff Toxicologist – Retired Annuitant	Safer Consumer Products Program

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Section B. External Participants.

Name	Title	Affiliation
Sara Hoover	Research Scientist III	Scientific Affairs Division, Office of Environmental Health Hazard Assessment
Gail Krowech	Staff Toxicologist	Scientific Affairs Division, Office of Environmental Health Hazard Assessment
Elizabeth Marder	Environmental Scientist	Office of Environmental Health Hazard Assessment
Gina Solomon*	Deputy Secretary for Science and Health	California Environmental Protection Agency

* No longer works for the listed department

Attachment 4: References Cited

Introduction

All references will be provided at an FTP site or are accessible using the links below.

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