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RE: External Scientific Peer Review

PROPOSED ADOPTION OF PLANT FIBER-BASED FOOD PACKAGING CONTAINING PERFLUOROALKYL OR POLYFLUOROALKYL SUBSTANCES AS A PRIORITY PRODUCT

This review relates to the proposed regulation in the State of California by the Department of Toxic Substances Control (DTSC) to adopt *plant-fiber based food packaging containing perfluoroalkyl or polyfluoroalkyl substances* as a priority product under the California Safer Consumer Products (SCP) regulatory framework. The review of this proposal is considered as an addendum to the 2020 proposal relating to the adoption of Treatments Containing Perfluoroalkyl or Polyfluoroalkyl Substances for Use on Converted Textiles or Leathers as a Priority Product as well as to the 2019 proposal to adopt Carpets and Rugs with Perfluoroalkyl and Polyfluoroalkyl Substances as a priority product due to the many similarities of the proposals. All three proposals addresses the same chemical class and relies on much of the same research and findings.

As part of this regulatory process, the DTSC is required to ensure that all product chemical combinations proposed as Priority Products meet the following criteria:

- 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
- There must be potential for one or more exposures to contribute to or cause significant or widespread adverse impacts.

Based on my expertise and experience, I am reviewing the findings, assumptions or conclusions I agreed I could review with confidence relating to Conclusion 1 outlined in the proposed regulation:

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, handling, recycling, or disposal of treatments containing PFASs for use on converted textiles and leathers, as well as disposal of the treated textile or leather products themselves.

My area of expertise and experience involve nearly 20 years of academic research relevant to the determination of the fate, transport and sources of perfluoroalkyl and polyfluoroalkyl substances (PFASs) in the environment.

This reviewer deems that the scientific portion of the proposed regulation as it pertains to Conclusion 1 is based on sound scientific knowledge, methods and practices. The extensive literature review compiled by DTSC as recent as December of 2020 and summarized in the report, "Product-Chemical Profile for Food Packaging Containing Perfluoroalkyl or Polyfluoroalkyl Substances" spans nearly two decades worth of scientific peer reviewed studies as well as recent industry, non-profit organization and regulatory reports examining investigations into the physical properties, transport, sources and fate of these persistent contaminants. As mentioned earlier, the technical component of this proposal is nearly identical to the 2019 and 2020 proposals. The basis of this regulation included a strong focus on data from historical and recent studies performed by leading scientists in the field of PFASs research as well as from available regulatory and industrial information.

The rationale for this proposal is clearly aligned with policy goals identified by the DTSC in its 2018-2020 Priority Product Work Plan that includes "to protect Californians from chemicals that migrate into food from food packaging" and "to protect children and women of child bearing age from exposure to harmful chemicals…..". This regulation is also timely under the current circumstances that we are under due to the pandemic. The pandemic may for a while longer change the way people avail of prepared foods from restaurants and groceries ultimately increasing reliance on takeout options due to the limited dine in options or many people who will remain apprehensive of potential exposure to the corona virus while dining in enclosed spaces. This increase in availing of takeout options for food will increase the use of plant-fiber food packaging and thus likely to increase potential exposure to PFASs if the application of these chemicals in these products is not addressed.

DTSC's decision to use a chemical class approach in this proposed regulation is consistent with the earlier proposals for carpets and rugs and converted textile and leather treatments. As per the previous proposals, clear and ample justification was provided in this approach and is considered a comprehensive, proactive and forward-thinking management and regulatory strategy by this reviewer. It is exhaustive that it closes the door completely on the use of per and polyfluorinated chemistry in any future applications of these chemicals on food packaging.

Even though more regulation is in place for food packaging by the FDA through Food Contact Notification (FCN), this proposal goes beyond the FCN standards by considering all exposure routes across the life cycle of the product. The proposal is clear that the product-chemical profile does not provide a comprehensive assessment of all available adverse impacts and exposure literature on PFASs on plant fiber-based food packaging products. I will highlight some weak areas of the report where improvements may be made (if data is available) to strengthen and better support the arguments made. The DTSC also states that the intent of the report is not to assert that the product-chemical pairing is not safe to use but it has simply the potential for exposure of people or the

environment to the Chemical of Concern in the Priority Product, and that such exposure could potentially lead or contribute to widespread adverse impacts and that safer alternatives should be explored. This seems a lower bar that is easily met given the studies and data included in the report.

Similar to the 2019 and 2020 proposals, this profile effectively highlights the crucial characteristic shared by all PFASs, namely the presence of the highly stable Carbon-Fluorine bonds. This is the primary determinant that renders these chemicals persistent in the environment. This persistence and longevity in the environment are of immense concern for plant fiber-based food packaging containing PFASs as they have been manufactured with the idea that they are compostable. The assertion that PFASs from plant-fiber based products can enter the environment through composting routes is a realistic one. Composting was not pathway relevant to the life cycle of carpets and textiles from the previous proposals. In addition, the refusal of composting companies to process PFAS treated material defeats the ultimate purpose and rational of the development of these degradable packaging materials.

Since the proposal in 2020, that also cited the staggering report by the Organisation for Economic Cooperation and Development (OECD) that identified 4,730 chemicals related to individual PFASs and commercial mixtures available in the global market, no significant improvement has been achieved in advancing the analytical techniques to identify majority of these chemicals. Again, bearing credence to the class approach by the DTSC.

The supporting points identified for Conclusion 1 outlined by the DTSC are all based on available sound scientific data and/or reliable information provided by industry and regulators. Some specific recommendations/points are discussed in the succeeding paragraphs.

Despite knowing the identities of the primary chemicals used and approved for application in food packaging under the Food Contact Notification (FCN) process by the FDA there is limited data on the physical properties and fate studies of these selected chemicals. Section 3 of the Profile cites 15 PFAS food contact substances currently available in the US marketplace but very limited direct data on these chemicals were included in the profile presumably because none were available. It is unclear whether the requirements for approval under the FCN process do not include basic physicochemical properties on these chemicals. Providing some language to clarify the limited availability of this basic information for these chemicals despite approval under the FDA process is recommended.

Under the section “Relevant physicochemical properties” (page 19) of the profile, it was noted that 6:2 FTOH and 4:2 FTOH are liquid at room temperature and most PFASs are solid. Other PFASs that are also liquid at room temperature are the 6:2 and 8:2 methacrylates and acylate versions often considered as “monomers” or building blocks

for fluorotelomer-based side-chain polymers.

Under the section “Environmental fate”, there is a typo on page 24, second paragraph from the bottom “…..**However**, However, since PFAAs are manufacturing aids, impurities or degradation products….”

In the discussion of PFASs in water also under the Environmental fate section, it is suggested to include, oxidation of precursors in the atmosphere and partitioning in rain water as another route of how PFAAs enter surface and groundwater.

Perhaps the weakest aspect in the proposal is the limited data or studies to support the potential for exposure to the candidate chemical in the product. Despite some basic understanding of the process of how the candidate chemicals are incorporated in the manufacture of paper used for food packaging, paperboard or molded fiber and knowing what the chemicals are that are used in these applications, there seems to inconsistent data showing detection of PFASs from the products themselves. The studies outlined in the profile reported varying % of detection of fluorine signature in samples. For example, it was reported that 10 of 78 samples from the study done by Safer Chemicals and Healthy Families et. al in 2018 and then 100% detection in paper bags used for fried foods also by Safer Chemicals and Healthy Families in a 2020 study. It is suggested that some discussion is included in the profile as to whether these percent detection aligns with the market share of the PFAS treated products. The gold standard study really would have been to identify plant-fiber based packaging with known PFASs treatment and analyze those directly to determine whether these chemicals are readily extractable from the products.

Some additional language is suggested to be incorporated in the profile that it is also likely that other processing, or handling procedures are likely to impact presence of PFASs in these food packaging materials due to the widespread use in variety of industrial and consumer materials. It was mentioned briefly but warrants additional mention in the summary of the Profile.

There is also limited evidence included in the Profile (likely because there are limited studies available) of direct link of migration of PFASs from packaging into food. There were studies presented that included PFAS concentration detected in food but it is not clear as to whether studies exist that provides good correlation between PFAS concentration in food and PFAS detection in their respective packaging material (only one study in butter was cited (Still et al. 2013). The Profile does include that types of food will impact how PFAS could migrate from its packaging (ie. greasier foods may increase transfer of PFAS from packaging to food due to similarities in their physicochemical properties.)

A review cited in the Profile by Trier et al. 2018 was not found in the bibliography. This citation is found in the first paragraph of page 49 that discussed migration potential of

PFOA and PFOS and other longer-chain PFASs from food packaging.

Very weak support in the Profile due to lack of studies that exist in the claim that recycling of PFAS treated food packaging can contribute to the increased cycling of these chemicals in the environment.

The Profile included increased California specific data regarding PFAS concentrations detected in various environmental matrices. This was an improvement from the 2019 and 2020 proposals.

There were instances when the organization of data presented in the Profile regarding PFAS concentration in environmental matrices was redundant in places.

The Profile included an excellent assessment of current state, US and international laws, regulations and agreements that puts into the context the current proposal.

Conclusion and Big Picture Comments:

Sound scientific data, methods and practices were used in formulating the overall conclusions outlined by DTSC in their proposed regulation of naming of *plant -fiber based food packaging containing perfluoroalkyl or polyfluoroalkyl substances* as a Priority Product. There was however, less considerable evidence in supporting migration of PFASs from food packaging and containers to food. It is also worth noting the limited studies that have been done on the known PFASs used and approved for use for food packaging. This Product-Chemical Profile based on this reviewer's assessment met the criteria specified by the DTSC of showing that there is potential for exposure to these Candidate Chemicals and a potential for widespread adverse impacts.