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RE: Review of the December 2020 narrative ESPR draft titled "Product- Chemical Profile for Food Packaging Containing Perfluoroalkyl or Polyfluoroalkyl Substances"

I have reviewed the December 2020 narrative ESPR draft titled "Product- Chemical Profile for Food Packaging Containing Perfluoroalkyl or Polyfluoroalkyl Substances", which DTSC based on the literature and in consultation with stakeholders for external scientific peer review (ESPR) supporting their proposed adoption of plant-fiber-based food packaging containing perfluoroalkyl or polyfluoroalkyl substances (PFAS) as a Priority Product. PFAS is a large family of chemicals that include several chemical subclasses and within each subclass, a wide range of fluorocarbon chain lengths.

I understand PFAS-containing plant-fiber-based food packaging includes paper, paperboard or molded fiber products treated with PFAS during the manufacturing process to impart oil, grease and water resistance and sold for packaging food and beverages regardless of temperature for to restaurants, grocery stores or consumers. I understand that the CA Safer Consumer Products Regulatory Program requires DTSC is to identify product-chemical combinations that pose risks to people or the environment and to adopt them as Priority Products. For the latter designation, this product chemical combination must meet the following two general regulatory criteria: (1) potential sources of exposure to humans and other environmental biota; and (2) these exposures have potential to cause significant or widespread adverse impacts.

In the case of PFAS in general and in this case, specifically, PFAS-containing plant fiber-based food packaging, DTSC's review determined that there is overwhelming evidence to support the required regulatory criteria. Specifically: (1) PFAS or their degradation products to other PFAS subclasses, which is the extent to their degradation naturally, are extremely persistent in the environment, leading to ubiquitous exposure to human and other ecological receptors. A subset of PFAS used in plant-fiber based food-packaging may be classified as polymeric and considered unlikely to mobilize or less likely to degrade to other PFAS, limited studies that have been conducted indicate degradation of these polymeric PFAS although slow, does occur. Also it is known that these polymeric PFAS do contain more easily degraded nonpolymeric PFAS impurities that can migrate from plant fiber-based packaging into food. In addition end-of-life, including composting, land-application of compost, combustion (both unintentional and intentional will result in continual PFAS release over time or during an event. (2) Humans, including sensitive subpopulations such as infants, children, and workers in a wide-range of occupations that involve continual handling of PFAS-containing plant fiber-based food packaging during production, service, use and/or disposal as well as other ecological receptors may be exposed to PFAS throughout the life cycle of PFAS-containing plant fiber-based food packaging. Theses exposure are compounded by the multiple sources of PFAS exposure temporally. (3) Human and ecological exposures to PFAS are known to 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). PFAS-containing plant fiber-based food packaging contributes to these PFAS exposures over a lifetime through multiple routes, which can be minimized by treating PFAS-containing plant-fiber based food packaging as a Priority Product.

Consistent with the evidence in support of the required regulator criteria, which is similar but updated to the evidence for PFAS-containing carpets and PFAS-containing textiles being labeled Priority Products previously acquired and reviewed, DTSC's over overarching conclusions are:

> **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.
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> **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.

My review of the ESPR draft is based on the directive to determine whether the scientific portion of the proposed regulation is based on sound scientific knowledge, methods and practices. I was already familiar with most of the literature cited in the ESPR draft. I had reviewed much of the same literature in my previous review of PFAS-containing carpets and PFAS-containing textiles in consideration for labeling them Priority Products. Also, I have conducted and published research on PFAS in municipal composts that contain plant-fiber based packaging as well as a just published review on PFAS sources, fate and plant uptake in agricultural systems (Costello et al. 2021, *Current Pollution Reports*, https://doi.org/10.1007/s40726-020-00168-y). A year prior to publication, we prepared a one-page white paper using data from my research group (cited as Lee and Trim 2019 in the ESPR draft), which was provided to the State of Washington legislative board with the help of Zero Waste Washington. This one-pager provided support of the proposed Bill 2658 to prohibit the sale of PFAS-containing food packaging in the State of Washington as of January 1, 2022 assuming replacements could be identified. Food packaging as defined by the WA Department of Ecology included paper wraps, liners, bags, sleeves, dinnerware (plates, bowls, trays) and food service containers. Non-PFAS replacements were identified and the prohibition is to planned as proposed. Lastly, I have also been an integral part of three research teams at Purdue University investigating PFAS effects to amphibians and animal models (e.g., zebrafish and *C-elegans*). As part of my assessment of the current ESPR document, any key citations that were new to me. There were a few 2020 peer-reviewed journal articles on adverse effects or new occurrence studies as well as a webinar that were new to me that I accessed for a quick review. This new material was consistent with other literature in which I was already familiar. I also accessed several 2020 web links to ensure I was updated on some of the guidance- and regulatory-related activities that are ongoing.

I am most qualified to address Conclusion 1 based on my training and the majority of my research over the past 30+ years; however, I have also been directly involved in research associated with Conclusion 2 as already noted for the past 7 years. I found all major claims made to be consistent with sound scientific knowledge or a reasonable extrapolation of what is known in cases where clear data gaps exist, which were acknowledged.

There is no doubt to DTSC's statements in support of Conclusion 1 regarding the extreme persistence and presence of PFAS and their degradation products in all environmental compartments including soil, water, plants, animals, humans and indoor air and dust. There release into water, soil, sediment, and air are numerous including but not limited to industrial discharges, landfill leachate, treated wastewater effluent irrigation, release from consumer products during use and disposal, combustion/incineration, and land-application of nutrient-rich biosolids derived from wastewater treatment plant (WWTP) sludge as well as composts derived from organic fractions of municipal wastes, especially those that include compostable food packaging, as soil amendments. In the wastewater treatment process, composting process and once land-applied to soils, PFAS will degrade to numerous intermediates with varying stability and subsequently to perfluoroalkyl acids (PFAAs), which are generally found to be the most common terminal (thus persistent) products from microbial degradation and are typically more mobile than the precursors. These degradable PFAS are referred to as precursors or PFAA precursors. Therefore, while many PFAS do degrade in the environment at varying rates depending on oxygen levels, nutrient content, bioavailability (media dependent) and microbial communities, they degrade to other PFAS subclasses.

There is even more evidence above what was provided in the ESPR draft that PFAS and PFAS-replacements that are just a new subclass within the PFAS family are prevalent in the environment, persistent, and have the potential to invoke similar or greater adverse effects. The review indicated data are limited for most PFAS including polyfluoroalkyl ether sulfonic acids (PFESAs). Work in my research group on two Cl-PFESAs (6:2 and 8:2 Cl-PFESAs) showed they are highly sorbed to soils, do not degrade microbial, and are also resistant to chemical degradation (Chen et al. 2018, *Environ. Sci. Technol*. 52:9827-9834). Other literature, mostly based out of China where they have been used as PFOS replacements for quite some time, shows that these same PFESAs were found in multiple environmental compartments (Ruan et al. 2015, *Environ. Sci. Technol*. 49:6519-6527; Wang et al. 2013, *Environ. Sci. Technol*. 47:10163-10170;

Gebbink et al. 2017, *Environ. Sci. Technol*. 51:110957-11065), bioaccumulate in biota (Shi et al. 2015, *Environ. Sci. Technol*. 49:14156-14165) and may have higher toxicity than PFOS (Li et al., 2018, *Environ. Sci. Technol.* .52:3232-3239).

The ESPR draft did a good job at reflecting bioaccumulation and toxicity potential of the PFAS that tend to be more routinely quantified, there was literature in the amphibian trophic level that could have been included on salamanders, frogs and toads. These works, in addition to current research that is in the process of being submitted, show that a diverse array of endpoints (e.g., body condition, neurotransmitter expression, immunotoxicity) from PFAS exposure are affected suggesting multiple mechanisms of toxicity and often at environmentally relevant concentrations (Flynn et al. 2020, *STOTEN* https://doi.org/10.1016/j.scitotenv.2020.142730; Foguth et al. 2020, *Neurotoxicology and Teratology,* 81:106907 https://doi.org/10.1016/j.ntt.2020.106907; Abercrombie et al. 2020, *Environ. Toxicol. Chem.*, https://doi.org/10.1002/etc.4711; Flynn et al. 2020, *Environ. Toxicol. Chem.*, https://doi.org/10.1002/etc.4690; Foguth e al. 2019, *Toxicol Appl Pharmacol*. 377:114623. https://doi.org/10.1016/j.taap.2019.114623; Hoover et al. 2017, *Environ. Sci. Technol. Letters,* 10:339-403; Abercrombie et al. 2019, *EES*, https://doi.org/10.1016/j.ecoenv.2019.04.022; Cannon et al., 2019, *Toxicology and Applied Pharmacology,* https://doi.org/10.1016/j.taap.2019.114623). Additional studies with the Norther leopard manuscript in preparation)and indicate that binary mixtures can act additively and non-additively (Lech et al., manuscript in preparation). Recent studies with salamanders showed an increase in trematode infections exposed to 10 ppb PFHxS indicating immunotoxicity (Pérez et al., manuscript in preparation).

It is well-established from multiple studies that PFAS including side-chain polymers only degrade in the environment to just other PFAS subclasses, e.g., perfluoroalkyl acids (PFAAs) and numerous intermediates prior to the terminal PFAA metabolites, which tend to be more mobile than their precursors. Even chemical means to trap or degrade PFAS are limited and expensive. Some of the intermediates will include volatile PFAS such as the fluorotelomer alcohols (FTOHs). Therefore, although FTOH residuals in consumer products have been reduced substantially in the manufacturing process, FTOHs can be generated from the degradation of precursor PFAS including but not limited to side-chain fluorinated polymers that are heavily used in consumer products. These side-chain fluorinated polymers will degrade at different rates depending on the side chain and use conditions with FTOH being the intermediate on the way to PFAAs. The ESPR draft did a good job of capturing this concept. One recent study on a PFAS subclass not represented in the draft showed that perfluorooctane-amido and -sulfonamido amine oxides disappear in 3 to 15 days in aerobic surface soils yielding PFAAs including PFOA and PFOS (Chen et al. 2020, *ES&T Letters* 7:714-720). While these two particular PFAS were initially found in aqueous film forming foams (AFFFs), thus currently not necessarily relevant to PFAS-containing plant fiber-based food packaging, they further highlight precursor transformation to PFAAs and aggregate exposures. Also there are new PFAS hitting the market on a regular basis and other residuals, manufacturing impurities or degradation products may be present and released relatively easily during product use, etc. even if less volatile than the FTOHs. Therefore, any action that will remove PFAS use in products that lead to PFAS exposure to humans and ecological receptors and foster exploration of safer alternatives, should be taken as is done in the current proposal. Given the fundamental truth that PFAS don't go away, there is no need to wait until the toxicological science is developed for each new PFAS subclass before making decisions regarding PFAS-containing plant fiber-based food packaging being labeled a Priority Product.

The realization of the expense and potential negative consequences of trying to minimize PFAS entry into our environment from our municipal wastes are growing as lower and lower PFAS levels are being considered a threat to human and ecosystem health. For example, many states are considering banning the land application of biosolids and composts used as soil amendment as one way to reduce PFAS inputs into the environment, which is problematic on many fronts. This translates to several millions of solids annually that would need to be treated, land-filled or incinerated, thus increasing cost (up to almost an order of magnitude in some cases) to the municipal tax payers from whom the hardest hit will once again be low-income populations that are already struggling.

In addition, it also means the loss of a large sequestered carbon source with numerous macro and micro-nutrients. Most all other anthropogenic contaminants in our wastes readily degrade when land applied, but as noted, this process does not reduce PFAS loads applied to soils. Their persistence coupled to their ability to transport large distances through air and water are what has led to ubiquitous presence and multiple exposure pathways to humans and environmental biota. Their extreme persistence means that even if we stopped using PFAS for all uses, PFAS presence from previous and current direct discharges as well as long-term use and disposal of existing consumer products will remain indefinitely in the environment although presumably become increasingly dilute over time with various dissipation mechanisms (not natural degradation processes). Therefore, it is imperative to minimize nonessential uses of PFAS, which include their use in food packaging, otherwise we will continue to be subject to both known and not yet fully realized health and economic consequences from their use. As noted in the ESPR draft, several steps are already being taken by other states, the food industry and food packaging entities to eliminate PFAS from food packaging, but .

Although currently EPA has only initiated the regulatory development process for listing PFOA and PFOS as CERCLA "hazardous substances", it is wise to treat the overall PFAS class of compounds as a whole because of the pervasive persistence of all PFAS. In addition, although long-chain PFAS are currently considered to invoke greater toxicity in humans than shorter-chain PFAS, studies on the toxicities of short-chain PFAS to both humans and other environmental biota are growing and indicate similar types of adverse effects. In addition, with shorter-chain PFAS being one of the most common PFAS alternatives currently, their global production and use is increasing, thus there are concomitant increases in their presence in the environment, thus exposure to humans and biota. They are also more mobile in soil and water, which makes them harder to remove from drinking water with common adsorptive processes and increases their plant uptake relative to PFOS and PFOA. Therefore, even if limited science currently available suggests that much higher levels are needed of the shorter-chain PFAS to cause adverse effects comparable to PFOS and PFOA, they may end up in being present in greater concentrations in water and plants, thus posing similar net risks especially given their use in a vast number of consumer products. Currently, the C6 perfluorocarboxylate (PFHxA) concentrations are increasing in land-applied biosolids while PFOS and PFOA are generally decreasing and PFHxA is the dominant PFAA in compostable food packaging (Choi et al., 2019, *ES&T Letters*. doi:10.1021/acs.estlett.9b00280). GenX, ADONA and other replacements are also now routinely found in many of the biosolids we have been analyzing in our research group. Given their growing presence coupled to their similar persistence and recent literature indicating they invoke similar adverse impacts in laboratory studies, PFAS-based replacements or alternatives are equally problematic as the longer-chain PFAS they replaced.

I also support the conclusions made in support of the overall Conclusion #2 regarding that PFAS exposure through product manufacturing, servicing, use, or end-of-life from PFAS-containing plant fiber-based food packaging may contribute to or cause significant or widespread adverse impacts to humans or ecological receptors. Again, while the concentrations that appear to cause measurable adverse effects varies with PFAS, we cannot ignore additivity, which is still not well researched. Also as noted, although the shorter chain PFAS and some of the other subfamilies of PFAS-based replacements such as the ethers (e.g., GenX and ADONA) may not bioaccumulate like PFOS and PFOA, they are being found to invoke similar adverse effects. Studies on the PFAS effects on humans and other species will continue to grow. Some additional work not included in the numerous adverse effects summarized in the ESPR draft were already noted, but not paramount to include since the ESPR draft already contains more than sufficient justification for proposing PFAS-containing plant fiber-based food packaging as a Priority Product.

Overall, the well-documented science in the peer-reviewed literature of the inherent persistency of PFAS and the subsequent intermediates precursors of varying stability or the terminal metabolites (PFAAs) from precursors are sufficient to warrant PFAS-containing plant fiber-based food packaging be adopted as Priority Products. In addition, this is further supported by the multiple exposure pathways to humans and the environment that are also well-known and the growing body of evidence indicating that PFAS alternatives will likely have similar toxicity profiles.