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<u>Conclusion #1</u>
Humans can be exposed to PFASs from the use of food service packaging. End-of-life processes, such as composting and recycling of food service packaging, may release PFASs to the environment, where they persist indefinitely and can expose humans and wildlife.

Conclusion 1 is supported by the following points, which are further described in the Initial Statement of Reasons (Specific Purpose and Necessity of Regulation, section 17989.2(a)(3)):

- PFASs may be found in fiber and plastic based food service packaging.
- PFASs can migrate from food service packaging, such as paper take-out items, into food.
- PFASs can enter the environment from end-of-life processes, such as composting and recycling of food service packaging.
- PFASs or their degradation products, such as perfluoroalkyl acids (PFAAs), persist in the environment after use.
- Plants that are consumed by humans and wildlife can take up PFASs when grown in contaminated soil.

Conclusion #1 is demonstrably supported by a significant literature:

Humans can be exposed to PFASs from the use of food service packaging

As shown in many studies to date, as well as review documents on this class of chemicals, various PFASs are clearly found in such materials in the U.S. (Schaider et al., 2017), where 46% of food contact papers and 20% of paperboard samples were found to contain fluorine. Further, evidence demonstrates that these chemicals can indeed migrate from food service packaging, with the highest apparent levels derived from paper and cardboard packaging but likewise occurring in other types of food service packaging. It is also notable that while some PFASs have been phased out, their replacements have this same problem as well. These conclusions have been reached by other risk assessment bodies in reviews of studies of migration of various PFASs from such containers.

End-of-life processes, such as composting and recycling of food service packaging, may release PFASs to the environment, where they persist indefinitely and can expose humans and wildlife.

Such containers ultimately are disposed of, whether via landfills, incineration or composting and recycling. In fact, because of the persistence of PFASs, these chemicals end up remaining as a source of contamination for decades to come (e.g., Trier et al., Nordic Council of Ministers, 2017). PFASs have been detected in municipal organic solid waste composts and landfill leachates (Choi et al., 2019; Solo-Gabriele et al., 2020). From such processes PFASs and or their associated degradation products are released back into the environment (including air, dust, wastewater treatment plant effluent, biosolids, soil, inland and ocean waters, drinking water and food (Lindstom et al., 2011; Wang et al., 2016), and can persist indefinitely because of resistance to degradation. They are mobile in aqueous environments, and also migrate in soil from which they can be transported into plants (Choi et al., 2019) and reach wildlife or agricultural sources of human food, e.g., cows (meat and dairy products). Studies have also shown accumulation of PFASs in agricultural plants that are consumed by humans, including potatoes, cereal seed and leafy vegetables and fruits, derived from contaminated water or soils (Ghisi et al., 2019). Thus, in essence there is a potential for recycling of these compounds and human and wildlife as well as environmental exposures.

<u>Conclusion #2</u>

PFASs in food service packaging may impact public health or wildlife because of the several hazard traits associated with the members of the PFAS class.

Conclusion 2 is supported by the following points, which are further described in the Initial Statement of Reasons (Specific Purpose and Necessity of Regulation, section 17989.2(a)(3):

- PFASs and their degradation products are associated with harm to humans and to wildlife, such as reproductive toxicity, developmental toxicity, carcinogenicity, and liver toxicity. In particular, short-chain PFASs are associated with hazard traits such as persistence, bioaccumulation, environmental mobility, and lactational and transplacental transfer.
- These hazard traits are further described in DTSC's rulemaking documents for their regulation on PFASs in carpets and rugs (reference 9 in Attachment 4). DTSC updated the scientific basis for their regulation (i.e., Product-Chemical Profile) to account for feedback received from their external scientific peer reviewers. DTSC's rulemaking documents include the conclusions that were posed to their reviewers, as well as the response letters from their reviewers.

Conclusion #2 is demonstrably supported by a significant literature:

An accumulating literature links exposures to PFASs with adverse health effects (hazard traits) as described in the DTSC's Product – Chemical Profile for Carpets and Rugs Containing Perfluoroalkyl or Polyfluoroalkyl Substances in 2019. Notably, the hazard traits encompass a breadth of target organs as reported in epidemiological studies as well as in animal models (Appendix 3). From epidemiological studies come associations of PFASs with effects on liver, heart, endocrine function, immune function, reproductive systems and developmental consequences (ATSDR Toxicological Profile for Perfluoroalkyls) with similar outcomes from animal models for liver, immune, reproductive and developmental toxicity. With respect to liver, these compounds increase serum lipid levels, both total cholesterol and LDL cholesterol. Similarly, in animal models, are reports of increases in liver weight, hepatocellular hypertrophy, and decreases in serum lipid levels. While some assessments suggested liver changes in rodent studies were due to effects on PPAR-α and thus not relevant to humans, it is the case that studies show gene expression changes in response to PPFA exposures in PPAR-α null mice. Human studies include immune effects including decreased antibody responses to vaccines and a possible link between serum PFOA levels and increased risk of asthma diagnosis, while animal studies indicate altered antigen responses. Reproductive effects in humans, specifically decreased fertility has been found. While such effects have not generally been seen in animal studies, evidence does indicate alterations in mammary gland development. Evidence is also suggestive of a link between PFASs and reduced birthweight, albeit of small magnitude, as well as pregnancy-induced hypertension and pre-eclampsia. The reductions in birth weight, however, are supported by decreases in pup body weights in animal studies as well as decreases in offspring survival and behavioral alterations. To date, numerous epidemiological studies have also reported associations of such exposures with thyroid dysfunction.

Evidence for carcinogenicity in association with PFAS exposures from human studies remains somewhat inconsistent to date, depending upon cancer type, with the most consistent findings to date in human populations for testicular and kidney cancers. Similarly, such findings in animal models have been somewhat inconsistent. However, based on the overall evidence, EPA (2016) did suggest evidence of carcinogenic potential specifically for PFOA and PFOS, while IARC concluded in 2017 that PFOA is a possible human carcinogen.

<u>Conclusion #3</u>

Total fluorine measurements are a suitable proxy for determining the presence of PFASs in food service packaging.

Conclusion 3 is supported by the following points, which are further described in the Initial Statement of Reasons (Specific Purpose and Necessity of Regulation, section 17989.2(a)(3):

- Chemical-specific chromatographic-based methods (i.e., liquid chromatography, gas chromatography) have not been developed for the large and structurally diverse class of PFASs.
- Total fluorine measurements (i.e., combustion ion chromatography (CIC), particle- induced γ-ray emission spectroscopy (PIGE), and instrumental neutron activation analysis (INAA) will quantify the total fluorine content, which includes PFASs, in food service packaging.

- Any organic fluorine detected in food service package would be due to the presence of PFASs. Inorganic fluorine in food service packaging, if any, would be an impurity and detected at trace levels.

Conclusion #3 is consistent with advances in the current analytical methods for assessments of PFASs:

For identification of health effects, screening of PFASs in various sources is needed; the reliance on measures of total fluorine is based on the chemical structure of PFASs as fluorine containing organics. Consequently, methods have progressed to differentiate the organic fluorine from inorganic fluorine in a total mass balance approach. However, as noted by Schaider et al. (2017), higher total fluorine levels from such analyses but low levels of specific PFASs may actually reflect the presence of volatile PFASs, PFAS polymers or newer replacements PFASs. As noted, inorganic fluorine would be an unintentional impurity and occur at trace levels.

The Big Picture

Reviewers are not limited to addressing only the specific issues presented above, and are asked to contemplate the following questions:

- In reading the PFAS-related section of the Initial Statement of Reasons, are there any additional scientific issues in the report not described above? If so, please comment with respect to the language given above.

  One note that may be important to include is that the understanding of the toxicity of aggregate exposures of PFASs, even of specific mixtures, is unknown, a problem further enhanced by the introduction and lack of information on newer PFASs. Humans are exposed to multiple PFASs of unknown interaction or cumulative toxicity risk; these are likely to differ by geographical areas and population behaviors and characteristics, and such differences may be related to inconsistencies across epidemiological studies in terms of health outcomes. Defining toxicity equivalents of various PFASs could assist in beginning to define these.

- Taken as a whole, is the PFAS-related section of the Initial Statement of Reasons based upon sound scientific knowledge, methods, and practices?

In this reviewer's opinion, the Initial Statement of Reasons is based upon sound scientific knowledge, methods, and practices.

CalRecycle means hazard traits to mean those that are identified in Chapter 54 of Division 4.5 of Title 22 of the California Code of Regulation (reference 10 in Attachment 4).