The PFAS Regulatory Coalition
Jeffrey Longsworth, Coordinator
jlongsworth@btlaw.com
Tammy Helminski, Coordinator
thelminski@btlaw.com
Barnes & Thornburg LLP
1717 Pennsylvania Avenue NW, Suite 500
Washington, D.C. 20006-4623

Via electronic mail

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VIA ELECTRONIC MAIL
Toxics in Packaging Clearinghouse
c/o NERC
139 Main Street, Suite 401
Brattleboro, VT 05301
info@toxicsinpackaging.org

Re: PFAS Regulatory Coalition's Comments on Toxics in Packaging Clearinghouse Draft Updates to Model Legislation

Dear Madam or Sir:

The PFAS Regulatory Coalition (Coalition) appreciates the opportunity to file comments regarding the Toxics in Packaging Clearinghouse (TPCH) draft updates to the Toxics in Packaging Model Legislation dated July 9, 2020. The draft updates include the addition of perfluoroalkyl and polyfluoroalkyl substances (PFAS) and phthalates as regulated chemicals, as well as new processes for identifying additional chemicals of high concern in packaging. The Coalition is limiting its comments to the proposed inclusion of PFAS compounds to the model legislation.

I. The Coalition's Interest

The Coalition is a group of industrial companies, municipal entities, agricultural parties, and trade associations that are directly affected by the development of legislation, policies and regulations related to per- and polyfluoroalkyl substances (PFAS). Coalition membership includes entities in the automobile, coke and coal chemicals, iron and steel, municipal, paper, petroleum, and other sectors. None of the Coalition members manufacture PFAS compounds. Coalition members, for purposes of these comments, include: Airports Council International – North America; American Coke and Coal Chemicals Institute; American Forest and Paper Association; American Fuel & Petrochemical Manufacturers; American Iron and Steel Institute; Barr Engineering; Brown & Caldwell; Gary Sanitary District (IN); Illinois Association of Wastewater Agencies; Lowell, MA; Pueblo, CO; Tempe, AZ; Trihydro; TRS Group; and Yucaipa Valley Water District (CA).

II. PFAS Regulatory Coalition's Comments on TPCH's Draft Model Legislation Updates

The Coalition supports actions that provide uniformity across the country of PFAS-related legislation, regulation and policy. The Coalition further advocates for legislation and regulations that do not duplicate efforts between jurisdictions, do not regulate PFAS compounds as a singular class, and do not impose requirements that are not technically supported or practically implementable. To those ends, the Coalition submits these comments on the draft updates to the TPCH model legislation. Our comments focus particularly on Section 4.c and the definitions of the terms used therein:

> c. Prohibition of sale or distribution of a package or packaging components containing PFAS. Beginning XXXXXX, a manufacturer, supplier or distributor may not offer for sale or for promotional purposes a package or packaging component to which PFAS has been intentionally introduced during manufacturing or distribution in any amount. There shall be no detectable PFAS in any package or packaging component.

A. PFAS should not be included in the model legislation.

PFAS compounds should not be included in TPCH's model legislation. PFAS compounds in food packaging are already regulated by the U.S. Food & Drug Administration (FDA), including through the food contact notification (FCN) process. Subverting federal legislative and regulatory authority to create state bans on otherwise-approved uses creates uncertainty and confusion not just for packaging manufacturers, but also for consumers. If TPCH insists on including PFAS compounds in its model legislation, then it should only address those specific PFAS compounds that are not otherwise already approved under federal statutory authority. The model legislation should not promote banning PFAS compounds approved by FDA for food packaging.

B. Model Legislation should not include "PFAS" as an entire class of compounds.

If TPCH proceeds to recommend regulating various PFAS in the model legislation, it should take the time to specify which specific PFAS compounds are being targeted. Proposed Section 3.l of the draft model legislation defines PFAS as "all members of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." That definition is problematic, and the Coalition believes that all PFAS legislation and regulations must clearly specify the individual PFAS compounds being regulated.

Given the wide variations in possible human toxicities, environmental threats, and other characteristics exhibited by different PFAS compounds, it is scientifically unsound to group all PFAS together for purposes of risk assessment or to assume that exposures to

mixtures of PFAS necessarily bioaccumulate in one's body in interchangeable 1:1 ratios. From a toxicological perspective, regulatory agencies must have adequate science for determining health-based values before promulgating individual-compound standards, limits, and related regulations. The most prevalent and available science regarding the incidence and potential health effects of PFAS is based on PFOA and PFOS. Indeed, there have already been voluntary phase outs of these two compounds in food packaging beginning at least five years ago and, recently, manufacturers have begun voluntarily taking steps to remove other PFAS compounds.

There is significant research ongoing on a wide variety of PFAS compounds, and new information is being released on a regular basis. As more is being learned about the multitude of individual compounds in this class and their variability in potential toxicities, there must be flexibility to allow use of those compounds that pose either a scientifically-acceptable risk or no risk. If TPCH includes PFAS in its model legislation, the definition in proposed Section 3.1 must be amended to specify which PFAS compounds the scientific data justify for inclusion at this time. Obviously, in the future, as more scientific data are developed for other compounds TPCH can further amend its model legislation, as necessary.

C. Model Legislation should include an alternatives analysis.

As discussed above, PFAS compounds used in food packaging are already regulated by FDA. These compounds are used in food packaging to provide certain functionality – not just for convenience of consumers – and to provide particular benefits for food safety and preparation. If the model legislation bans the use of certain compounds, it should first ensure that viable substitutes can be identified. This approach is being taken by the State of Washington, as TPCH notes on page 2 of the Request for Comments.

TPCH states that the proposed changes are intentionally "without any provisions for alternatives analysis or exemptions" as a way to "to spur innovation, prevent regrettable substitutions with other chemicals in the PFAS family, and create new expectations and standards of performance (for consumers and industry) that are defined by safe alternatives and not by PFAS chemicals." Such a rationale presumes without any scientific basis that there are no PFAS compounds that could be safely used as substitutes. There certainly could be other "regrettable substitutions" outside of the PFAS family of compounds that pose risks to consumer. A more reasonable "protective approach" focuses first and foremost on allowing FDA-approved uses and then encouraging an analysis and phase-in process of alternatives that meet safety and functionality needs.

D. The "no detectable" PFAS language should be removed.

Proposed Section 4.c focuses its ban on PFAS that "has been intentionally introduced during manufacturing or distribution in any amount." The definition of "intentional introduction" in proposed Section 3.g focuses on the deliberate use of a regulated chemical where "its continued presence is desired in the final package or

packaging component to provide a specific characteristic, appearance, or quality." It also specifically states that amounts contained in post-consumer recycled materials for feedstock are not considered "intentional introduction." This definition is helpful and pragmatic and should be retained for any PFAS that may be included in TPCH's final model legislation.

However, proposed Section 4.c also states: "There shall be no detectable PFAS in any package or packaging component." That language is at odds with the support for the use of post-consumer content expressed by the model legislation, as well as the provision on "intentional introduction." PFAS compounds are now ubiquitous in the environment, and very low levels of PFAS can be introduced into manufacturing processes from other ambient sources such as process intake water. Moreover, as stated above, certain PFAS compounds are approved by the FDA for their safe use in food packaging. Accordingly, very low levels of PFAS compounds could end up in post-consumer recycled material feedstock. Laboratory testing using very low limits of detection in the parts per trillion range might result in the discovery of PFAS compounds that were introduced through these means and yet pose no risk to consumers. Furthermore, due to advances in analytical chemistry, "no detectable" is a moving target, as test methods for PFAS are largely under development and presently only cover a very small percentage of the broad universe of PFAS. Even if the testing methods were mature, the burden for analysis of approximately 4600 chemicals to prove compliance would be immense for the manufacturers who are required to submit documentation of compliance to customers and agencies upon request. Thus, the "no detectable PFAS" language is counterproductive and should be removed.

III. Conclusion

The Coalition appreciates the opportunity to submit these comments concerning TPCH's proposed updates to its Packaging Model Legislation. Please feel free to call or e-mail if you have any questions, or if you would like any additional information concerning the issues raised in these comments.

Jeffrey Longsworth
Tammy Helminski
Coordinators
Barnes & Thornburg LLP
1717 Pennsylvania Avenue NW
Suite 500
Washington, D.C. 20006-4623
jlongsworth@btlaw.com
thelminski@btlaw.com