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August 24, 2020

3M Comments on Proposed Amendments to Toxics in Packaging Model Legislation

Dear Sir or Madam:

3M appreciates the opportunity to comment on the proposal to update the Toxics in Packaging Model Legislation by the Toxics in Packaging Clearinghouse (TPCH). We focus on the proposed addition of perfluoroalkyl and polyfluoroalkyl substances (PFAS) as substances to be addressed by the Model Legislation. We support the Model Legislation's objective of protecting public health and safety and the environment from the hazards of toxic chemicals, but the proposed amendments are not appropriate for or necessary to achieving that objective. We appreciate the opportunity to participate in this important stakeholder dialogue with TPCH.

As set forth in greater detail below, the proposed amendments to the Model Legislation are overly broad, unduly burdensome, and do not reflect sound public policy. PFAS is a broad generic term encompassing classes of substances stretching from gases and liquids to small molecular weight solids and high molecular weight fluoropolymers. PFAS are defined based on small chemical structural elements that apply to a broad range of substances with such diverse properties and effects that it is impractical to regulate them as a single class. While some low molecular weight PFAS and some fluorinated polymers for paper and cardboard coating have been and are being phased out by the industry, working with the FDA, certain other distinct fluoropolymers are critical to the production of lightweight, flexible plastic packaging. Fluoropolymers are a subset of fluorinated polymers. Fluoropolymers used as components in polymer processing additives (PPAs) are high molecular weight polymers, have low levels of residual monomers or oligomers, exhibit very low water solubility, and are non-reactive and thermally stable. As an indication for the low risk, they generally meet simplified regulatory criteria – like OECD criteria of polymer of low concern – which indicate the overall low risk of environmental impacts of polymers used in packaging. They are present in certain plastic packaging components in only very small amounts. There are no commercially available alternatives to these fluoropolymers, so banning their presence in packaging would necessitate reverting to outdated and inefficient packaging technologies that would not meet modern environmental standards.

The proposed amendments also fail to reflect federal efforts regarding PFAS. The Food and Drug Administration (FDA) comprehensively regulates PFAS in food packaging materials, and the Environmental Protection Agency (EPA) regulates and is evaluating other uses of PFAS, as well as potential impacts on the environment. Well-settled principles of federal preemption significantly constrain the actions states could formulate with respect to these materials. TPCH should not lead states down a path that would ultimately result in preempted laws.

TPCH suggests it is building on state actions regulating PFAS in Maine and Washington, but TPCH's proposal would dramatically expand the scope of these existing state laws without undertaking a risk assessment. The TPCH proposal would apply to "any type of packaging – not just food packaging" without an assessment of the compound composition or whether alternatives are available, while the state laws TPCH cites include alternatives analyses, are limited to food packaging, and, in Washington's case, apply only to food packaging comprised of "materials originally derived from plant fibers."

It would also be unworkable and unwise to ban "any detectable" PFAS in packaging, with no available exemptions. Such a ban would undermine efforts to make packaging lighter and stronger, while favoring heavy glass or metal over flexible polymers. It would stifle innovation and deflate the market for recycled plastic, in direct contravention of TPCH's stated goals. It would also unduly burden the regulated community, as detection limits vary widely based on a number of factors. Such a ban would conflict with sound scientific principles and would be based on an incorrect assumption that persistence alone is equivalent to harm.

In sum, 3M believes that the proposed amendments to the Model Legislation as written are inappropriate. 3M appreciates the opportunity to provide these comments. Thank you for your consideration.

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I. Certain PFAS fluoropolymers are critical to the production of lightweight packaging and help to reduce the environmental impacts of packaging.

PFAS is a class of thousands of substances, only some of which are used in the production of a variety of plastic packaging and products. Certain PFAS substances, like fluoropolymers used in polymer processing additives (PPAs), have different compound profiles and are critical for manufacturing strong, lightweight packaging with a minimized environmental impact. PPAs contain high molecular weight fluoropolymers, have low levels of residual monomers or oligomers, exhibit very low water solubility, and are non-reactive and thermally stable. 'Fluoropolymers' are a distinct subset of fluorinated polymers. They are made by (co)polymerization of olefinic monomers, at least one of which contains fluorine bound to one or both of the olefinic carbon atoms, to form a carbon-only polymer backbone with fluorine atoms directly attached to it.

3M's PPAs enable our customers to produce very thin, lightweight, high-quality plastic films. These products facilitate the passage of molten plastic through an extruder to form and fabricate various packaging articles. They are used to improve dimensional stability, prevent surface defects, increase processing speed, improve plastic extrusion processing efficiency, and expand freedom of design for plastic packaging materials. In addition, PPAs improve the printability and transparency of packaging, enhancing opportunities to communicate with consumers about the product contained in the packaging. Polymer processing additives are not used as a treatment to impart any particular qualities to the surface of the packaging item (e.g., oil repellency or waterproofing). Fluoropolymers are one of the components of the 3M PPA products which are embedded within the resin pellet or blended within the molten polymer extrudate and then remain embedded within the finished packaging film. PPAs are present only at trace levels (2,000 ppm and often lower) within the finished packaging item. They have been approved by FDA as safe for use in food packaging and do not degrade under typical environmental conditions.

The use of PPAs as an extrusion aid results in significant benefits. They are critical to the production of lightweight packaging materials, which, in turn, help companies reduce key life-cycle environmental impacts associated with the packaging materials they produce (e.g., through reduced volumes of packaging and related waste, more efficient logistics, and avoided greenhouse gas emissions linked to transport).

PPAs help reduce the amount of materials used in packaging. Plastic films provide an alternative to thicker, heavier, more resource-intensive packaging materials. However, packaging producers are confronted with manufacturing challenges in producing plastic films, which the use of PPAs helps solve. As market demands and environmental laws have evolved to require stronger and thinner films to satisfy circularity and sustainability requirements (e.g., light-weighting, resource efficiency, and reducing carbon footprints), PPAs have helped make these advances possible.

PPAs also enable packaging to be more recyclable. Plastic films produced with PPAs can help avoid the use of multi-layer, multi-material packaging designs that are complicated to disassemble and are thus not readily recyclable. The use of PPAs is necessary to produce plastic films that are as sturdy and reliable as the multi-layer, multi-material designs they are replacing.

PPAs enable increased uptake of recycled plastics. One of the limiting factors preventing adoption of recycled content into product designs is the diminished mechanical properties associated with recycled plastic resins. However, with the advent of new polymers having improved strength and mechanical properties – which require PPAs to produce efficiently – it is possible to maximize the level of recycled content in packaging designs while still maintaining the necessary level of performance. In addition, as more recycled content is added to plastics, they can be more difficult to extrude efficiently and with high quality, and PPAs facilitate improvements of both.

PPAs minimize waste associated with the manufacturing of plastics and plastics packaging. They improve overall processing efficiency by, for example, reducing defects and reducing energy consumption associated with production. This further minimizes the environmental footprint of packaging production.

Given all of their benefits, PPAs are used in flexible packaging for food and other products, as well as secondary packaging used for transport and warehousing. With some of these uses, like shrink wrap for pallets, the end consumer never comes into contact with the packaging and would, therefore, have no exposure. Even where the end consumer would have contact with packaging potentially containing PPAs, the fluoropolymers are embedded within the finished packaging item, and will not migrate to the surface, resulting in extremely low exposure, if any.

Reformulating these products to exclude fluoropolymers is simply impracticable. It would require years-long redesign and retooling of manufacturing equipment, at significant capital costs. In the interim, the industry would be forced to regress to outdated and inefficient resin technologies that would not meet modern environmental standards. Commercially viable alternatives that duplicate the performance of fluoropolymer PPAs have not been developed. Some prototypes of alternatives impact transparency or printability of films so that they negatively impact the functionality of the packaging for consumers. Other alternatives would require the need for thicker packaging equating to more plastic needed for the same packaging. No non-fluorine commercial products exhibit the same combination of critical properties that are required to provide the necessary benefits to industry, society, and consumers.

II. Adding PFAS to Section 4 of the Model Legislation is unnecessary and contrary to the stated purpose of the Model Legislation.

Proposed Section 6 of the Model Legislation sets forth the factors states should consider when deciding whether to regulate a chemical in packaging. Those factors include "the extent to which a chemical known to be used or present in a package or packaging component is adequately regulated by the Federal Government or an agency of [the state] to reduce or prevent the same public health threats that would be the basis for addressing the chemical under [Section 6 of the Model Legislation]." The same considerations should govern the consideration of including PFAS in Section 4 of the Model Legislation.

FDA, EPA, and state regulators collectively address the same public health concerns that TPCH is seeking to address through the proposed revisions to the Model Legislation. Those existing

efforts provide an equivalent or greater level of public health and environmental protection than would be provided as a result of the proposed revisions to the Model Legislation. Accordingly, TPCH and states should support the PFAS and packaging-related activities of FDA and EPA (and others) rather than separately pursue regulation of PFAS that would not meaningfully enhance human health or environmental protection.

a. FDA's comprehensive and ongoing regulation of PFAS in food packaging adequately addresses TPCH's concerns.

All PFAS used in food packaging are subject to comprehensive FDA regulation, including rigorous premarket safety review and approval, as well as ongoing review of approved food packaging substances based on the latest available scientific literature. FDA has already considered that degradation products of PFAS approved by FDA may migrate into food. And, FDA has approved the use of these PFAS after determining that they are safe. FDA is also actively monitoring emerging science on PFAS, as well as conducting its own evaluations and studies to ensure that any continued use in food packaging materials is safe. PPAs, for example, are used in processing packaging that has non-food contact applications, but we focus here on food contact applications because of FDA's rigorous process for evaluating food contact products to protect consumers. Something safe for food contact applications does not present a higher risk in other packaging applications.

i. PFAS used in food packaging must undergo FDA's rigorous approval process.

FDA must approve all PFAS used in food packaging. Under section 402(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), a food is deemed to be adulterated (and thus unable to be distributed in commerce) if it contains a food additive that is "unsafe" – i.e., if FDA has not approved it as safe, through either a food additive regulation or an effective food contact notification (FCN).

FDA has adopted several food additive regulations expressly allowing for the use of common Polymer Processing Additives, for example, in indirect food contact (generally, food packaging). *See* 21 C.F.R. § 177.1520, Olefin polymers.

FDA has also reviewed and allowed to become effective approximately 70 FCNs for specific PFAS in certain food contact applications.[1] Only the manufacturer or supplier listed for an effective FCN may market that food contact substance for the specified use, and such use must be strictly in accordance with the parameters of the FCN.[2]

[1] *See* Inventory of Effective Food Contact Substance (FCS) Notifications, which identifies the food contact substance, the manufacturer or supplier, and the effective date of each FCN. (To find the PFAS FCNs among those 1,449 effective FCNs, search "fluoro.")
[2] FFDCA § 409(h)(2)(C); 21 C.F.R. § 170.100(a).

ii. FDA's approval process includes a thorough safety review.

In deciding whether to approve a petition for a food additive regulation or to allow an FCN to become effective, FDA must determine that the proposed use of the food additive would be safe. This is an ongoing process, not one fixed in time. Thus, the food additive regulations and FCNs that allow the use of specific PFAS for particular food packaging applications reflect FDA's current expert scientific judgment that those uses are safe.

Under the FFDCA, FDA may not adopt a food additive regulation if a fair evaluation of the data fails to establish that the proposed use of the food additive under the specified conditions of use would be safe.[3] Similarly, FDA may not allow an FCN to become effective if it determines that the requested use has not been shown to be safe under that same standard.[4] FDA defines "safe" in its regulations to mean that there is "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use."[5] In determining safety, the FDA specifically takes into account:

(1) The probable consumption of the substance and of any substance formed in or on food because of its use;
(2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet; and
(3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.[6]

FDA must also give "full consideration to the specific biological properties of the compound" and "the adequacy of the methods employed to demonstrate safety for the proposed use," guided by the latest scientific principles and procedures.[7]

In reviewing FCNs, FDA calculates an acceptable dietary intake for the FCN chemical. FDA recently reduced the acceptable daily intake that it uses for PFAS by a factor of 10, indicating increased scrutiny of PFAS FCNs.

iii. FDA has determined all PFAS currently approved for use in food packaging are safe.

FDA is well aware of concerns regarding the potential migration of PFAS from packaging materials into food. In making its safety determinations for approved PFAS food additives and effective FCNs, FDA specifically considered this possibility and the potential for any associated health effects. As noted above, the FDA definition of "safe" includes consideration of "the probable consumption of the substance and of any substance formed in or on food because of its

[3] FFDCA § 409(c)(3).
[4] FFDCA § 409(h).
[5] 21 C.F.R. § 170.3(i).
[6] *Id.*
[7] 21 C.F.R. § 170.20(a).

use." FDA's approvals relating to PFAS therefore reflect the agency's expert determinations that these uses and applications are safe for their intended conditions of use.

iv. FDA's safety approvals are subject to ongoing review, and FDA has revoked safety approvals for PFAS when appropriate.

Once FDA approves a PFAS additive for use in food packaging or allows an FCN, its approval remains subject to review and withdrawal if appropriate.[8] For example, in 2016, FDA amended a food additive regulation to remove approval of two PFAS as oil and water repellents for paper and paperboard components for use in contact with aqueous and fatty foods.[9]

In addition, the manufacturer or supplier of a food contact substance that is the subject of an effective FCN may notify FDA that it has ceased marketing that substance, often in response to FDA's request. For example, FDA initiated a comprehensive review of the available data on C8 compounds and worked with several manufacturers to remove grease-proofing agents containing C8 perfluorinated compounds from the marketplace. As a result of FDA's initiative, these manufacturers volunteered to stop distributing products containing C8 compounds in interstate commerce for food-contact purposes as of October 1, 2011. Similarly, FDA recently engaged with manufacturers on new analyses of certain PFAS used in food packaging, informing the voluntary phase-out of certain 6:2 fluorotelomer alcohol PFAS for use in food contact substances described above.

v. FDA is actively reviewing the safety of PFAS used in food packaging in coordination with other federal, state and local regulatory entities.

FDA is undertaking its own studies with respect to PFAS, collaborating with other federal agencies as well as state and local governments to review current science regarding the safety of PFAS in food packaging, and is prepared to move swiftly if the agency determines that any further measures are needed to protect public health. Notably, FDA's recent and thorough examination of PFAS levels in the food supply, which considered both food packaging and the presence of PFAS in the environment, identified very few foods with any detectable levels of PFAS – none of which raised a likely health concern according to FDA. If food packaging were a contributor to PFAS in foods, these studies likely would have detected PFAS in foods more broadly. The following highlights of FDA activity further demonstrate the scale and comprehensive nature of these efforts.

FDA is collaborating with other federal agencies as well as state and local governments to review current science with respect to the safety of PFAS in food packaging. As explained on its website:[10]

[8] 21 C.F.R. §§ 171.130, 170.105(a).
[9] Publications on this work are available on the FDA's PFAS webpage: https://www.fda.gov/food/chemicals/and-polyfluoroalkyl-substances-pfas.
[10] *Per and Polyfluoroalkyl Substances (PFAS)*, FDA, https://www.fda.gov/food/chemicals/and-polyfluoroalkyl-substances-pfas (last visited Aug. 7, 2020).

> To advance knowledge of potential exposure to PFAS from food, the FDA conducts limited testing of foods from the general food supply. The FDA also conducts limited testing of food grown or processed in areas with environmental contamination to detect and evaluate potential contamination of human and animal food.
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> In addition, as part of the FDA's role in authorizing substances for use in food contact applications, we monitor developments in scientific data on authorized substances, including those containing PFAS. As with all authorized food contact substances, when the FDA identifies health concerns associated with the food contact use of specific substances containing PFAS, we take action to ensure that these substances are no longer used in food contact applications.
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> As the science on PFAS advances, the FDA will continue working with other Department of Health and Human Services agencies including the National Institutes of Health and the Centers for Disease Control and Prevention, as well as other federal agencies, including the U.S. Environmental Protection Agency, the U.S. Department of Agriculture, and the U.S. Department of Defense, in addition to our state and local partners, to identify routes of PFAS exposure, understand associated health risks, and reduce the public's exposure to those health risks.

FDA has also explained:[11]

> To better understand the exposure to PFAS from foods for people in the United States, we are focused on testing foods from the general food supply. We are also providing technical consultation to states, when requested, to help determine if there is a potential health concern for foods that are grown or produced in specific geographic areas contaminated with PFAS.

FDA is also actively studying PFAS levels in the food supply, from both food packaging and the presence of PFAS in the environment:[12]

> To understand the occurrence of PFAS in foods, the FDA first had to develop reliable analytical methods to detect and measure these very complex chemicals in foods. In 2012, we began testing for certain types of PFAS in milk and later expanded testing to seafood and cranberries. In 2019, we were able to expand and validate the testing method with a diverse group of foods including breads, cakes, fruits, dairy vegetables, meats, poultry, fish, and bottled water for 16 types of PFAS. We posted our validated method in October 2019. . . .
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> As of December 2019, the FDA has conducted eight surveys designed to measure certain PFAS in foods generally and from specific areas with environmental contamination. Overall, we have found that very few foods have detectable levels

[11] *Questions and Answers on Per and Polyfluoroalkyl Substances (PFAS) in Food*, FDA, https://www.fda.gov/food/chemicals/questions-and-answers-and-polyfluoroalkyl-substances-pfas-food (last visited Aug. 7, 2020).
[12] *Id.*

> of certain PFAS. From our recent surveys of foods that are part of the general food supply, the results of our first round of testing showed that out of 91 foods, two samples—ground turkey and tilapia—had detectable levels of one type of PFAS called PFOS. The PFOS levels that were measured in these samples were very low and are not likely a health concern. The second round of testing included 88 foods and showed that one sample—tilapia—had a detectable level of same type of PFAS. Again, the PFOS level found in the tilapia sample is very low and is not likely a health concern.

Lastly, as noted above, FDA is working with manufacturers on the phase-out of certain PFAS. In announcing that work, the FDA stated:[13]

> As part of fulfilling the FDA's public health mission, the agency continued to review the latest data and science regarding these short-chain grease-proofing agents and engaged with the manufacturers on the new analyses that informed the voluntary phase-out being announced today. . . .
>
> In addition to monitoring the latest science and data regarding food contact applications, including reviewing the limited authorized uses of certain PFAS in food contact applications, the agency continues to assess foods for possible PFAS contamination, with the goal of monitoring levels in the food supply. Today's announcement demonstrates the FDA's commitment to advance the science surrounding potential health risks of PFAS, and work with industry to take steps to reduce consumer exposure to certain PFAS consistent with scientific advances and understanding. The FDA will continue to share further updates as our ongoing work on potential PFAS exposure in foods continues.

In summary, FDA has been and is continuing to address the safety of PFAS in food packaging, per its statutory obligation. While FDA is the expert federal agency on the safety of food packaging components, state health and environmental regulatory agencies may choose to support FDA's information gathering and evaluation activities (e.g., by reviewing existing science or undertaking further studies) with respect to PFAS.

b. Various federal and state initiatives are collectively evaluating the potential environmental impacts of PFAS and how to address them.

With the launch of EPA's PFAS Action Plan in 2019, EPA is taking a proactive, cross-agency approach to evaluating and addressing the presence of PFAS in the environment. EPA has already begun implementing key steps in the PFAS Action Plan. For example, in March 2020, EPA published a proposed regulatory determination to regulate PFOA and PFOS. The regulatory determination is the first step in potentially establishing a federal maximum contaminant level for those substances under the Safe Drinking Water Act. EPA also published

[13] Stephen M. Hahn, MD, Comm'r of Food & Drugs, Food & Drug Admin., "FDA Announces Voluntary Agreement with Manufacturers to Phase Out Certain Short-Chain PFAS Used in Food Packaging" (July 31, 2020), *available at* https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-agreement-manufacturers-phase-out-certain-short-chain-pfas-used-food.

an amended Significant New Use Rule (SNUR) under the Toxic Substances Control Act on July 27, 2020. This SNUR will require companies undertaking uses of certain PFAS – including as part of surface coatings on articles – to notify EPA in advance, giving EPA an opportunity to prohibit the proposed use. Finally, EPA finalized guidance on soil and groundwater remediation standards for PFOS and PFOA.

In addition to EPA action, the Center for Disease Control and Agency for Toxic Substances and Disease Registry have taken and are in the midst of taking numerous actions to study potential human health risks from environmental exposures to PFAS.[14]

On December 20, 2019, the National Defense Authorization Act (NDAA) was signed into law and includes a number of provisions that will increase research, reporting and monitoring obligations related to PFAS and accelerate the pace of certain initiatives already underway pursuant to EPA's Action Plan. Many of the actions laid out in the NDAA are already underway. Specifically, the NDAA:

- Added more than 600 PFAS substances to the Toxics Release Inventory effective January 1, 2020;
- Requires EPA to issue a final rule by January 1, 2023, requiring manufacturers of PFAS to report detailed information about the PFAS substances they manufacture;
- Requires EPA to issue interim guidance within one year on the destruction and disposal of PFAS and materials containing PFAS, including aqueous film-forming foam; soil and biosolids; textiles (other than consumer goods) treated with PFAS; spent filters, membranes, resins, granular carbon, and other waste from water treatment; landfill leachate containing PFAS; and solid, liquid, or gas waste streams containing PFAS from facilities manufacturing or using PFAS;
- Requires EPA to include any PFAS for which a method to measure the level in drinking water has been validated by EPA and is not already subject to a national primary drinking water standard in the fifth publication of the list of unregulated contaminants to be monitored; and
- Provided money for research on PFAS.

Although some states are also considering or may consider regulating certain PFAS in certain types of packaging, there is no evidence of consensus among the states or of states taking sweeping actions to address all PFAS in all types of packaging, with or without an alternatives analysis. The statement in the TPCH proposal that "[s]everal states have taken actions to address PFAS in food packaging without an alternatives analysis" is therefore overbroad and misleading.

This substantial activity at the federal and state level is generating more information regarding PFAS uses and potential impacts, such that regulation of PFAS in food packaging under the Model Legislation would be premature. These initiatives together indicate that states' and TPCH's resources would be more impactful if directed elsewhere or much more narrowly.

[14] https://www.atsdr.cdc.gov/pfas/index.html.

III. Well-settled principles of federal preemption significantly constrain states in regulating PFAS in packaging.

FDA's approvals of PFAS in food packaging reflect FDA's determinations that those chemicals are safe for their intended uses, and that those food additives should be available for use in food packaging. If a state were to promulgate regulations or adopt legislation that conflicts with FDA's determinations, it would raise serious FFDCA preemption concerns.

Under the Supremacy Clause of the Constitution (Article VI, Clause 2), laws of the United States are the supreme law of the land, regardless of anything in the laws of any State to the contrary. FDA's food additive regulations and decisions to allow FCNs to take effect are laws of the United States.

Preemption of state requirements may be based on express conflict with federal requirements or based on federal occupation of a field. Conflict preemption applies where a state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. . . ."[15] The FFDCA does not include an express preemption provision for use of food additives. Nevertheless, state requirements disallowing or unduly restricting the use of a food additive approved by FDA for its intended conditions of use would conflict with the Congressional objectives underlying that FDA determination,[16] and thus would be subject to conflict preemption.

The first objective of the food additive amendments to the FFDCA was to establish a uniform safety standard that all food additives must meet. The legislative history states, "safety requires proof of a reasonable certainty that no harm will result from the proposed use of an additive."[17] If TPCH were to fashion a different standard – such as that proposed to be included in the Model Legislation – it would conflict with the safety standard established by Congress. The legislative history emphasized that "[t]he concept of safety . . . does not – and cannot – require proof beyond any possible doubt that no harm will result under any conceivable circumstance," and recognized the impossibility of establishing with "complete certainty the absolute harmlessness of any chemical substance."[18]

Congress's second objective was to remove regulatory obstacles to consumer access to useful food additives that meet that safety standard. The legislative history reflects an effort to address a flaw that had "inadvertently served to unnecessarily proscribe the use of additives" that could enable consumers to safely keep food longer, make food more tasteful and appetizing, and enable

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[15] *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 873 (2000).

[16] Congress amended the FFDCA by adopting the Food Additives Amendment of 1958 to achieve two objectives:

> The purpose of the legislation is twofold: (1) To protect the health of consumers . . . ; and (2) to advance food technology by permitting the use of food additives at safe levels.

H.R. Rep. No. 2284, 85th Cong., 2d Sess. 1 (1958).

[17] H.R. Rep. No. 2284, 85th Cong., 2d Sess. 4 (1958); S. Rep. No. 2422, 85th Cong., 2d Sess. 6 (1958), *reprinted in* 1958 U.S. Code Cong. & Admin. News, pp. 5300, 5301.

[18] H.R. Rep. No. 2284, 85th Cong., 2d Sess. 4-5 (1958); S. Rep. No. 2422, 85th Cong., 2d Sess. 2-3 (1958), *reprinted in* 1958 U.S. Code Cong. & Admin. News, pp. 5300, 5301.

advances in technology to increase and improve our food supplies.[19] If a state were to prevent its consumers from receiving the benefits of food additives that FDA has determined to be safe for their intended uses, that action would be an obstacle to this second Congressional objective.

Federal courts have held state laws regarding the use of partially hydrogenated oils in food to be preempted, due to FDA and Congress's determination to the contrary.[20] A state restriction on the use of FDA-approved PFAS in food packaging – as TPCH proposes here – would be similarly preempted. TPCH should not lead states down a path that would ultimately result in a preempted statute.

IV. PFAS should not be regulated as a class.

PFAS are a class of thousands of individual chemicals, each with different physical and physiological characteristics. Befitting this diversity, different PFAS are or have been in the past used for different purposes. Fluoropolymers are a type of PFAS used in PPAs that are distinct from other PFAS and should not be regulated together with them. For the reasons described throughout, regulating PFAS, including PPAs, as a class would be inappropriate and contrary to the science.

a. Fluoropolymers are distinct from non-polymeric PFAS.

Fluoropolymers used in PPAs provide a critical example of PFAS that are vastly different from other PFAS and should, therefore, not be regulated together with other PFAS, particularly non-polymeric PFAS. Specifically, due to fluoropolymers' unique capabilities in maintaining thermal, chemical, oxidative, hydrolytic, and biological stabilities, it is imperative for TPCH to recognize the distinct difference between fluoropolymers and other non-polymeric PFAS. As such, a comprehensive review by Henry et al. (2018 Integr Environ Assess Manag 14 3 316-334) elegantly documented that "fluoropolymers satisfy widely accepted assessment criteria to be considered as "polymers of low concern" (PLC). These authors also concluded that fluoropolymers should be separated from other non-polymeric PFAS for the purpose of hazard assessment under regulatory settings, again, due to distinct difference in various properties. Therefore, for the reasons described below, it is scientifically unjustified to regulate this large class of chemicals as a group.

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[19] S. Rep. No. 2422, 85th Cong., 2d Sess. 2 (1958), *reprinted in* 1958 U.S. Code Cong. & Admin. News, pp. 5300, 5301.

[20] See, e.g., *Beasley v. Lucky Stores, Inc.*, 400 F. Supp. 3d 942 (N.D. Cal. 2019); *Backus v. Biscomerica Corp.*, 378 F. Supp. 849, 856 (N.D. Cal. 2019) ("But the Sherman Law could not independently prohibit the use of PHO, because federal law would preempt such a conclusion."); *Beasley v. Conagra Brands, Inc.*, 374 F. Supp. 3d 869, 876 (N.D. Cal. 2019) ("The Court agrees with the reasoning in these two *Backus* cases and thus rules in line with the numerous other judges in this district who have found plaintiffs' California state law claims regarding the use of PHOs in food prior to June 18, 2018, are conflict preempted by federal law."); *Baucus v. General Mills, Inc.*, 2018 WL 6460441 (N.D. Cal. Dec. 10, 2018); *Walker v. Conagra Foods, Inc.*, 15-CV-02424-JSW, Dkt. No. 55 (N.D. Cal. March 31, 2017); *Backus v. Conagra Foods*, 2016 WL 3844331 (N.D. Cal. July 15, 2016) ("In sum, the Court finds that Backus's Section 17200 claims, which would impose an immediate prohibition on the use of partially-hydrogenated oils in all foods under all circumstances, would stand as an obstacle to the fulfillment of the FDA's objectives. . . . Accordingly, Backus's remaining use claims are DISMISSED as preempted."); *Backus v. Nestlé USA, Inc.*, 167 F. Supp. 3d 1068, 1074 (N.D. Cal. 2016) (similar).

Furthermore, PPAs used in packaging may present different exposure compared to other compounds. As described above, fluoropolymers are one of the components of the 3M PPA products and then encapsulated within the finished packaging item, as compared to coatings and other packaging components that can be in direct contact with the product and consumer. PPAs are also often used in industrial-type applications, like secondary packaging, that do not result in consumer exposure. The proposed revisions to the Model Legislation seem to focus primarily on hazards like toxicity without assessing the range of potential exposure, but a proper assessment would require analysis of both hazard and exposure.

b. Regulating PFAS as a class fails to recognize varying uses and existing phase outs.

The thousands of different PFAS have widely varying uses and some have been or are being voluntarily phased out. Particularly relevant to this proposal, the use of certain PFAS in packaging has declined. For instance, on July 31, 2020, the FDA announced a voluntary phase-out of PFAS that contain 6:2 fluorotelomer alcohol (6:2 FTOH), which may be used for grease-proofing paper and paperboard packaging for food.[21] Beginning in January 2021, three manufacturers will begin a three-year phase-out of sales of certain 6:2 FTOH substances for use in food contact substances in the U.S. marketplace. Another manufacturer has also reported that it already stopped sales of their short-chain PFAS products in the U.S. market. While manufacturers have agreed to phase out certain 6:2 FTOH PFAS, it is not practically feasible or necessary, based on FDA's analysis of the science, to phase out other PFAS products used in packaging, particularly those used during packaging production. For further discussion of the FDA's assessment of PFAS in food packaging, see section II.a.

c. The Model Legislation's proposed standards for regulating new chemicals are inconsistent with regulating PFAS as a class.

The Model Legislation would regulate PFAS as a class, contrary to the principles that underlie the Model Legislation. Regulating PFAS as a class would be too vague and burdensome for the regulated community. Worse, there is no scientific basis for treating PFAS as a class. Such treatment would not reflect the wide range of characteristics, including toxicity profiles, across the thousands of PFAS substances that would be regulated. Failure to consider the variability of PFAS necessarily equates to a failure to fully consider or capture the potential for the legislation to protect or harm public health and the environment. In the same vein, regulating PFAS as a class is inconsistent with the evaluation of health and environmental risks that the Model Legislation itself, as proposed, would require to regulate new chemicals.

[21] Stephen M. Hahn, MD, Comm'r of Food & Drugs, Food & Drug Admin., "FDA Announces Voluntary Agreement with Manufacturers to Phase Out Certain Short-Chain PFAS Used in Food Packaging" (July 31, 2020), *available at* https://www.fda.gov/news-events/press-announcements/fda-announces-voluntary-agreement-manufacturers-phase-out-certain-short-chain-pfas-used-food.

i. PFAS have different chemical properties and should not be regulated as a class based on the Model Legislation's own proposed criteria.

The proposed revisions to the Model Legislation would apply to the full class of PFAS – "all members of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." In a similar fashion, the proposed revisions define "chemical" very broadly to be "a substance with a distinct molecular composition or a group of structurally related substances and include[] the breakdown products of the substance or substances that form through decomposition, degradation or metabolism." This divergence from the Model Legislation's previous focus on specific substances (i.e., lead, cadmium, mercury, and hexavalent chromium) is without scientific support.

The thousands of PFAS substances have widely varying characteristics and chemical properties, including toxicity profiles, chemical structure, and fate and transport characteristics. In addition to their diverse structures, PFAS do not have shared or interrelated persistence or toxicity characteristics that should necessarily drive regulation as a group. Given the variety among the thousands of PFAS substances, any evaluation of toxicity, bioaccumulation, or persistence characteristics, as well as any occurrence in packaging, will vary depending on the specific PFAS under consideration.

As noted above, the proposed revisions to the Model Legislation provide several criteria that could qualify new chemicals for regulation; two such criteria are that the chemical be persistent, bioaccumulative, and toxic or be very persistent and very bioaccumulative. PFAS are not uniform and do not share the same toxicity, bioaccumulation, or persistence traits, and, yet, contrary to its own proposed criteria, the proposed revisions to the Model Legislation would regulate PFAS as a class.

As an example, perfluorooctanesulfonate (PFOS) is one of the non-polymeric PFAS that was phased out from production in early 2000's; in many cases, it was replaced with perfluorobutanesulfonate (PFBS). Among the laboratory toxicology data available for both compounds, the extent of the bioaccumulation potential, toxicity profile, and even mode of action between PFOS and PFBS are distinctly different. Scialli et al. (2007 Reg Toxicol Pharmacol 49 195-202) and Peters and Gonzalez (2011 Chem Res Toxicol 24 1601-1609) independently evaluated the scientific feasibility of combining perfluoroalkyl exposures for risk assessment. They concluded that perfluoroalkyl exposure should not be combined or treated as a single class based on wide difference in toxicokinetic profiles as well as inconsistencies of toxicities observed, in addition to the lack of a common biological mode of action among the perfluoroalkyls. Therefore, from both qualitative and quantitative perspective, it is scientifically unjustifiable for TPCH to assume all the PFAS have the same toxicological effects (because they do not). This broad conjecture by TPCH is not supported by data, and the resulting uncertainties bring into question the appropriateness of the current proposal to regulate all PFAS as a class.

ii. Persistence does not equate to health risk.

Persistence on its own is not enough to assess or demonstrate an unacceptable risk to human health and environment and therefore to ban or restrict substances used in packaging. Regulation

based solely on persistence would undermine innovation to produce durable and high performing materials that may support societal sustainability goals. The Model Legislation is designed to protect against "hazards to public health and safety and to the environment", and focus on persistence alone does not demonstrate that a chemical presents such hazards. Potential effects on human health or the environment – or lack thereof – must also be considered. This consideration must be based on state-of-the-art, generally agreed-upon scientific principles, which requires holistic, substance-specific determinations.

According to the criteria in EU REACH, U.S. EPA and the Stockholm Convention on Persistent Organic Pollutants, many substances that may qualify as "PFAS," like the PPAs described above, do not have potential effects on human health or the environment, e.g. PBT, vPvB or any equivalent level of concern required for a potential EU REACH restriction. For example, among other properties, these fluoropolymers are chemically stable under normal use conditions, stable in the presence of microorganisms and biological fluids and tissues, are not bio-available, and are not precursors to currently regulated PFAS via hydrolytic degradation.

iii. PFAS as a class do not meet the Model Legislation's proposed criteria for regulation based on potential health and environmental risks.

As described above, PFAS vary widely in their toxicity profiles, fate and transport characteristics, and other traits that underlie potential risks, if any, to public health and safety. The Model Legislation is intended to protect against "hazards to public health and safety and to the environment", which raises the question of how a decision on the safety of PFAS in packaging could be reached for a group of PFAS without understanding the actual traits and potential risks, if any, to public health, safety, and the environment of the individual substances. Contrary to what TPCH has stated, there is no concordance on the scientific evidence that PFAS chemicals as a class meet the defined criteria for toxic chemicals. While 3M is aware that some governmental agencies have stated (certain) PFAS are associated with some health outcomes, we are unaware of any governmental regulatory body that has declared exposure to PFAS has caused a specific disease in humans (which would require thorough medical diagnosis rather than reliance on statistical association).

Furthermore, proposed Section 6 would allow new chemicals to be added if, for example, a state agency determines that there is strong credible scientific evidence that the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen. Such a determination requires substance-specific analysis. As described above, for example, fluoropolymers used in PPAs are a subset of PFAS that are not toxic based on the available science. Since individual PFAS substances vary widely with regard to their toxicity profiles as well as the strength of scientific evidence underpinning such assessments, they should not be regulated as a class.

For the above reasons, it would be inaccurate to draw conclusions about whether the class of PFAS meet the criteria identified by TPCH for regulation – to say that there is a "preponderance of the evidence that PFAS chemicals as a class meet the criteria for toxic chemicals" without providing citations and support for such a claim is not only unfounded but ignores the unique nature of each PFAS substance. Fluoropolymers (and the PPAs that contain them) are safe for

their intended use and are not "toxic chemicals." And, the failure to provide evidence supporting TPCH's conclusions (or countering the understanding that fluoropolymers used in PPAs are not toxic) indicates that the TPCH process for revising the Model Legislation has not been sufficiently transparent, and that TPCH has not evaluated the available science for the full scope of chemicals it plans to regulate under the Model Legislation.

iv. It is unworkable to regulate PFAS as a class because of the size of the class.

Regulating PFAS as a class creates an unnecessary burden for the regulated community because there are so many substances that could potentially be covered. The proposed revisions to the Model Legislation implicitly acknowledge the need to limit the number of substances in packaging that are newly regulated at any given time. See Section 6(2), which would limit states to only 10 packaging chemicals of high concern on their list at any one time. Adding the full class of PFAS – thousands of substances – to Section 4 would directly contradict this principle, unduly burdening the regulated community with expansive and unnecessary new requirements.

V. Regulating PFAS in packaging without allowance for trace amounts and without exemptions available is not workable, nor is it an environmentally preferable outcome.

PFAS may be used as a manufacturing aid for packaging for any number of reasons, including to ensure compliance with health and safety requirements, to reduce environmental footprint by reducing packaging weight or improving recyclability, to enable or facilitate industrial processing, or as a result of using post-consumer recycled material. In these cases, it is possible that residual amounts of PFAS may be incidentally present in the final packaging product. Prohibiting all "detectable" PFAS in packaging, regardless of its source or purpose, is not workable or appropriate.

a. The Model Legislation must allow for PFAS incidentally present in packaging or packaging components.

The proposed revisions to the Model Legislation would prohibit intentionally introduced PFAS and "detectable PFAS" in any package or packaging component. The term "detectable PFAS" is not defined, is not subject to a de minimis exemption, and there would be no available exemptions for critical uses where alternatives to PFAS may not be available. This contrasts with how heavy metals are currently treated under the current Model Legislation, which allows lead, cadmium, mercury, or hexavalent chromium up to 100 parts per million. The proposed revisions are problematic for several reasons.

As a threshold matter, it would be poor public policy to prohibit incidentally present PFAS. The proposed revisions to the Model Legislation identify no distinctions between PFAS and other regulated chemicals that would justify regulation of PFAS at all detectable concentrations. TPCH should not take actions regulating PFAS more strictly than other chemicals without reason or explanation. This is particularly true considering the countless benefits PFAS like fluoropolymers provide, described further in Section I above. If regulation is appropriate at all

for a particular PFAS, those benefits should be considered before TPCH decides to establish a "detectable" or numerical threshold limit for PFAS incidentally present in packaging. Moreover, any numerical threshold limit should be set for a specific PFAS rather than a class, for the reasons described in Section IV.

A prohibition on "detectable PFAS" is also too vague and would create uncertainty and potential business disruption across the value chain. Limits of detection vary depending on the testing lab used and the materials tested. Additionally, detectability is an inherently moving target, as analytical chemistry methods are constantly evolving. It is not reasonable or appropriate to require the regulated community to meet a standard that is so variable and inconsistent.

Additionally, some PFAS may be used "as a processing agent or intermediate to impart certain chemical or physical changes during manufacturing, whereupon the incidental retention of a residue of said . . . chemical in the final package or packaging component is neither desired nor deliberate. . . ." Under the proposed revisions to the Model Legislation, PFAS used in that way are, however, not eligible for the related exclusion from the definition of "intentional introduction." If incidental retention of PFAS used as a processing agent is considered to be prohibited "intentional introduction," it would dramatically limit how PFAS can be used in manufacturing processes, as any "detectable" levels of PFAS used in that way would be prohibited. PFAS like PPAs are a valuable processing agent and intermediate in the manufacturing process for countless packaging products, as explained further above in Section I of these comments, but their use may result in incidental presence of PFAS in the packaging. PFAS like PPAs used as a processing agent should not be considered to be intentionally introduced, just as regulated metals used in this way are not.

Lastly, the same considerations related to post-consumer recycled material should apply to PFAS as apply to other regulated chemicals. The proposed revisions to the Model Legislation make clear TPCH's support for increasing the use of post-consumer recycled material, but, by prohibiting any detectable PFAS, the proposed revisions would make it much more difficult to use "post-consumer recycled materials as feedstock for the manufacture of new packaging materials, where some portion of the post-consumer package or packaging component may contain amounts of the regulated metals or chemicals but is neither desired nor deliberate. . . ." Rather than "spurring innovation," the proposed changes could stifle investment in post-consumer recycled materials.

b. The exemptions in Section 5 of the Model Legislation must include all chemicals restricted by Section 4.

The Model Legislation includes several exemptions that, under the proposed revisions, would not apply to PFAS, despite PFAS's multitude of uses for compliance with health and safety requirements and the lack of effective alternatives. The proposed revisions would retain two exemptions, in addition to the definitional exclusions described above, but none would be available to PFAS. TPCH tries to justify these revisions by suggesting that they will "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." However, the effects of the proposal would be

quite the opposite – prohibiting any use of PFAS in packaging would lead to negative health and safety impacts and is not necessary to drive innovation.

First, the proposed revisions would include an exemption for lead, cadmium, mercury or hexavalent chromium that "have been added in the manufacturing, forming, printing or distribution process in order to comply with health or safety requirements" so long as the manufacturer petitions for and is granted an exemption. This exemption would not be available for PFAS. However, PFAS are critical to meeting health and safety requirements for food packaging and other packaging. For instance, PPAs improve printability on packaging, enabling the printing of nutrition information, expiration dates, or product warnings, and they improve packaging transparency, allowing inspection of product quality. In addition, PPAs are critical to flexible plastic packaging used to ensure foods remain fresh and are protected during transport and storage. Allowing stakeholders to petition for an exemption on these grounds would benefit public health and safety, and, because the exemptions must be renewed every two years, industry would continue to have an incentive to innovate around alternative chemicals and processes to achieve the same health and safety protections.

Second, the proposed revisions would also include an exemption for packaging with lead, cadmium, mercury, or hexavalent chromium "added in the manufacturing, forming, printing or distribution process for which there is no feasible alternative" so long as the manufacturer petitions for and is granted an exemption. The Model Legislation clarifies that a there is no feasible alternative for a use "in which the petitioner conclusively demonstrates that the regulated substance is essential to the protection, safe handling, or function of the package's contents and that technical constraints preclude the use of alternatives." This exemption also would be unavailable for PFAS. However, some PFAS for which no commercially available alternatives exist are essential for precisely these reasons, as explained above in Section I. Allowing for the use of PFAS when there is no feasible alternative would ensure continued production of packaging necessary to the protection and safe handling of products, while simultaneously incentivizing innovation through the limited duration of an exemption.

Third, the proposed revisions to the Model Legislation would remove an exemption for packaging that would not exceed the Section 4 maximum contaminant levels but for the addition of recycled materials. If a maximum contaminant level were provided for PFAS, packaging with PFAS should be eligible for this exemption. As discussed in section V.a, TPCH is interested in facilitating the use of post-consumer recycled materials, but removing this exemption or omitting PFAS from the chemicals eligible for the exemption directly undermines TPCH's objective.

For the reasons described above, 3M believes that it would be inappropriate to include PFAS in any amended Model Legislation. 3M appreciates the opportunity to provide these comments. Thank you for your consideration.