



TPCH Response to Comments on Update of Toxics in Packaging Model Legislation

Contact Information:

info@toxicsinpackaging.org

Minnesota (February 2021) –Today, the Toxics in Packaging Clearinghouse (TPCH) announces the organization’s 2021 update to their Toxics in Packaging Model Legislation. The update includes the addition of PFAS and ortho-phthalates as regulated chemicals, as well as new processes for identifying additional chemicals of high concern in packaging.

Background

On July 9, 2020 the Toxics in Packaging Clearinghouse (TPCH) announced it was seeking comments on the organization’s draft update to their Toxics in Packaging Model Legislation. The draft Model Legislation including call for comments can be found [here](#). The draft update included the addition of PFAS and ortho-phthalates as regulated chemicals, as well as new processes for identifying additional chemicals of high concern in packaging. The current TPCH Model Legislation and laws enacted in 19 states prohibit the intentional use of cadmium, lead, mercury, and hexavalent chromium in any finished package or packaging component. The laws also limit the total incidental concentration of the four metals to 100 ppm. Incidental concentration may result from the use of post-consumer recycled content to manufacture new packaging and components. The laws take a pollution prevention approach by prohibiting intentional use, and they place the primary burden of compliance on the supply chain by requiring manufacturers and suppliers to verify that the products they manufacture, sell, and use meet the requirements of the laws, maintain that documentation, and provide it to the public and units of government upon request.

Response to Comments

Twenty-nine comments were filed with TPCH over a 45-day period, ending August 24, 2020. Full comments can be found [here](#). All comments received were read and considered by all TPCH members during multiple meetings during the months of September, October, November and December 2020. As part of the comment consideration process, TPCH asked one of its advisory members, the American Chemistry Council (ACC), to provide TPCH with more information on ortho-phthalates used in packaging. See ACC's response [here](#).

TPCH members do not have formal responses to all comments received, but do offer the following responses, grouped in these focus areas:

[Definitions](#)

[Concentration Limits](#)

[Analytical Methods](#)

[Recycling and Incidental Presence](#)

[Substances Covered](#)

[Exemptions](#)

[Section 6 Criteria and Process](#)

[P2 vs. Risk Management](#)

[Scope of TPCH vs. Other Jurisdictions](#)

Definitions

'Credible evidence'

Commenters suggested that the language in the definition for credible evidence that states "a study" be replaced with "multiple peer-reviewed studies" or "two or more" studies.

Response: TPCH states that the definition in the draft model is strictly a definition of what is credible scientific evidence for the purposes of this model law, not criteria for listing or taking action. This is also addressed in Sec. 6. This is not a weight of evidence criteria or definition. TPCH chooses to keep the existing definition in the model.

'Intentional Introduction'

A commenter suggested TPCH include mold release agents as an intentional introduction for chemicals other than the four metals in the original law.

Response: TPCH agrees and added it to a separate definition of intentional introduction for substances other than the original four metals.

'Package'

A commenter suggests TPCH consider adding the term 'single use' to the definition.

Response: TPCH states that the definition in the draft model is a longstanding American Society for Testing and Materials (ASTM) definition and it includes reusable/refillable packaging, as well as single use packaging. TPCH chooses to keep the existing definition in the model.

TPCH added definitions for PBT, vPvB, PMT and vPvM to the model legislation.

'PBT vPvB'. "Persistent, Bioaccumulative, and Toxic (PBT)" substances and "very Persistent and very Bioaccumulative (vPvB)" substances means substances meeting the criteria established in Section 1 of Annex XIII to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation of the European Union (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006, as amended.

'PMT vPvM'. "Persistent, Mobile, and Toxic (PMT)" substances and "very Persistent and very Mobile (vPvM)" substances mean substances meeting the criteria established in "REACH: Improvement of guidance and methods for the identification and assessment of PMT/vPvM substances: Final Report." TEXTE 126/2019. Environmental Research of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. Project No. (FKZ) 3716 67 416 0, Report No. FB000142/ENG. November 2019.

'Post-consumer recycled material'

A commenter suggested TPCH consider the definition from the International Organization for Standardization (ISO): *Means a material generated by households or by commercial, industrial and institutional facilities in their role as end-users of the product which can no longer be used for its intended purpose. This includes returns of material from the distribution chain.*

Response: This is a new definition in the model and TPCH agrees with the suggestion and changed the definition in the model to the ISO definition.

'Recycling'

A commenter suggested TPCH change the definition to the definition of 'material recycling' from the International Organization for Standardization (ISO): *'Material Recycling' is reprocessing, by means of a manufacturing process, of a used packaging material into a product, a component incorporated into a product, or a secondary (recycled) raw material; excluding energy recovery and the use of the product as a fuel.*

Response: TPCH chooses to keep their proposed draft definition as it is a longstanding definition used by states with toxics in packaging laws.

Concentration Limits

A commenter suggests TPCH lower the concentration levels for the four heavy metals from 100ppm to 50ppm.

Response: TPCH potentially interested in this for a future model legislation update, including research as well as a potential option of adding time to enforcement to allow for manufacturers to make design adjustments in their packaging and packaging components.

A commenter suggested TPCH add the words 'the sum of' in front of 'concentration levels'.

Response: TPCH supports this change, keeping consistency with the language for the four heavy metals. The comment was directed to the sum of PFAS chemical concentration levels and the sum of ortho-phthalate concentration levels, parallel to the existing 'sum of concentration levels of the four metals' addressed in the original legislation.

Analytical Methods

A commenter stated that "The law does not address specific analytical methods".

Response: Since analytical standards and methods can change, TPCH prefers to provide specific analytical methods in future guidance documents since they are updated periodically and it's not really appropriate to put specific methods in a law. Each entity covered by the law is responsible for ensuring that they are following accepted international laboratory standards.

Commenters suggested TPCH remove the language 'no detectable limit' on PFAS

Response: TPCH wants strict limits on PFAS. TPCH acknowledges that a number could be helpful for industry, and possibly acceptable by TPCH for future model legislation updates...possibly using rolling averages. This could include an SOP and a QAP process is done for ensuring upstream due diligence. TPCH may consider any potential future language for a model legislation update that includes a number or a range of numbers and a process for residual or background PFAS.

A commenter suggested TPCH consider the following language to be added for laboratories: ‘testing laboratories must certify they have undergone a third-party proficiency testing demonstrating that their protocols and analytical methods are capable of measuring ortho-phthalates at levels below 100 ppm (0.01% by weight). Laboratories testing for total organic fluorine must certify they have undergone third party proficiency testing demonstrating that their protocols and analytical methods are capable of measuring total fluorine at levels at or below 10 ppm.’

Response: TPCH will update their Guidance document for laboratories in the future.

Recycling and Incidental Presence

A commenter suggested that TPCH define a quantitative limit for PFOS/PFOA to provide criteria for ensuring compliance with the model legislation, and that the residual level of PFOS/PFOA also be limited to 100 ppm in the packaging.

Response: TPCH agrees that the model legislation needs to have common criteria for compliance. It is the intention of TPCH to encourage phase out of both the intentional use and incidental presence of PFAS that results from the use of post-consumer content. TPCH believes this is an achievable goal.

Substances Covered

Commenters suggested TPCH not define PFAS as a class.

Response: TPCH chooses to keep it as a class. The expanding scientific research and consensus on perfluorinated chemicals continue to indicate that there are virtually no safe applications or products for human and environmental health, taking into account the entire life cycle of manufacturing, use, disposal, and recycling. ⁱ ⁱⁱTPCH is replicating the actions recently taken by the state of New York ^{iv} for PFAS (since our public comment period) and Maine for PFAS and ortho-phthalates as chemical classes and expanding the coverage to all packaging. The actions of Maine and New York focus on food packaging, which is a primary use sector, whereas TPCH covers all packaging and TPCH believes it is appropriate and necessary to address all uses of these two classes of chemicals. Washington’s 2018 amendment to their toxics in packaging law also addresses PFAS as a class in food packaging.

Commenters suggested TPCH consider that there are safe ortho-phthalates.

Response: As stated above, TPCH is replicating the actions taken by the state of Maine for ortho-phthalates as a class. TPCH is guided by the pollution prevention approach.

Some commenters suggested adding additional chemicals or chemical classes to the prohibited chemicals, in addition to the new listings for PFAS and ortho-phthalates.

Response: TPCH considered inclusion of additional chemicals or chemical classes. TPCH has determined that the strongest cases could be made for PFAS and ortho-phthalates, **and** they have already been addressed in the toxics in packaging laws of two states (a third state – New York – has passed a similar law since the public comment period). TPCH included Sec. 6 as a mechanism for states and other parties to identify and add more chemicals to the law at the state level.

Exemptions

A commenter suggested TPCH consider that packaging and packaging manufacturers would have difficulty tracing PFAS chemicals from upstream suppliers.

Response: TPCH responds that it will be the manufacturers obligation under the regulation to get this information from their suppliers. This requirement has always been in place for the four heavy metals.

Sec 6 Criteria and Process

A commenter suggested TPCH consider adding criteria to Section 6 to address chemicals that are persistent, mobile, and toxic, or very persistent and very mobile, or PMT/vPvM.

Response: TPCH agrees to add these criteria to Section 6 as well as a definition for PMT/vPvM that was added to Section 3.

A commenter suggested TPCH consider adding 'immunotoxicity' in the list of health endpoints.

Response: TPCH believes immunotoxicity is covered under the broader category of toxics.

P2 vs. Risk Management

Some commenters proposed detailed risk assessments to justify the continued use or phaseout of chemicals within the PFAS and ortho-phthalate classes, or new chemicals addressed through Section 6.

Response: This is not the Pollution Prevention approach that has been the fundamental principle of the Toxics in Packaging law since the Council of Northeastern Governors first met and began to formulate a long term solution to these issues. No industry or trade association requested that the exemption clauses in Section 5 for the four metals be extended to PFAS, ortho-phthalates or new chemicals adopted under Section 6.

Scope of TPCH vs. Other Jurisdictions

A commenter suggests TPCH follow the lead of EPA, FDA and European REACH chemical restrictions.

Response: TPCH states that the State of Maine has adopted this language and has already enacted it for food packaging. We are following Maine's lead. The approach of the toxics in packaging laws is to cover all packaging components and applications. EPA and FDA actions in this area do not take this approach and focus more narrowly for example on specific chemicals and packaging applications. The toxics in packaging law has been the leading content law for all packaging since it was developed and first enacted in 1990.

APPENDIX – A

Overview of Revisions to TPCCH Model Legislation

Start with current Model Legislation, then....	Changes	Basis/rationale
<p>Address presence of/ limits on regulated metals due to use of post-consumer recycled materials</p> <p>PFAS and ortho-phthalates may not be used as processing agents or intermediates (Sec. 3)</p>	<ol style="list-style-type: none"> 1. Add definition of post-consumer recycled material. 2. Revise definition of intentional introduction to clarify that use of post-consumer recycled material with regulated metals content constitutes ‘incidental presence.’ The finished package or packaging component must comply with the total concentration limit of 100 ppm for the four metals or ortho-phthalates. 3. Definition of Intentional Introduction: Only the regulated metals may be used as processing agents or intermediates. 	<p>The model legislation does not differentiate between industrial scrap and post-consumer recycled materials as feedstock for new packaging components. However, the law has always had an explicit objective of promoting the use of secondary materials while maintaining compliance. These changes recognize the importance of and continue to encourage the use of post-consumer recycled materials, which should be compliant and not contributing to elevated levels when used for new packaging.</p>
<p>Add new substances (Sec. 4)</p>	<p>Add PFAS and ortho-phthalate bans for all packaging, effective 2 years after enactment. PFAS shall not be present above the detection limit, ortho-phthalates may be present up to 100 ppm incidental presence.</p>	<p>Many state TIP laws have provisions to identify and add new chemicals of concern. There are broadly acknowledged concerns with both substances, and both are used in packaging.</p>
<p>Remove Exemptions (Sec. 5)</p>	<ol style="list-style-type: none"> 1. Date of package manufacture 2. Vitrified labels testing criteria 3. Reusable packaging in closed loop system with end of life recovery 4. State option for higher metals content due to recycled materials 	<ol style="list-style-type: none"> 1. No longer needed 2. Advances in vitrified label materials to reduce/eliminate regulated chemicals; testing criteria provision has not been adopted by all states 3. Expired in all states at end of 2010 4. Adopted by only one state, maintaining original 100 ppm ensures consistency across states
<p>Retain exemptions for metals only (Sec.5)</p>	<ol style="list-style-type: none"> 1. State/federal health or safety requirements, must apply for renewable state exemption 	<ol style="list-style-type: none"> 1. May still be needed, exemption process identifies outstanding issues

Start with current Model Legislation, then....	Changes	Basis/rationale
<p><i>Note that these exemptions have never been requested. To support pollution prevention and promote alternatives, the model does not provide parallel exemptions for PFAS and ortho-phthalates.</i></p>	<p>2. No feasible alternative, must apply for renewable state exemption</p>	<p>2. May still be needed, exemption process identifies outstanding issues</p>
<p>Add criteria for new toxic chemicals (Sec. 6)</p>	<p>Properties of Packaging Chemicals of High Concern: <i>Credible scientific evidence of:</i></p> <ul style="list-style-type: none"> • <i>Known developmental/health effects</i> • <i>PBT/vPvB (see criteria in model legislation)</i> • <i>PMT vPvM (see criteria in model legislation)</i> • <i>Biomonitoring detection in human fluids/tissues</i> • <i>Used/found in packaging</i> <p><i>[First four may also be used to identify chemicals not currently used in packaging to prevent future uses]</i></p>	<p>Establishing criteria for what constitutes a toxic chemical will ensure that TIP laws focus on those substances that cause the most harm to both humans and the environment</p>
<p>Add process options to phase out new toxic chemicals (Sec. 6)</p>	<p>1. State agency may prohibit by rule 2. State agency may recommend prohibition to Legislature</p>	<p>States have existing legal mechanisms for phasing out chemicals by rule or legislative recommendation</p>

ⁱ The High Persistence of PFAS is Sufficient for their Management as a Chemical Class (Royal Society of Chemistry) <https://toxicsinpackaging.org/wp-content/uploads/2020/12/The-High-Persistence-of-PFAS-is-sufficient-for-their-management-as-a-chemical-class.pdf>

ⁱⁱ Scientific Basis for Managing PFAS as a Chemical Class <https://pubs.acs.org/doi/pdf/10.1021/acs.estlett.0c00255>

ⁱⁱⁱ Immunotoxicity Associated with Exposure to Perfluorooctanoic Acid or Perfluorooctane Sulfonate https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf

^{iv} An Act to Amend the Environmental Conservation law, in Relation to the Use of Perfluoroalkyl and polyfluoroalkyl Substances in Food Packaging <https://legislation.nysenate.gov/pdf/bills/2019/a4739c>