August 24, 2020

Toxics in Packaging Clearinghouse
c/o NERC, 139 Main ST., Suite 401
Brattleboro, VT 05301

Filed Electronically at: info@toxicsinpackaging.org

Re: Comments on Draft Model Legislation for Toxics in Packaging, July 9, 2020

Dear TPCH Program Manager:

The Vinyl Institute appreciates the opportunity to comment on the draft update to the Toxics in Packaging Clearinghouse Model Legislation referenced above.[1] The Vinyl Institute represents producers of vinyl resins, monomers, additives, plasticizers, and vinyl compounds in the United States.[2] Because the Vinyl Institute does not endorse or promote specific processes or additive ingredients, such as plasticizers, our comments address broader scientific and regulatory concerns with the current draft. In particular, we focus on the lack of best science and the inappropriate grouping of dissimilar substances in TPCH's draft.

As a general matter, families of substances, such as orthophthalates, contain individual substances of differing physiochemical and toxicological properties and should not be treated or clustered as if they share common physiochemical and toxicological properties. This is particularly important when a TPCH assessment will guide future product regulation. VI's comments demonstrate how other authoritative bodies have treated individual orthophthalates using data specific to each orthophthalate.

Similarly, human health risk assessments should rely on the best available, current science, and recognize reviews by other authoritative bodies. Regarding orthophthalates, TPCH should consider much more fully the comprehensive weight of evidence assessments conducted by the European Chemicals Agency (ECHA) Risk Assessment Committee (RAC), Health Canada, US Food and Drug Administration (FDA), US Environmental Protection Agency (EPA), and Consumer

[1] TPCH Requests Comments on Updates to their Model Legislation for Toxics in Packaging, July 9, 2020 https://toxicsinpackaging.org/?wysija-page=1&controller=email&action=view&email_id=14&wysijap=subscriptions&user_id=225

[2] Founded in 1982, the Vinyl Institute, Inc. (VI) is a U.S. trade association representing producers of vinyl resins, monomers, additives, and plasticizers and vinyl material compounders. The VI serves as the collective voice for the vinyl industry, engaging industry stakeholders in shaping the future of the vinyl industry. More information about the Vinyl Institute can be found on our website: www.vinylinfo.org.

Product Safety Commission (CPSC) Chronic Hazard Advisory Panel (CHAP). Each have concluded that there are certain orthophthalates that can be safely relied upon in their intended use without adverse health impacts.

Given that the proposed TPCH Model Legislation inappropriately groups orthophthalates as a class of substances and, to a large degree, ignores the most recent chemical reviews of specific orthophthalates, we request that TPCH revise the updated Model Legislation to address only those substances that authoritative bodies have found to present adverse health impacts under specific conditions of use in packaging.

1. Exposure Potential from Orthophthalates in Packaging is Low

Many widely used phthalates display physical properties that minimize significant human or environmental exposure when properly used in vinyl materials. A human health risk assessment must be based on both a hazard assessment and an exposure assessment. Risk cannot be assessed in the absence of an exposure assessment. When a risk assessment is focused on exposure from the presence of a substance in a product or class of products, the assessment must reflect the product's intended use and the potential for exposure. In the case of certain phthalates, physical property considerations indicate low exposure potential.

Vapor pressure and water solubility – Vapor pressure and water solubility are good indicators of how volatile a substance is at various temperatures and how soluble the substance will be in contact with environmental media when finished with its intended use. The higher the vapor pressure, the greater the exposure an individual might experience. Selected relevant phthalate ester vapor pressures at 25 °C are compared to water in Table 1 below. The table demonstrates that the vapor pressures of the selected phthalates are extremely low, being 8 to 9 orders of magnitude less volatile than water. As a result, none of these phthalate plasticizers would be expected to evaporate to any significant amount at normal room temperature, suggesting a very low potential for inhalation exposure from these substances in any consumer product. Low volatilization potential also indicates the substance may not be present to a measurable degree in a closed container such as a package, or migrate via the volatilization route into the product in the package. In addition, the extremely low water solubility mitigates any route of ingestion exposure from aqueous contact applications or extraction if in contact with environmental media such as water.

Table 1. Physical Properties of Selected Phthalates Compared to Water

Plasticizer	Vapor Pressure (Pa) @ 25° C	Water Solubility Mg/L
DIDP	16.1×10^{-5} to 0.7×10^{-5} (1)	1.7×10^{-4} (3)
DINP	7.2×10^{-5} (1)	6.0×10^{-4} (4)
DEHP	85.3×10^{-5} (1)	3.0×10^{-3} (4)
Water	3.2×10^{3} (2)	infinite

(1) REACH Submission on DINP, ExxonMobil, January 7, 2014
(2) CRC Handbook, Chemistry and Physics, 85th edition
(3) Letinski et al. 2002
(4) ECHA c2007-2015b

Plasticizer retention in substrate – Certain plasticizers are strongly bound in vinyl products. During the manufacturing process of plasticized PVC, liquid plasticizer is infused into the interstitial porosity in the resin particle at high processing temperatures, creating a capillary effect that holds the plasticizer tightly in place. The polarizable ring structures of certain plasticizers produces electrostatic bonds between PVC chains and the plasticizer known as Van de Waal forces, further limiting consumer exposure when incorporated in a vinyl material.

2. US Food and Drug Administration Review Does Not Support the Prohibition of Orthophthalates in Food Contact Materials

According to an extensive review of scientific studies focused on orthophthalate and other plasticizer use in PVC for food contact materials, the FDA concluded that "There have been no studies to date which show any connection between human dietary exposure to phthalates and adverse health effects."[3] FDA goes on to explain that rodent studies often referenced were conducted at orthophthalate feeding levels significantly higher than amounts available in food packaging. FDA questions whether these observed health effects in rodents are a concern for human health because exposures are much lower in humans and there is no evidence of adverse effects directly translatable into human health from these studies. FDA also questions the biological relevance, that is, how closely the reactions seen in mice and rats would mimic those in humans:

[3] Katherine S. Carlos, Lowri S. de Jager & Timothy H. Begley (2018): Investigation of the primary plasticisers present in polyvinyl chloride (PVC) products currently authorized as food contact materials, Food Additives & Contaminants: Part A, DOI: 10.1080/19440049.2018.1447695

> "Both the Centers for Disease Control and Prevention (CDC) and the National Institutes for Health believe that there is not enough data on the topic to decide whether low levels of phthalate exposure have any potential to cause problematic health effects in humans (Centers for Disease Control and Prevention. 2013; U.S. National Library of Medicine. 2017)."[4]

3. Environment and Climate Change Canada (ECCC) and Health Canada (HC) Review of Phthalate Substance Grouping Under Canada Chemicals Management Plan Should be Followed

Health Canada and Environment and Climate Change Canada completed an extensive review of the Phthalate Substance Grouping under the Canada Chemicals Management Plan. VI submitted comments in December 2017 in support of HC and ECCC's proposed conclusion that 13 of the 14 substances in the Phthalate Substance Grouping are not harmful to the environment or to human health including in their use in packaging. For more information on the HC and ECCC assessment, see http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=516A504A-1#toc-06.

The final Canadian screening assessment is expected late summer/early fall 2020 (see, e.g., https://chemicalwatch.com/123971/canada-to-resume-publication-of-chemical-assessment-updates), so it will not be in time for these comments, but the draft screening assessment provides additional support on the question of risk to the environment from phthalates.

4. Other authoritative regulatory agencies find ortho-phthalates safe for use in packaging applications

TPCH must consider the conclusions that have been reached by other regulatory agencies around the world, indicating that orthophthalates do not pose a human health concern when used in packaging applications. Considering that use in food packaging would be considered the most sensitive applications, a few of the regulatory agency decisions that have been issued with respect to the potential human health concerns with the use of orthophthalates in food packaging are presented herein. For example, in 2017 the New Zealand Ministry of Primary Industries (MPI) conducted a study to characterize the food

[4] Ibid.

safety risk of potential migration of orthophthalates used in packaging.[5] Overall, the Agency concluded that migration of these substances into packaged food was not a concern to human health. In 2018, Food Standards Australia and New Zealand (FSANZ) conducted an evaluation of orthophthalates use in 65 different packaged foods and beverages.[6] The Agency summarized that these substances may be used in plastic, paper and cardboard food packaging as well as food grade adhesives and sealants. The Agency concluded that the levels of orthophthalates in foods are generally low and are "*unlikely to pose a public health and safety concern*". Other Agencies that have reviewed the use of orthophthalates in food packaging or as food contact materials include the Food Standards Agency of Ireland (FSAI)[7] and the European Food Safety Authority (EFSA)[8]. Both Agencies, including the EFSA report recently published in December 2019, conclude that orthophthalates are not a concern for human health. More specifically, EFSA established temporary daily tolerable intake levels for 5 specific orthophthalates while a full body of evidence is considered on health effects other than reproductive ones and the estimate of contribution of food contact material to overall consumer exposure of phthalates:

> "Our experts set a new safe level – a group Tolerable Daily Intake (TDI) – for four of the five phthalates (DBP, BBP, DEHP and DINP) of 50 micrograms per kilogram of body weight (µg/kg bw) per day based on their effects on the reproductive system. The TDI is an estimate of the amount of a substance that people can ingest daily during their whole life without any appreciable risk to health. The key effect on which this group-TDI is based is a reduction in testosterone in fetuses. The fifth phthalate in the assessment, DIDP, does not affect testosterone levels in fetuses, therefore we set a separate TDI of 150 µg/kg bw per day based on its effects on the liver (as in our 2005 evaluation)."[9]

VI requests TPCH consider the weight of scientific evidence from international regulatory agencies on how phthalates are being regulated.

[5] Pearson, A. et al., "Occurrence and risk characterisation of migration of packaging chemicals in New Zealand foods" MPI Technical Paper No: 2017/61, Oct. 2017.
[6] "Survey of Plasticisers in Australian Foods", An Implementation Subcommittee for Food Regulation Coordinated Survey, Food Standards Australia and New Zealand, March 2018.
[7] REPORT ON A TOTAL DIET STUDY CARRIED OUT BY THE FOOD SAFETY AUTHORITY OF IRELAND IN THE PERIOD 2012 – 2014, Food Safety Authority of Ireland, March 2018.
[8] https://www.efsa.europa.eu/en/news/faq-phthalates-plastic-food-contact-materials
[9] Ibid.

5. The Consumer Product Safety Commission (CPSC) Chronic Hazard Advisory Panel (CHAP) Reversed its Restriction on DIDP and DNOP

As further evidence that orthophthalates should not be treated as a class of substances, scientists on the CPSC CHAP assessed health effects in children's articles for specific orthophthalates:

> "Section 108 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) established permanent and interim prohibitions on the sale of certain consumer products containing specific phthalates. That provision also directed the CPSC to convene a Chronic Hazard Advisory Panel (CHAP) to study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles and to provide recommendations to the Commission regarding whether any phthalates or phthalate alternatives, other than those already permanently prohibited, should be prohibited."[10]

By carefully examining the available scientific data on health effects, the CHAP concluded that certain orthophthalates indeed can be safely used in children's articles:

> "The Commission agreed with the CHAP that DIDP and DNOP are not antiandrogenic, and therefore, they do not contribute to the cumulative risk from antiandrogenic phthalates. The CHAP determined that neither phthalate poses a risk in isolation. Therefore, the Commission concluded that continuing the prohibitions regarding DIDP and DNOP is not necessary to ensure a reasonable certainty of no harm to children, pregnant women, or other susceptible individuals with an adequate margin of safety."[11]

6. California Proposition 65 Considers Exposure Levels

The State of California recognizes that exposure is a key consideration of potential risk in its Proposition 65 list of substances. For carcinogens, Proposition 65 provides a "No Significant Risk Level" (NSRL) below which products are not regulated. For reproductive toxicants, Proposition 65 allows a "Maximum Allowable Dose Level" (MADL) below which products are not regulated. The list of regulated orthophthalates and their allowable no significant risk and allowable dose levels appear Table 2:

[10] CPSC Final Rule, "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates", FR 82, 49938, Oct. 27, 2017.
[11] Ibid, 49939.

Table 2

Chemical	Type of Toxicity	Listing Mechanism	CAS No.	Date Listed	NSRL or MADL (µg/day)[a]
Butyl benzyl phthalate (BBP)	developmental	AB	85-68-7	2-Dec-05	1200 (oral)
Di(2-ethylhexyl)phthalate (DEHP)	cancer	SQE	117-81-7	1-Jan-88	310
Di(2-ethylhexyl)phthalate (DEHP)	developmental, male	AB	117-81-7	24-Oct-03	
Di-isodecyl phthalate (DIDP)	developmental	AB	68515-49-1/ 26761-40-0	20-Apr-07	2200
Diisononyl phthalate (DINP)	cancer	SQE	---	20-Dec-13	146
Di-*n*-butyl phthalate (DBP)	developmental, female, male	AB	84-74-2	2-Dec-05	8.7
Di-*n*-hexyl phthalate (DnHP)	female, male	AB	84-75-3	2-Dec-05	2200 (oral)

While not a comprehensive list of all orthopthalates used in packaging, this listing confirms the approach to establish "safe harbor" threshold exposure levels for health effects based on reviews by either an authoritative body (AB) or scientifically qualified experts (SQE). The mere presence of these orthophthalates in an article does not prohibit its continued safe use in the article. Also, the NSRL and MADL are specific for each specific orthophthalate listed as opposed to a general limit for the entire class of orthophthalates. The conclusions of the Office of Environmental Health Hazard Assessment (OEHHA) with the California Environmental Protection Agency conflict with the draft TPCH approach.

7. Most Vinyl Packaging is in Food Contact Films

The majority of vinyl used in packaging is in films for food packaging. Most of these films do not contain orthophthalates, having been replaced decades ago with non-phthalate plasticizers. An FDA survey recently confirmed that phthalates are no longer used in meat and produce films in the U.S.[12] The FDA report indicates that overall food packaging use for orthophthalates is minor, if at all. Hence, TPCH prohibition will have minimal impact and likely will create undo concern and alarm over materials that may not even contain orthophthalates. Other than food service films, vinyl packaging has many diverse uses, many of which are rigid unplasticized materials such as pharmaceutical blister packaging, clear point of purchase clamshells for rugged applications like large packs of batteries, and many other function uses where vinyl alternatives have significant performance deficiencies.

[12] Katherine S. Carlos, Lowri S. de Jager & Timothy H. Begley (2018): Investigation of the primary plasticisers present in polyvinyl chloride (PVC) products currently authorized as food contact materials, Food Additives & Contaminants: Part A, DOI: 10.1080/19440049.2018.1447695

8. Medical Device Industry has Decades of Safe Use of PVC Plasticized with DEHP

PVC medical devices plasticized with DEHP have been in use since the 1960's. Many detailed studies on its use and health impacts have proven its safe use. In fact, one large U.S. medical device manufacturer states it has over 40 years and 8 billion patient days of acute or chronic exposure use of PVC medical devices without report of significant adverse effects.[13]

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Orthophthalates have been safely used in vinyl products, including all types of packaging, for six decades. The physical properties of orthophthalates indicate low potential for exposure, especially from packaging. The weight of scientific evidence shows no translatable relevance in humans compared to health effects observed in rodents at high dose levels of orthophthalates. TPCH must eliminate the language prohibiting orthophthalates in packaging as proposed in its July 9, 2020 update to its Model Legislation. A strikeout/underline version of VI's requested changes is included as Attachment A.

We appreciate TPCH's consideration of these comments.

Sincerely,

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e-mail: rkrock@vinylinfo.org

[13] https://www.baxter.com/policies-positions/medical-materials-use

Attachment A: Vinyl Institute Revisions to Updated Model Legislation

DRAFT – Toxics in Packaging Clearinghouse Model
Legislation Update 2020

Section 1. The Toxics in Packaging Act
Section 2. The legislature finds and declares that:
a. The management of solid waste can pose a wide range of hazards to public health and safety and to the environment;
b. Packaging comprises a significant percentage of the overall solid waste stream;
c. The presence of heavy metals and other toxic chemicals in packaging is a part of the total concern in light of their likely presence in emissions or ash when packaging is incinerated, in leachate when packaging is landfilled, or when packaging has elevated levels of toxic chemicals due to post-consumer materials being recycled into new packaging components;
d. Lead, mercury, cadmium, hexavalent chromium, phthalates, and perfluoroalkyl and polyfluoroalkyl substances (PFAS), on the basis of available scientific and medical evidence, are of particular concern;
e. It is desirable, as a first step in reducing the toxicity of packaging waste, to eliminate the addition of these heavy metals, ~~phthalates,~~ and PFAS to packaging; and
f. The intent of this Act is to achieve this reduction in toxicity without impeding or discouraging the expanded use of recycled materials in the production of packaging and its components.
Section 3. Definitions:
a. Alternative. "Alternative" means a substitute process, product, material, chemical, strategy or combination of these that serves a functionally equivalent purpose to a chemical in a package or packaging component.
b. Chemical. "Chemical" means a substance with a distinct molecular composition or a group of structurally related substances and includes the breakdown products of the substance or substances that form through decomposition, degradation or metabolism.
c. Credible scientific evidence. "Credible scientific evidence" means the results of a study, the experimental design and conduct of which have undergone independent scientific peer review, that are published in a peer-reviewed journal or in a publication of

an authoritative federal or international governmental agency, including but not limited to the United States Department of Health and Human Services; National Toxicology Program; Food and Drug Administration and Centers for Disease Control and Prevention; the United States Environmental Protection Agency; the World Health Organization; and the European Union, European Chemicals Agency.

d. Distribution. “Distribution” means the practice of taking title to (a) package(s) or packaging component(s) for promotional purposes or resale. Persons involved solely in delivering (a) package(s) or packaging component(s) on behalf of third parties are not considered distributors.

e. Distributor. “Distributor” means any person, firm or corporation who takes title to packages or packaging components, produced either domestically or in a foreign country, purchased for resale or promotional purposes.

f. Incidental Presence. “Incidental Presence” means the presence of a regulated metal or other regulated chemical as an unintended or undesired ingredient of a package or packaging component.

g. Intentional Introduction. “Intentional Introduction” means the act of deliberately utilizing a regulated metal or other regulated chemical in the formation of a package or packaging component where its continued presence is desired in the final package or packaging component to provide a specific characteristic, appearance, or quality.

The use of a regulated metal as a processing agent or intermediate to impart certain chemical or physical changes during manufacturing, whereupon the incidental retention of a residue of said metal or chemical in the final package or packaging component is neither desired nor deliberate, is not considered intentional introduction for the purposes of this Act where said final package or packaging component is in compliance with Section 4 of this Act.

The use of 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, is not considered intentional introduction for the purposes of this

Act where said final package or packaging component is in compliance with Section 4 of this Act.

h. Manufacturer. “Manufacturer” means any person, firm, association, partnership, or corporation producing (a) package(s) or packaging component(s) as defined in this Act.

i. Manufacturing. “Manufacturing” means: Physical or chemical modification of (a) material(s) to produce packaging or packaging components.

j. Package. “Package” means any container, produced either domestically or in a foreign country, providing a means of marketing, protecting or handling a product and shall include a unit package, an intermediate package or a shipping container as defined in American Society of Testing and Materials (ASTM) specification D 996. “Package” shall also mean and include such unsealed receptacles as carrying cases, crates, cups, pails, rigid foil and other trays, wrappers and wrapping films, bags and tubs.

k. Packaging Component. “Packaging Component” means any individual assembled part of a package which is produced either domestically or in a foreign country, such as, but not limited to, any interior or exterior blocking, bracing, cushioning, weatherproofing, exterior strapping, coatings, closures, inks, dyes, pigments, adhesives, stabilizers, labels or any other additives. Tin-plated steel that meets the American Society for Testing and Materials (ASTM) specification A 623 shall be considered as a single package component. Electro-galvanized coated steel and hot dipped coated galvanized steel that meets the American Society for Testing and Materials (ASTM) specifications A653, A924, A879 and A591 shall be treated in the same manner as tin-plated steel.

l. Perfluoroalkyl and polyfluoroalkyl substances; PFAS. "Perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" means all members of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom.

~~m. Phthalates. "Phthalates" means all members of the class of organic chemicals that are esters of phthalic acid and that contain 2 carbon chains located in the ortho position.~~

n. Post-Consumer Recycled Material: "Post-Consumer Recycled Material" means a finished material that would normally be discarded as a solid waste having completed its

life cycle as a consumer item but instead is separated from mixed municipal solid waste for the purpose of recycling or reuse, including but not limited to paper, glass, plastics, and metals. Refuse-derived fuel or other material that is destroyed by incineration is not a recycled material.

o. Recycling. "Recycling" means the process of collecting and preparing recyclable materials and reusing the materials in their original form or using them in manufacturing processes that do not cause the destruction of recyclable materials in a manner that precludes further use.

p. Substitute material. “Substitute material” means a material used to replace lead, cadmium, mercury, hexavalent chromium, ~~phthalates~~ or PFAS in a package or packaging component.

q. Supplier. “Supplier” means any person, firm, association, partnership, or corporation who sells, offers for sale, or offers for promotional purposes packages or packaging components which shall be used by any other person, firm, association, partnership, or corporation to package (a) product(s).

r. Toxic Chemical. “Toxic chemical” is a chemical listed as a packaging chemical of high concern as listed in Section 6.

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Section 4. Prohibition/Schedule for Removal of Intentional Amounts; Substitute Materials.

a. Prohibition of sale or distribution of package or packaging components containing lead, cadmium, mercury or hexavalent chromium. Beginning XXXXXX a manufacturer, supplier or distributor may not offer for sale or for promotional purposes a package or packaging component to which lead, cadmium, mercury or hexavalent chromium has been intentionally introduced during manufacturing or distribution in any amount greater than an incidental presence. The sum of the concentration levels of lead, cadmium, mercury or hexavalent chromium incidentally present in any package or packaging component shall not exceed 100 parts per million by weight (0.01%). (for states newly adopting this legislation, Section 4(a) can take place immediately as it has already been enacted for 25+ years in 19 U.S. states)

~~b. Prohibition of sale or distribution of package or packaging components containing phthalates. Beginning XXXXXX, a manufacturer, supplier or distributor may not offer for sale or for promotional purposes a package or packaging component to which phthalates have been intentionally introduced during manufacturing or distribution in any amount. The concentration levels of phthalates incidentally present in any package or packaging component shall not exceed 100 parts per million by weight (0.01%).~~

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.

d. Substitute materials. No material used to replace a chemical regulated by this Act in a package or packaging component may be used in a quantity or manner that creates a hazard as great or greater than the hazard created by the chemical regulated by this Act. The Certificate of Compliance will require an assurance to this effect.

Section 5. Exemptions. All packages and packaging components shall be subject to this Act, unless, an individual state adopts into their law, any or all of the below exemptions, which shall then apply only in that state.

a. those packages or packaging components to which lead, cadmium, mercury or hexavalent chromium have been added in the manufacturing, forming, printing or distribution process in order to comply with health or safety requirements of State or Federal law, provided that the manufacturer of a package or packaging component must petition the [state administrative agency] for any exemption from the provisions of this subsection for a particular package or packaging component based upon either criterion; and provided further that the [state administrative agency] may grant an exemption for up to two years if warranted by the circumstances; and provided further that such an exemption may, upon reapplication for exemption and meeting the criteria of this subsection, be renewed at two-year intervals; or

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b. those packages or packaging components to which lead, cadmium, mercury or

hexavalent chromium have been added in the manufacturing, forming, printing or distribution process for which there is no feasible alternative, provided that the manufacturer of a package or packaging component must petition the [state administrative agency] for any exemption from the provisions of this subsection for a particular package or packaging component based upon the criterion and submit such documentation as necessary to support the request for the exemption; and provided further that the [state administrative agency] may grant an exemption for up to two years if warranted by the circumstances; and provided further that such an exemption may, upon reapplication for exemption and meeting the criterion of this subsection, be renewed at two-year intervals. For purposes of this subsection, a use for which there is no feasible alternative is one 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. "No feasible alternative" does not include use of any of the regulated metals for the purposes of marketing.

Section 6. Identification and Prohibition of packaging chemicals of high concern:

In accordance with the requirements of this section, the department may periodically revise and publish a list of packaging chemicals of high concern.

1. Criteria. A chemical may be included on the list under this section only if:

A. The chemical and its threshold levels of concern are ~~is~~ included on the list of chemicals of concern published by the [state administrative agency] ~~or~~ and the chemical has been identified by an authoritative governmental entity on the basis of credible scientific evidence as being:

(1) A carcinogen, a reproductive or developmental toxicant or an endocrine disruptor; or

(2) Persistent, bioaccumulative and toxic; or

(3) Very persistent and very bioaccumulative; or

B. The [state administrative agency and authoritative governmental entity] determines by consensus that there is strong credible scientific evidence that the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen; and

C. The [state administrative agency authoritative governmental entity] determines by consensus that there is strong credible scientific

evidence that the chemical meets one or more of the following additional criteria:

(1) The chemical has been found through biomonitoring studies to be present in human blood, human breast milk, human urine or other human bodily tissues or fluids; or

(2) The chemical has been found through sampling and analysis to be present in packaging at levels exceeding threshold exposures of concern; or

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(3) The chemical has been added to or is present in a package at levels exceeding threshold levels of concern, and.

(4) The exposure to the chemical from the intended use in packaging is sufficient to exceed scientifically determined thresholds of exposure below which no reasonable health concerns are anticipated.

2. Revisions. The [state administrative agency] may periodically review the list published pursuant to this section and shall remove from the list any packaging chemical of high concern that no longer meets the criteria of subsection 1. The [state administrative agency] may add to the list additional packaging chemicals of high concern that meet the criteria of subsection 1, except that the list under this section may not at any one time include more than 10 packaging chemicals of high concern.

3. Toxic Chemical. A packaging chemical of high concern listed pursuant to this section is defined as a toxic chemical. To fulfill this statute's goal of reducing the toxicity of packaging waste, the [state administrative agency] may:

A. prohibit by rule the sale of packaging and packaging components to which the toxic chemical has been intentionally introduced at levels where threshold safe exposures are exceeded, or;

B. recommend to the state legislature that the toxic chemical be added to the prohibited chemicals identified in Section 4 of this statute, with an effective date no later than 2 years after date of enactment.

4. Regulatory efficiency. The [state administrative agency] may, in exercising its discretionary authority under this section, consider 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 this State to reduce or prevent the same public health threats that would be the basis for addressing the chemical under this section.

Section 7. Certificate of Compliance:

a) A Certificate of Compliance stating that a package or packaging component is in compliance with the requirements of this Act shall be furnished by its manufacturer or supplier to its purchaser (upon request). Where compliance is achieved under any state exemption(s) provided in Section 5, the Certificate of Compliance shall state the specific basis upon which the exemption is claimed. The Certificate of Compliance shall be signed by an authorized official of the manufacturing or supplying company. The purchaser shall retain the Certificate of Compliance for as long as the package or packaging component is in use. A copy of the Certificate of Compliance shall be kept on file by the manufacturer or supplier of the package or packaging component.

b) Public Access. Certificates of Compliance, or copies thereof, shall be furnished to the [state administrative agency] and to members of the public upon request.

1. Any request from a member of the public for any Certificate of Compliance from the manufacturer or supplier of a package or packaging component shall be:

- Made in writing with a copy provided to the [state administrative agency];
- Made specific as to package or packaging component information requested;
- Responded to by the manufacturer or supplier within 60 days.

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c) If the manufacturer or supplier of the package or packaging component reformulates or creates a new package or packaging component, the manufacturer or supplier shall provide an amended or new Certificate of Compliance for the reformulated or new package or packaging component to all current purchasers.

d) Enforcement: Certificate of compliance. If there are grounds to suspect that a package is being offered for sale in violation of this chapter, the [state administrative agency] may request that the manufacturer or distributor of the package provide a certificate of compliance with the applicable provisions of this chapter. Within 30 days of receipt of a request under this subsection, the manufacturer or distributor shall:

1. Provide the [state administrative agency] with the certificate attesting that the package does not contain a chemical regulated under this act; or

2. Notify persons who sell the package in this State that the sale of the package is prohibited and provide the [state administrative agency] with a copy of the notice and

a list of the names and addresses of those notified.

Section 8. State Review:

The [state administrative agency] shall, in consultation with the Toxics in Packaging Clearinghouse (TPCH), review the effectiveness of this Act within five years of its adoption and every 5 years thereafter. The [state administrative agency] may provide a report based upon that review to the Governor and Legislature. The report may contain recommendations to add other chemicals contained in packaging to the list set forth in this Act in order to further reduce the toxicity of packaging waste, and a description of the nature of the substitutes used in lieu of lead, mercury, cadmium, hexavalent chromium, PFAS, ~~phthalates~~ and other regulated chemicals.

Section 9. Toxics in Packaging Clearinghouse:

The [state administrative agency] is authorized to participate in a multi-state clearinghouse to assist in carrying out the requirements of this [Title/Act/section] and help coordinate joint outreach and education, responses to manufacturer inquiries, review of exemption requests, and any other activities or related functions that benefit from the cooperative efforts of multiple states regarding implementation of their toxics in packaging provisions.

Section 10. Implementation, administration and enforcement; rules; violations:

1. The department shall implement, administer and enforce this chapter and may adopt rules as necessary for the implementation, administration and enforcement of this chapter.

2. Violations. A person that violates any provision of this chapter is subject to penalties in accordance with (the appropriate state authority). Each state to add its own enforcement provisions as necessary.

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Section 11. Severability and Construction.

The provisions of this Act shall be severable, and if any court declares any phase, clause, sentence, or provision of this Act to be invalid, or its applicability to any government, agency, person, or circumstance is declared invalid, the remainder of the Act and its relevant applicability shall not be affected. The provisions of this Act shall be liberally construed to give effect to the purposes thereof.

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271 Section 12. Effective Date.

272 This Act shall become effective immediately upon adoption.

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275 As revised, December 1998, October 2004, December 2008, July 2012 (pending new

276 2020 date once finalized).

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