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RE: Formaldehyde: Draft Risk Evaluation Peer Review by the Science Advisory Committee on Chemicals (SACC); Notice of Availability, Public Meetings and Request for Comment
(Docket Number EPA-HQ-OPPT-2023-0613)

This letter is being submitted in response to the Draft Risk Assessment relating to formaldehyde under the Toxic Substances Control Act (TSCA). These comments are provided on behalf of The Toy Association and its 900+ members, representing manufacturers, importers, designers, retailers, inventors, and toy safety testing labs, all working to ensure safe and fun play for families. Toy safety is the number one priority for the industry, as evidenced by the fact that the industry and The Toy Association have been global leaders in advancing toy safety for decades. By law, all toys sold in the United States, no matter where in the world they are produced, must meet 100+ rigorous U.S. safety standards and requirements which are in place to ensure the safety of children at play. Product compliance must be verified by a third-party laboratory before toys are placed on store shelves, and the comprehensive mandatory standards for toy safety include, among others, requirements for mechanical & physical, electrical, and microbiological safety, flammability and, importantly, material & chemical safety[1].

Formaldehyde is a naturally occurring substance that is present throughout our environment. All organic life forms naturally produce formaldehyde. More than 90% of the formaldehyde in the environment can be attributed to natural sources[2]. Additionally, formaldehyde is a critical building block used in the production of a number of consumer and commercial products (such as plastics, processed wood materials and other catalyst and preservative functions). Due to formaldehyde being a critical building block of many materials, there are no substitutes for a number of the uses and applications that involve formaldehyde.

On March 15, 2024, the U.S. Environmental Protection Agency (EPA) released a proposed risk evaluation on formaldehyde. EPA's proposed assessment has determined that virtually all uses of formaldehyde that were reviewed (including manufacturing, processing, distribution, industrial, commercial and consumer uses) constitute an "unreasonable risk" under the Toxic Substances Control Act (TSCA), a classification which appears likely to trigger bans and unachievable workplace standards.

[1] https://www.ecfr.gov/current/title-16/chapter-II/subchapter-B/part-1250
[2] https://en.wikipedia.org/wiki/Formaldehyde

The toy industry is a downstream user of a number of formaldehyde-dependent materials; the individual companies are not able to revise or affect the supply of materials needed for safe and reliable toys other than by selecting from what is already available, and rely on the availability of those appropriate materials from upstream suppliers. Additionally, the majority of Toy Association members are small business entities who will face significant adverse effects from the implementation of the draft risk evaluation as currently presented.

The EPA is proposing to set unachievable worker exposure limits for most manufacturing and commercial uses of formaldehyde that are below concentrations found in American homes, background levels in outdoor air, and right around the levels observed in human breath. These proposed limits are 30 times lower than those set for the European Union's recently updated worker exposure limit of 300 ppb, which was determined to be appropriate based on a comprehensive review of the available science[3].

Based on a review of the key elements of EPA's TSCA risk evaluation of formaldehyde[4] and draft IRIS assessment of formaldehyde,[5] EPA has excluded or dismissed key scientific information, including peer-reviewed publications, peer reviews, reviews by other authoritative bodies, responses, and presentations. It is concerning that EPA is relying on the draft IRIS assessment despite the numerous concerns and criticisms raised related to its adequacy and accuracy, as well as the fact that the IRIS assessment has not been authorized by Congress, yet it is used as the basis for "safe" levels for regulatory and enforcement action at EPA as well as state and federal agencies. This is the case even though they are not designed to look at actual risk or exposure and are developed without going through the process for regulation (notice-and-comment, interagency review, response to public and scientific comments).[6]

The Draft Consumer Exposure Assessment for Formaldehyde[7] entry on modelling scenario for toys, playground and sporting equipment lists the range of formaldehyde identified at 30% by volume as the worst case from the review. This value is concerning, since it hugely overstates the amount of formaldehyde by weight, and bears no relation to the actual amount of formaldehyde present in the consumer products. The 30% assumption is based solely on two prior Chemical Data Reporting (CDR) entries and each only in a single year. One is for a liquid, spreadable coating used for playgrounds (the company itself describes its business as creating "...protective coatings for concrete and asphalt; recreational coatings for sport courts, tracks, and playgrounds; and a line of customizable specialty coatings to suit more particular needs),

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[3] https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2024/acc-comments-on-epa-s-draft-formaldehyde-tsca-risk-evaluation

[4] This review included searches of these elements of the risk evaluation (including citations) as posted by EPA on March 15, 2024: Executive Summary; Conditions of Use; Chemistry, Fate, and Transport Assessment; Environmental Release Assessment; Environmental Risk Assessment; Environmental Hazard Assessment; Environmental Exposure Assessment; Human Health Risk Assessment; Human Health Hazard Assessment (supported by EPA's Draft IRIS Assessment for Formaldehyde); Occupational Exposure Assessment; Consumer Exposure Assessment; Indoor Air Exposure Assessment; Ambient Air Exposure Assessment; Unreasonable Risk Determination.

[5] For additional background, see: https://www.americanchemistry.com/industry-groups/formaldehyde/resources/appendix-a-list-of-excluded-studies

[6] https://www.feedinfo.com/our-content/insight-concerns-about-the-process-and-science-underpinning-changes-to-formaldehyde-regulation-in-the-us-part-ii/371502

[7] https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-consumer-exposure-assessment-for-formaldehyde-public-release-hero-march2024.pdf

and as such, is neither a solid or a toy[8] and the other is from one company's reporting from a single year[9]. Furthermore, the CDR dropdown entry for this category is 1 – 30%, which is an indication that the CDR is not an appropriate best-science information source for this evaluation. No product in the toy sector presents at anywhere near 30% formaldehyde and, per review of the entries as noted above, it is important to note that neither of the CDR entries depict an actual toy.

POM Copolymer

Polyoxymethylene (POM) is a copolymer, which is produced from a reaction process which begins with formaldehyde. POM is a hard, durable, specialized engineering polymer that, since it is relatively expensive compared to other polymers, is only used in specific applications that require its unique hardness and durability properties in order to provide the necessary properties to ensure that safety considerations are met.

For toys, in the limited applications where POM is used, it is predominantly used to make gears for internal mechanisms, and a limited number of external applications such as clips (both cases comprising of only a small proportion of the overall component or product). POM is a high molecular weight polymer, which contains very little unreacted formaldehyde monomer. POM does not degrade over a period of years to generate formaldehyde. Formaldehyde is released from molded POM at low levels during the first three weeks or so after manufacture of the POM, and virtually no formaldehyde is released from POM thereafter. The data on this topic has established that the potential releases are very low[10]. POM is used in applications that require strength, low moisture absorption, creep resistance, and dimensional stability.

De Minimis

The Toy Association requests that EPA consider and implement a *de minimis* threshold for formaldehyde, similar to the *de minimis* of 0.1 % (1000 ppm) which was included in the recently published Methylene Chloride Final Rule[11]. As outlined in that publication, products that have a presence below the threshold are not subject to the rulemaking restrictions. EPA has advised previously that the Methylene Chloride Final Rule can be considered to be a template for future rulemaking[12], and it is helpful for EPA to have provided a *de minimis* threshold in that publication[13].

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[8] Advanced Polymer Technology's website describes its business as "Our manufacturing facilities create protective coatings for concrete and asphalt; recreational coatings for sport courts, tracks, and playgrounds; and a line of customizable specialty coatings to suit more particular needs." https://advpolytech.com/about/

[9] For a more detailed discussion of the significance and causes of the 30% assumption see comments from Exponent Inc. on *Assessment of the Draft Consumer Exposure Assessment for Formaldehyde for Specific Conditions of Use,* submitted as part of the Celanese comments available at: https://www.regulations.gov/docket/EPA-HQ-OPPT-2023-0613.

[10] https://www.regulations.gov/comment/EPA-HQ-OPPT-2018-0438-0132

[11] https://www.govinfo.gov/content/pkg/FR-2024-05-08/pdf/2024-09606.pdf

[12] https://insideepa.com/daily-news/epa-finalizes-methylene-chloride-rule-seen-model-tsca-standards?s=nae

[13] https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0465-0389

Processed Woods

The toy industry also produces products that are made from processed wood which, since 2018, are continually assessed & conform to the requirements of TSCA Title VI (15 U.S.C. §2697), which imposes comprehensive formaldehyde standards for composite wood products[14]. This legislation was a result of the Formaldehyde Standards for Composite Wood Products Act (CWP Act), enacted in 2010. The requirements apply to the materials themselves, as well as to the composite wood products that are incorporated into finished goods or component parts (such as those used in consumer products). While Congress, through the Frank Lautenberg Chemical Safety Act for the 21st Century (the "Lautenberg Act"), made detailed amendments to the Toxic Substances Control Act, it did not change 15 U.S.C. §2697 in any way.

The Toy Association is gratified that EPA's preliminary determination on the Conditions of Use (COUs) states that "… the COUs related to exposure in residences from wood articles does [sic] not contribute to the unreasonable risk of formaldehyde…"[15]. TSCA Title VI is recognized internationally as an effective requirement and is in the process of being recognized as a requirement for Canada as well as the US[16]. While EPA's intention has been to review the presence of a chemical as broadly as possible under the 'whole chemical' approach, it is important to note that the formaldehyde emissions for particleboard, hardwood plywood, MDF and thin MDF are specifically and explicitly addressed by a separate congressional mandate.

The Toy Association requests that EPA confirm that, since the formaldehyde considerations related to composite wood products are statutorily addressed independent of this action, the materials and conditions covered by TSCA Title VI will be excluded from further consideration and do not need to be covered further under the current risk evaluation review or following risk assessment review.

Conclusion

The Toy Association recognizes the importance of TSCA and EPA's associated work on chemical safety, and appreciates the opportunity to comment at this stage. As currently presented, the Draft Risk Evaluation is not based on a full consideration of the available science and data, relies on a draft ISIS assessment for most human health conclusions that lacks a pre-established systematic review protocol, and imposes a worker exposure limit of 10 ppb that is below background levels. At best, for the many companies that work to meet their duty and responsibility to supply the US market with products that meet the necessary safety standards, this would significantly increase the cost of manufacturing materials in the US that conform to the critical safety requirements needed for the market and, more likely, would impact the competitiveness of domestically manufactured product to a level that is no longer economically feasible. This rulemaking, if followed through without revision in the Risk Assessment and Final Rule stages, by imposing unachievable or punitive requirements, would remove the viability of domestic manufacturing of products or component of toys for critical materials that are necessary to conform to the required safety requirements.

We thank you for your attention to these comments. If you would like to further discuss any of the issues raised, please do not hesitate to contact me.

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[14] http://uscode.house.gov/view.xhtml?path=/prelim%40title15/chapter53&edition=prelim

[15] https://www.epa.gov/system/files/documents/2024-03/formaldehyde-draft-re-unreasonable-risk-determination-public-release-hero-march-2024.pdf

[16] Canada Gazette Part 1, June 17 2023

Regards,

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About The Toy Association and the toy industry:

The Toy Association is the North American based trade association; our membership includes more than 900 businesses, from inventors and designers of toys to toy manufacturers and importers, retailers and safety testing labs, and all members are involved in bringing safe & fun toys and games to children. The toy sector is a global industry of more than US $90 billion worldwide annually, and our members account for more than half of this amount.

Toy safety is the top priority for The Toy Association and its members. Since the 1930s, we have served as leaders in global toy safety efforts; in the 1970s we helped to create the first comprehensive toy safety standard, which was later adopted under the auspices of ASTM International as ASTM F963. The ASTM F963 Toy Safety Standard has been recognized in the United States and internationally as an effective safety standard that has been incorporated by reference in 16 CFR 1250 and adopted as a mandatory toy safety standard for all toys sold in the U.S. Additionally, toys are subject to numerous safety requirements such as the Federal Hazardous substances Act (FHSA), the Consumer Product Safety Act (CPSA) as amended by the Consumer Product Safety Improvement Act (CPSIA) in 2008 and the Child Safety Protection Act. It also serves as a model for other countries looking to protect the health and safety of their citizens with protective standards for children. The Toy Association continues to work with medical experts, government, consumers and industry to provide technical input to ensure that toy safety standards keep pace with innovation and potential emerging issues.

The Toy Association is committed to working with legislators and regulators around the world to reduce barriers to trade and to achieve the international alignment and harmonization of risk-based standards that will provide a high level of confidence that toys from any source can be trusted as safe for use by children. Standards alignment assures open markets between nations to maximize product availability and choice.
