November 20, 2019

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Panel Liaison
Scientific Review Panel on Toxic Air Contaminants
California Air Resources Board
1001 I Street
Sacramento, CA 95814

Re: Draft Proposed Updates to the chemical substances list in Appendix A of the AB 2588 Air Toxics Hot Spots Emission Inventory Criteria and Guidelines regulation

Dr. Miyasoto:

The American Chemistry Council (ACC) appreciates the opportunity to provide comments on the proposed updates to the chemical substances list (Appendix A) for reporting under the Air Toxics Hot Spots regulation. To ensure transparency and to facilitate a rigorous assessment of the scientific basis for including an additional 800 compounds in the Emission Inventory, ACC suggests that the underlying toxicological threat or risk associated with each compound that is being proposed for addition be explicitly identified. It would also be helpful to provide evidence which demonstrates that each compound can be present in ambient air. This additional information would support an assessment of the extent to which each compound represents a risk to public health from exposure in ambient air. In addition, the individual substances within many of the groups proposed for listing vary significantly in their physical, chemical, and toxicological properties. Consequently, it is inappropriate, and scientifically indefensible, to make broad conclusions about the public health impacts of such a wide range of substances in the absence of specific information.

While ACC appreciates ARB's interest in transitioning from a traditional chemical-by-chemical approach to one that considers multiple chemicals within a group or class, such a broader approach must be founded in scientific principles. The importance of a robust scientific process was recently highlighted by the National Academy of Sciences, Engineering and Medicine (NASEM) which noted --

> The class approach relies on using data on tested chemicals to draw inferences about the potential hazard associated with class members that have not been tested. That approach is scientifically supported most strongly when many of the available data support a single conclusion (for example, when a specific toxicity is observed). When class members on which there are data appear to yield

> discordant findings on an end point, a key question is how to evaluate class members on which there are no data. Several inferences would be possible from the discordant findings, although they will have greater uncertainty than if the findings were concordant. Inferences would include the idea that the class members on which there are no data are similar in toxicity to class members on which there are data—for example, similar to the most toxic chemical or similar to a distribution of observed findings. Each inference could be considered in developing a hazard assessment of the class that would use policy choices to provide appropriate protection of public health. [1]

Before attempting to group multiple chemicals for the purposes of reporting or other regulatory requirements, ARB must first outline a process it will follow to make decisions about the likely similarity of the potential public health impacts of the substances under consideration.

While we object to listing of group of substances, generally, we offer the following additional information on the following groups --

- brominated and chlorinated flame retardants
- isocyanates
- perfluoro and polyfluoro compounds/poly- and per-fluorinated chemical functional groups
- phthalates

Brominated and Chlorinated Flame Retardants

The ARB proposal would lump multiple organohalogens used as flame retardants together with little consideration for their safety or risk. Such an approach was rejected by NASEM, which concluded that a single class approach in assessing the potential hazards of additive, non-polymeric organohalogen flame retardants (OFRs) was not appropriate.[2] More recently, in October 2019, the U.S. Consumer Product Safety Commission (CPSC) voted as part of its Fiscal Year 2020 Operating Plan to move forward with withdrawing the Guidance Document on additive, non-polymeric OFRs in certain products that took effect in September 2017. The action taken by the CPSC was influenced by the NASEM Report, which rejected the factual predicate of the Guidance Document.

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1 National Academies of Sciences, Engineering, and Medicine. A Class Approach to Hazard Assessment of Organohalogen Flame Retardants. Washington, DC: The National Academies Press (2019). at 41. https://doi.org/10.17226/25412

2 Ibid, at 2.

The SwRI study used three replicates of identical rooms for each of the countries tested (United Kingdom, France, and United States) and contained commonly available upholstered furniture and home furnishings for each of the three countries. Test rooms were burned to determine the impact of each country's fire codes on the burning performance of upholstered furniture and an overall furnished room. The research shows that furniture containing more flame retardants burned more slowly and produced less acutely toxic smoke and less total smoke than relatively less flame-retarded upholstered furniture and home furnishings.

Flame retardants are an essential tool for meeting fire safety standards and keeping people and property safe. The CPSC recall data reinforces that fire risk is an important factor for product safety. In the last few years, there have been over 7,000 product recalls of consumer products based on fire hazards. A more selective approach based on the weight of scientific evidence is needed in adding any OFRs to Appendix A.

Isocyanates

It is not appropriate to group all isocyanates into one category based on the assumption that any chemical containing the isocyanate functional group can be expected to have the same or similar health impacts. Different isocyanate substances can have different exposure routes, different metabolic pathways, different target organs, and different health hazards. Bengtstrom *et al.* provide just a sampling of the diversity of potential health hazards across a wide range of commercially- and environmentally-important isocyanate substances.[3]

In addition, the physical/chemical properties of the various isocyanates (i.e. mono-isocyanates, di-isocyanates and poly-isocyanates) are very different. For example, phenyl isocyanate and methyl isocyanate (MIC) are mono-isocyanates and are highly volatile liquids while polymeric methylene diphenyl diisocyanate (MDI) is a viscous liquid with a very low vapor pressure and monomeric MDI is a solid at room temperature. In particular, MIC should not be grouped with the diisocyanates. MIC is a different chemical from diisocyanates. They have considerably different chemical structures as well as physical and toxicological effects. These differences warrant individual consideration of the various isocyanates.

Furthermore, some substances with an isocyanate functional group can be generated from sources not directly linked to production, use, or emission of commercial isocyanate substances. Thus, if a regulation is based on a defined regulatory or action level for total isocyanates, substances like isocyanic acid (ICA) and other simple mono-isocyanates can contribute to this total isocyanate level without the impacted facility having any potential to influence or control them. For example, non-commercial emissions of ICA and simple mono-

[3] Bengstrom L *et al.* The role of isocyanates in fire toxicity. *Fire Science Rev* 5(1):Article 4. https://doi.org/10.1186/s40038-016-0013-2

isocyanates can include fossil fuel combustion (engines), tobacco smoking, forest fires, and photochemical transformations of volatile amine substances. There may be potential scenarios where a regulatory threshold for total isocyanate can be exceeded even if all known commercial emissions of isocyanates are fully controlled or eliminated. A challenge for industry will be to propose methods for monitoring of the listed isocyanate substances from which relevant commercial substances could be segregated from substances which have natural or irrelevant commercial sources at a particular location.

Perfluoro and Polyfluoro compounds/Poly- and Per-Fluorinated Chemical Functional Groups

CARB lists many entries for two similar categories -- Perfluoro and Polyfluoro compounds and poly- and per--fluorinated chemical functional groups. Together, the listed chemistries encompassed by these two categories essentially cover the entire broad universe of per- and polyfluoroalkyl substances (PFAS). PFAS is a general term that includes a wide variety of groups of chemical substances and polymers with very diverse properties. PFAS vary significantly in their hazard profiles. For instance, not all PFAS and related products are persistent, bioaccumulative, and/or toxic, particularly at concentrations typically present in the environment. While some PFAS remain in the environment for years, other PFAS are short-lived and convert to other substances in a matter of hours or days. Not all PFAS persist in biological tissues. Certain PFAS compounds, including short-chains, are readily eliminated from the human body and do not bioaccumulate.[4] Kinetics studies in animals further demonstrate that the persistence of PFAS compounds decreases with decreasing chain length.[5]

PFAS also do not share a common toxicity profile. For example, toxicity testing on some PFAS substances shows the potential for chronic toxicity while similar testing on other substances does not show any evidence of such effects. [6] In addition, even when toxicity testing of PFAS substances may show some similarity of effects, the exposure associated with those effects can vary by orders of magnitude from substance to substance. [7] Furthermore,

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[4] Chengelis CP *et al.* 2009a. Comparison of the toxicokinetic behaviour of perfluorohexanoic acid (PFHxA) and nonafluorobutane-1-sulfonic acid (PFBS) in cynomolgus monkeys and rats. *Reprod Toxicol* 27(3-4):342-351 (2009). https://doi.org/10.1016/j.reprotox.2009.01.006; Gannon SA *et al.* Absorption, distribution, metabolism, and excretion of [1-14C]-perfluorohexanoate ([14C]-PFHx) in rats and mice. *Toxicol* 283: 55–62 (2011). https://doi.org/10.1016/j.tox.2011.02.004; Iwai H. Toxicokinetics of ammonium perfluorohexanoate. *Drug and Chem Toxicol* 34: 341–346 (2011). https://doi.org/10.3109/01480545.2011.585162

[5] Ohmori K *et al.* Comparison of the toxicokinetics between perfluorocarboxylic acids with different carbon chain length. *Toxicol* 184:135–40 (2003). https://doi.org/10.1016/S0300-483X(02)00573-5

[6] Klaunig JE *et al.* Evaluation of the chronic toxicity and carcinogenicity of perfluorohexanoic acid (PFHxA) in Sprague-Dawley rats. *Tox Pathol* 43:209-220 (2015). https://doi.org/10.1177%2F0192623314530532

[7] Agency for Toxic Substances and Disease Registry. Draft toxicological profile for perfluoroalkyls. Agency for Toxic Substances and Disease Registry. U.S. Department of Health and Human Services Public Health Service (June 2018). https://www.atsdr.cdc.gov/ToxProfiles/tp.asp?id=1117&tid=237

PFAS chemicals that occur as mixtures may not share the same target organ, mode of action for toxicity, or dose-response relationship, across concentration ranges. [8]

As a result of this significant diversity within the family of PFAS, it is inappropriate to address PFAS as a broad class. Rather, regulatory and policy measures should be substance-specific. CARB is statutorily required to include qualifying chemistries on the air toxics list unless (1) no evidence exists that the substance has been detected in the air and (2) the substance is not manufactured or used in California. For many of the PFAS captured in the updated air toxics list, we are not aware of existing data demonstrating that they have been detected in air. For example, fluoropolymers, one group of PFAS broadly captured on the updated air toxics list, are extremely stable chemistries that are not volatile or water soluble, and are therefore not expected to be detected in air or pose a risk to human health or the environment. Furthermore, while the broad family of PFAS includes some substances that have been developed and are actually used in commercial applications, a large number have not been developed for commercial use. Consequently, not all of the PFAS chemistries that are captured on the updated air toxics list are manufactured or used in California. Therefore, many of the PFAS chemistries are not appropriate additions to the air toxics list and should be removed.

Phthalates

The potential health impacts of phthalates has been well studied over the past 30 years and have been the subject of numerous regulatory assessments. Phthalates constitute a broad class of chemicals with a range of physical, chemical and toxicological properties. The properties are structure-dependent and can be differentiated into Low Molecular Weight (LMW) phthalates with C3-C6 carbon backbone (such as DEHP (DOP), DBP, and BBP) and High Molecular Weight (HMW) phthalates with C7-C9 backbone (such as DINP and DIDP). When evaluating the hazard profile of "phthalates," it is important to evaluate these two groups separately.

Numerous risk evaluations have been published in the United States, European Union and Canada. All these evaluations conclude that exposure to phthalates, especially high molecular weight phthalates like di-isononyl phthalate (DINP) and di-isodecyl phthalate (DIDP) is low and of no public health concern to infants, children or adults.

Although "phthalates" in general are reported to have been measured in ambient air, there are no reports of DINP or DIDP measurements. While there is limited information about

[8] Wolf CJ *et al.* Evaluating the additivity of perfluoroalkyl acids in binary combinations on peroxisome proliferator-activated receptor-α activation. *Toxicol* 316:43-54 (2014). https://doi.org/10.1016/j.tox.2013.12.002

ambient concentrations, concentrations of "phthalates" were measured around specific processing or production plants; however measured concentrations outdoor are much lower than indoor measurements.[9] In particular, DINP have been detected in the indoor environment at concentrations below 0.5 micrograms per cubic meter (as it reaches saturation concentration),[10] and is mostly detected in airborne particles or settled dust. All measurements for DINP and DIDP in indoor environments have been reported at levels below health-based limits.

ACC urges the Panel to reject the addition of substances to Appendix A based on chemical groupings and to encourage ARB to develop a scientific principles for determining whether addition of less well studied substances is appropriate. Please do not hesitate to contact me if you have any questions on the information provided above.

Sincerely,

Steve Risotto

Stephen P. Risotto
Senior Director

[9] Ouyang, X. Pollution characteristics of 15 gas- and particle-phase phthalates in indoor and outdoor air in Hangzhou. *J of Environ Sci* 86:107-119 (2019) https://www.sciencedirect.com/science/article/pii/S100107421930244X?via%3Dihub; Moreau-Guigon, E *et al.* 2016. Seasonal fate and gas/particle partitioning of semi-volatile organic compounds in indoor and outdoor air. *Atmos Environ* 147: 423-433 (2016). https://hal-enpc.archives-ouvertes.fr/hal-01379888/document

[10] Schossler P *et al.* Beyond phthalates: gas phase concentrations and modeled gas/particle distribution of modern plasticizers. *Science of Total Environment,* 2011 409(19):4031-8 (2011). https://www.ncbi.nlm.nih.gov/pubmed/21764421