HEAL-CPES - Follow-up comments to CARACAL 48 discussion on ECHA regulatory strategy for flame retardants

The Health and Environment Alliance (HEAL) and its member organisation the Cancer Prevention and Education Society (CPES) thank ECHA for developing the Regulatory strategy for flame retardants, and the European Commission for organising a discussion on this important topic during the CARACAL 48 meeting as well as the opportunity to send follow-up comments. The restriction roadmap released last year includes an important commitment to consider a comprehensive restriction on all flame retardants.

The proposed regulatory strategy for flame retardants is an important step in the right direction of applying a broad and generic grouping approach to restricting them, but it is not fully delivering on necessary regulatory action. To completely realise the commitments made in the restriction roadmap, while also addressing regrettable substitution, the strategy must further develop recommendations that cast a wider regulatory net on flame retardants.

We support a regulatory approach towards flame retardants that is comprehensive and takes into account the latest scientific evidence to better protect the public’s health and the environment. In order for the strategy to do so, it must support a faster, broader group restriction for flame retardants, including organophosphorus flame retardants (OPFRs), polymer flame retardants, and recycled products containing flame retardants. Justifying more regulatory delays for OPFRs for instance, based on the need for further data generation is neither acting in the public’s best interest, nor the reality of the current state of the science.

To this end, we would like to provide additional information to support the strategy recommendations. Accounting for the large body of peer-reviewed scientific literature on this topic would strengthen the strategy and its intended purpose to further minimise the harm of flame retardants on both the environment and humans, particularly the young and future generations.

Broadening the recommended scope for restriction:

We would like to provide additional scientific data for consideration to broaden the scope of the recommended restriction proposed in the strategy. Specifically, there are four areas we would like to offer feedback on in more detail, which include:

- Regrettable substitution: organophosphorus flame retardants
- Increasing use of polymeric flame retardants
- End-of-life hazards in recycling and disposal
- Efficacy of flame retardants vs. other fire safety interventions
1. Regrettable substitution: Organophosphorus flame retardants (OPFR)

As a result of regulatory and industry voluntary action, older generation flame retardants particularly the PBDEs are increasingly being replaced with OPFRs. In fact, the HBM4EU study found, “OPFR metabolites, particularly BDCIPP and DPHP, have ubiquitous distribution in Europe, with limited differences between countries, perhaps due to the open market conditions.” Based on the robust published scientific literature on OPFRs, we argue that there is sufficient evidence to support immediate regulatory action due to OPFR’s growing use and associated irreversible human health and environmental hazards.

We are concerned with the proposed approach in the strategy contingent on ongoing and planned data generation to verify the hazards of OPFRs. Waiting for the United States National Toxicology Program (US NTP) studies on the carcinogenicity of tris(2-chloro-1-methylethyl) phosphate (TCPP) (technical report still unavailable) does not justify delaying regulatory action on tris(2-chloroethyl) phosphate (TCEP), tris(2-chloro-1-methylthyl) phosphate (TCP), tris[2-chloro-1-(chloromethyl)ethyl] phosphate (TDCP). The restriction roadmap already identifies these substances as CMRs in childcare articles. Data generation under current REACH provisions is also notorious for taking years, while substances such as OPFRs are increasingly being used and people remain exposed. In addition, the strategy mentions a restriction for professional uses of BMP and TBNPA based on their carcinogenic properties, but does not provide details on the related timeline and next regulatory steps.

Waiting on more data on OPFRs until 2025 to reassess their hazards will unnecessarily delay scientifically justified regulatory action that is urgently needed now, in essence allowing for continued use of OPFRs as regrettable substitutes. A list of the scientific reviews to support broadening the scope of a recommended restriction to include OPFRs without delay are listed in Appendix A.

Reviews of the literature cite mounting evidence that OPFRs are increasingly being found in surface and groundwater and sediment due to their high solubility in water. Studies also discuss the relatively high prevalence of OPFRs detected in indoor air, house dust, and food from numerous sources in industrial and consumer products (i.e. building materials, textiles,
electronics, childrens’ articles, recycled plastics, food contact material etc. In fact, OPFRs are a common chemical class applied to a number of infant products and were measured at concentrations up to 7% by weight. In addition, data shows increasing levels of OPFRs and their metabolites detected in the human body and breastmilk. The use of OPFRs in infant products likely contributes to the higher levels of OPFRs detected in infant and toddler urine samples in the US and is likely why infants living in homes that had a higher number of infant products were associated with higher urinary levels of OPFRs. And in fact, based on the levels of OPFRs measured in infants urine, researchers estimated that 2-9% of infants were receiving exposures that were above the acceptable daily dose established by the US Consumer Product Safety Commission for an increased health risk. Similarly, the HBM4EU

study analysed OPFR metabolites in children’s urine in eight European countries and found that DPHP and BDCIPP, were detected most frequently and at the highest levels in all countries.\textsuperscript{17}

Epidemiological, \textit{in vitro}, and \textit{in vivo} studies also indicate a potential wide breadth of associated adverse health outcomes linked to OPFRs exposure including carcinogenicity, mutagenicity, and reprotoxicity (CMR), endocrine disruption (ED), neurotoxicity, developmental toxicity, specific target organ toxicity (STOT), and respiratory and dermal sensitisation.\textsuperscript{18,19,20} In fact, a large portion of the literature indicates that neurotoxicity, in particular, is a general intrinsic hazard of OPFRs.\textsuperscript{21,22,23} As ECHA’s screening report and the current scientific literature suggest, certain vulnerable populations such as pregnant women, foetuses, young children, workers, and marginalised communities are at particular risk of harm from increased OPFRs exposure.\textsuperscript{24,25,26,27}

The potential disproportionate impacts of OPFRs on these vulnerable groups provide sufficient justification to include OPFRs in a proposed restriction. Furthermore, chemical replacement of flame retardants should be thoroughly evaluated for health and environmental effects before being put on the market. Additionally, alternative non-
chemical fire safety management strategies should be considered in crafting policy alongside data on replacement flame retardants.

2. Increasing use of polymeric flame retardants

The strategy also importantly identifies a trend in the increasing use of oligomeric or polymeric flame retardants in the EU market, which pose additional regulatory challenges as polymers are not currently required to be registered under REACH. This loophole must be closed as it allows unregistered flame retardants to enter the EU market without any required data on their intrinsic hazards, in direct contradiction with REACH’s no data, no market principle.

Furthermore, data suggests that some reactive flame retardants migrate from polymers and may be associated with adverse health outcomes. In fact, many of the OPFRs used in polymers are linked to the range of environmental and human health endpoints. Another major challenge that ECHA highlights in the strategy is the difficulty or impossibility of separating the reactive flame retardant from the polymer material during recycling and disposal. We will go into more detail on this topic in the next section, but the main point here is that the increasing use of polymeric flame retardants undermines achieving a clean and safe circular economy. Therefore, we also urge ECHA to consider the literature about polymeric flame retardants and use this new data to recommend developing a restriction on these substances.

3. End-of-life hazards in recycling and disposal

We support the Commission’s and ECHA recognising the importance of reducing downstream impacts from flame retardants in the strategy. The significant hazards posed by end-of-life recycling and disposal of materials containing flame retardants from sources such as recycled e-waste are of paramount importance in the discussion of a future restriction scope.

There is important research demonstrating flame retardants’ irreversible harms to human health and the environment due to their toxic lifecycle, specifically during end-of-life

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Two reports detected brominated flame retardants (BFR) and brominated dioxins in new consumer products including children’s toys, hair accessories, and kitchen utensils stemming from plastic recycling. These reports bring to light evidence of e-waste contamination in consumer products. In addition, as ECHA rightly points out in regards to FR’s toxic life-cycle, “Uncontrolled burning and dismantling/recycling of electronic and electric waste that contains brominated or chlorinated FR can result in contamination and formation of brominated and chlorinated dioxins and furans; these substances are highly toxic, thus causing concern both for the health of individuals and for the environment.”

Overall, a large body of literature covers flame retardants and end-of-life hazards (see Appendix B for list of references). There is evidence in particular of exposure to informal e-waste activities and their disproportionate impact on low- and moderate-income countries, which contribute to health and environmental disparities globally.

In considering this research, we urge ECHA to include recycled materials containing flame retardants in the recommended restriction scope. Moving forward, it is also critical that the European Commission raises the standards for products with recycled materials to correspond to the same limits as those of substances used in virgin materials. This is a necessary step in protecting the public’s health and the environment from flame retardants contaminating recycled materials and achieving a truly safe and clean circular economy.

4. Efficacy of flame retardants vs. other fire safety interventions

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Finally, as the strategy suggests, there is a critical need to assess the actual efficacy from use of flame retardants and open flame tests compared with other non-hazardous fire safety interventions. In fact, a report from the EU commission supports the conclusion that non-flammability requirements such as open flame tests are not indicative of real-life scenarios and these requirements have little bearing on fire safety overall.\(^{(40)}\) Instead, flame retardants may actually be compounding the injuries and harms associated with exposure to toxic fumes and smoke during a fire that contain such hazards as carbon monoxide, cyanide, dioxins and furans.\(^{(41, 42, 43, 44)}\)

A new consensus statement compiled by experts in the field puts forth a comprehensive list of policy recommendations that prioritise innovation and intelligent product design in lieu of chemical flame retardants use.\(^{(45, 46, 47)}\) And as ECHA has reiterated when referring to challenges and uncertainties,

\[\text{[G]enerally controlling release of, and exposure to, hazardous flame retardants during and after service life must focus on inherently safe material design. In other words, hazardous flame retardants may need to be phased out, or there may need to be a demonstrably very low mobility of the flame retardant or degradation products in the material, combined with dedicated end-of-life collection and waste management systems (including recycling and destruction e.g. via incineration), as well as controlled use by industrial or professional users.}\(^{(48)}\)


Taking into account this evidence, it is clear that flame retardants may be posing more health risks than benefits for fire safety. **In order to minimise the hazards associated with the use of flame retardants, regulatory chemical management that accurately reflects the known benefits and risks associated with flame retardants’ use vs. more sustainable alternatives must be used to better inform member states’ flammability standards and regulations.**

**Conclusion**

There is a large body of scientific evidence justifying urgent and strong regulatory action and a broad grouping approach to restrict flame retardants in the EU. HEAL and CPES urge ECHA to consider the additional scientific evidence presented here in order to strengthen the recommendations under the strategy on flame retardants for a group restriction. Furthermore, it is imperative that current scientific literature is continuously monitored, scrutinised, and incorporated into REACH regulatory action. The literature on chemicals thought to be unproblematic or lacking data in the past may well be shown to have scientific evidence demonstrating associated harmful effects to human health and environment at present or in the near future.
Appendix A.

Recent OPFR reviews


Appendix B:

Recent articles on flame retardants and recycling


Li, Q. et al. (2021) ‘Insights into Persistent Toxic Substances in Protective Cases of Mobile Phones: Occurrence, Health Risks, and Implications.’, Environmental science & technology, 55(9), pp. 6076–6086. Available at: https://doi.org/10.1021/acs.est.0c07603.
Lu, R. et al. (2023) ‘Organophosphate flame retardants and plastics in soil from an abandoned e-waste recycling site: significant ecological risks derived from plastic debris’, Environmental Science and Pollution Research International [Preprint]. Available at: https://doi.org/10.1007/s11356-023-26625-x.


Mäkinen, M.S.E. et al. (2009) ‘Respiratory and dermal exposure to organophosphorus flame retardants and tetrabromobisphenol A at five work environments.’, Environmental science & technology, 43(3), pp. 941–947. Available at: https://doi.org/10.1021/es802593t.


Paliya, S. et al. (2022) ‘Assessment of polybrominated diphenyl ether contamination and associated human exposure risk at municipal waste dumping sites.’, Environmental geochemistry and health [Preprint]. Available at: https://doi.org/10.1007/s10653-022-01208-w.


