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NOTE

From:	Presidency
To:	Working Party on Technical Harmonisation (Safety of Toys)
Subject:	Proposal for Regulation on the safety of toys : justification as regards the extension of the scope of the generic ban

Parliament's justification as regards the extension of the scope of the generic ban

The Parliament extends in its mandate the generic ban on the use of hazardous substances in toys to:

- substances identified as substances of high concern under REACH
- substances and mixtures meeting the criteria for classification within new hazard classes recently included in the Regulation (EC) No 1272/2008:
 - endocrine disruptors for human health
 - endocrine disruptors for environment
 - substances which are persistent, bioaccumulative and toxic (PBTs),
 - substances which are very persistent and very bioaccumulative (vPvB),
 - substances which are persistent, mobile and toxic (PMT),
 - substances which are persistent and very mobile (vPvM).
- PFAS
- bisphenols

1. Substances identified as substances of high concern under REACH

Substances that may have serious and often irreversible effects on human health and the environment can be identified as substances of very high concern (SVHCs). If a substance is identified as an SVHC, it will be added to the Candidate List for eventual inclusion in the Authorisation List. ECHA regularly assesses the substances from the Candidate List to determine which ones should be included in the Authorisation List as a priority. The prioritisation is based on information on the intrinsic properties, wide dispersive use or high volumes that fall within the scope of the authorisation requirement. The inclusion in the authorisation list is not automatic though and it does not automatically imply that a restriction will materialise within a short timeframe or that the restriction will address the consumer products such as toys given that there is a sectorial legislation in place to address the most problematic substances. Therefore EP proposes that substances that are all included in the list of candidates for substitution automatically fall under the generic ban in the TSR.

2. Substances meeting the criteria for classification

Under the current Toy Safety Directive and in COM proposal only chemicals with a harmonised classification under the Classification, Packaging and Labelling Regulation (CLP) can be restricted. This means that action must first be taken under CLP to classify the substance. On average, it can take five years to adopt harmonised classification.

Until April 2023, harmonised classification under CLP only covered CMR substances and respiratory sensitisers. New hazard classes (such as for endocrine disruptors) are applicable only since then. As such, for instance no endocrine disruptors have yet been classified under CLP. It is thus not sufficient to refer only to those substances that have already been subject to

harmonised classification as also industry has an obligation to self-classify substances (for instance mixtures).

The Parliament decided to extend the restriction mechanism to chemicals that do not hold a harmonised classification under CLP, but meet the criteria of classification in any of the categories included until now, as well as the new categories recently included in the CLP Regulation. According to EP, all substances meeting the criteria for classification in the relevant hazard categories should be prohibited in toys.

Under the REACH Regulation (Article 68.2), the Commission can ban chemicals 'that meet the criteria for classification' from consumer products, therefore allowing the restriction of chemicals that do not hold a harmonised classification under CLP. The European Commission pointed out in its impact assessment that "scientific knowledge on chemical substances is constantly evolving" and that "it is essential that the rules can easily adapt to emerging knowledge and risks". The revised Toy Safety Law must allow for regulatory flexibility to act quickly on new scientific data, without being held up by lengthy classification procedures under CLP.

Moreover, toy manufacturers are already expected to use various sources of information outside the harmonised classification framework of the CLP and act accordingly - if a chemical substance meets the classification criteria, toy manufacturers must avoid using that material in their toys. According to the [technical documentation guidance](#) on implementing the current Toy Safety Directive, manufacturers in order to perform the chemical assessment of the toys they produce, should check the chemical safety data sheets they receive from the suppliers, which contain the following information:

- Substances with a harmonised classification under CLP;
- Substances which have been self-classified by the supplier – the toy producer should use this self-classification in case it exists (page 73);
- Substances which are included in the candidate list for authorisation, also known as 'substances of very high concern' (Article 31 REACH)

They also should check any additional information, such as Member States' or ECHA's intention to prepare dossiers:

- for identification of substances of very high concern;
- for proposing harmonised classifications of certain chemicals;
- for proposing restrictions on certain chemicals.

Endocrine disruptors for environment

Chemicals that have a major environmental impact such as endocrine disruptors for the environment, but also PBT, vPvB, PMT, vPvM are not included in the generic ban in the proposal. To be in line with the Chemicals Strategy for Sustainability, which is aimed at phasing out all of the most harmful substances from consumer products, these hazards need to be included as well.

Scientific research shows that the endocrine system has been well conserved throughout evolution, indicating that the same endocrine disrupting chemical can affect the endocrine systems of various animal groups. Therefore, it is highly likely that the same chemicals have endocrine disrupting effects on both humans and the environment, although identifying them as such may take time due to gaps in data. If a substance is an ED for other vertebrate species, it is likely also an ED for human health, and may be identified as such in future. Consequently, endocrine disruptors for the environment would be expected to also have effects on human populations.

Therefore, EDs for the environment should be regulated as substances of equivalent concern – such as EDs for human health or CMRs – unless it can be unequivocally shown that their mode of action is not relevant to humans.

Several chemicals have been identified under REACH as endocrine disruptors affecting both human health and the environment.

Moreover, the Commission promised in the Chemicals Strategy for Sustainability that consumer products, including toys, should not contain substances that affect the endocrine system, without distinguishing between different types of endocrine disruptors.

PBTs, vPvB, PMT and vPvM

PBT, vPvB, PMT and vPvM substances are substances of very high concern under REACH, like e.g. CMR substances. Therefore they should not be used in toys. Classification for PBT, vPvB, PMT and vPvM substances has been recently added to the CLP Regulation.

Chemicals that have a major environmental impact such as endocrine disruptors for the environment, but also PBT, vPvB, PMT, vPvM are not included in the generic ban in the proposal. To be in line with the Chemicals Strategy for Sustainability, which is aimed at phasing out all of the most harmful substances from consumer products, these hazards need to be included as well.

Chemicals classified under these hazard classes may be released from toys during use – they can leach or evaporate from toys, leading to direct exposure of children via dermal, inhalation via house dust, oral via mouthing, etc. Persistent chemicals are also released during the manufacturing processes of toys and eventually end up either in the food chain (PBTs / vPvBs) or in the drinking water (PMTs / vPvMs). Many persistent chemicals are of concern to children's health as they are toxic. Some of these substances have been linked to reduced immunity and increased risk of developing certain cancers, and even at low doses, some can harm children's development. There are examples where P, M, and B properties were discovered first, with toxicity only identified later (for instance PCBs - polychlorinated biphenyls or PFAS). As science progresses, unexpected effects can occur, and due to the potential for irreversible damage, it is advisable to take a precautionary approach.

PMT, PBT, vPvM and vPvB are all considered 'most harmful substances', as defined in the guidance on essential use (2024) and recommendations on safe and sustainable by design chemicals (2022). The Commission's regulatory understanding is that the most harmful substances should be subject to generic restrictions. Therefore, excluding PMT, PBT, vPvB, and vPvM chemicals from the revised Toy Safety Regulation will establish a different

understanding and practice than the expressed intention by the Commission. Such a situation does not help with predictability and clarity among market actors. It also introduces different levels of protection, depending on the EU legal instrument.

It also makes sense to address these chemicals from the environmental point of view. It is not logical to take a silos approach to the chemical pollution issue by making a distinction between the hazards for human health and the environment. The presence of hazardous chemicals in toys can cause environmental pollution during their use or later on at the waste phase. As environmental pollution is a direct cause for many human diseases, not covering the environment hazard classes will lead to inconsistencies between on the one hand the toy safety law and on the other hand the EU waste, air, soil and water policies, which all foresee an obligation to limit pollution from harmful chemicals and substances. In particular, toys must be able to be recycled without recycling harmful chemicals, therefore these products must also be free of substances that can cause damage to the environment.

Additionally, under REACH, Commission prioritises restrictions of consumer products not covered by other sectoral legislation, which means that covering toys under REACH just for environmental hazards will not be necessarily prioritised. And given the amount of the REACH restrictions in the pipeline and the huge workload and delays in the process, it is highly unlikely that a restriction on toys covering just the missing hazard classes from the new toys law will be undertaken.

3. PFAS

The EP amendment stems from the overarching approach on the PFAS and bisphenols, two groups of highly hazardous substances, that the EU is pursuing at the moment. The adoption of more protective EU rules on toy safety is an opportunity to speed up the ban of these harmful chemicals in toys, without waiting for the long process of the broader EU PFAS restriction for the other multiple uses of the chemicals, which will take years.

A recent study has shown that PFAS is more easily absorbed by the skin than initially thought. This can be especially problematic if children keep PFAS-treated toys in contact with their skin for long periods.

In the light of the emerging scientific evidence and the ongoing work on the proposal for restriction, as well as in line with the positions taken on other files, such as for instance Packaging and Packaging Waste Regulation, PFAS should not be present in toys (FYI, PPWR includes a clause stating that the universal PFAS restriction will override the ban once it comes into force).

Industry is already transitioning towards PFAS-free alternatives, such as cosmetic, food contact materials, green technologies, textiles ones and more. The toys sector should follow suit, especially as it caters to one of the most vulnerable groups in society.

4. Bisphenols

The EU has identified Bisphenol A (BPA), the best-known member of the bisphenol family, as a ‘Substance of Very High Concern’, but other bisphenols are believed to present at least the

same level of concern, according to the EU Chemicals Agency. BPA has been restricted as a substance on its own and in mixtures intended for consumer use in the EU since March 2018. However, companies have commonly used other bisphenols to replace BPA which are also suspected of damaging human reproductive and hormonal systems.

For years, the EU has sought to protect children against BPA, first by banning it in baby-feeding bottles followed by restrictions on BPA in tableware meant for children and in toys. The research shows that BPA exposure among children has decreased, yet, at same time, exposure to other bisphenols is increasing.

There is a limit on the amount of BPA that is allowed to leach out of toys for children up to the age of three and in any toys that are intended to be placed in a child's mouth. This migration limit is 0.04 mg/l of BPA. But low-level exposure to BPA is a health concern for consumers across all age groups, according to EFSA, which concluded in April 2023 that the safe exposure limit is 20,000 times lower than what was previously thought safe. EFSA also estimates that today the average consumer's dietary intake of BPA vastly exceeds the new, much lower limit. And this is even without considering other sources of BPA exposure – such as consumer products – or the combined exposure to BPA and other bisphenols.

It is thus crucial to tackle all bisphenols as a group. Under the current law, as well as in the Commission's proposal, only bisphenols with a harmonised classification under CLP Regulation can be banned in toys. However, some harmful bisphenols are present in toys but do not hold a harmonised classification, despite the fact that they likely have similar properties. ECHA assessed that there are 34 bisphenols known or suspected to be endocrine disruptors or toxic to reproduction, but only 6 bisphenols are classified under CLP.

The EU has recently decided to ban several types of bisphenols from food contact materials (2024). There is no good reason why the same approach cannot be applied to toys.

Germany has already proposed an EU-wide restriction on BPA and four other bisphenols. This is an important step, but it is not sufficient to protect children's health, as ECHA has recommended that the EU restricts additional 25 bisphenols – including for example BPB and BPC.