



Toy Industries of Europe

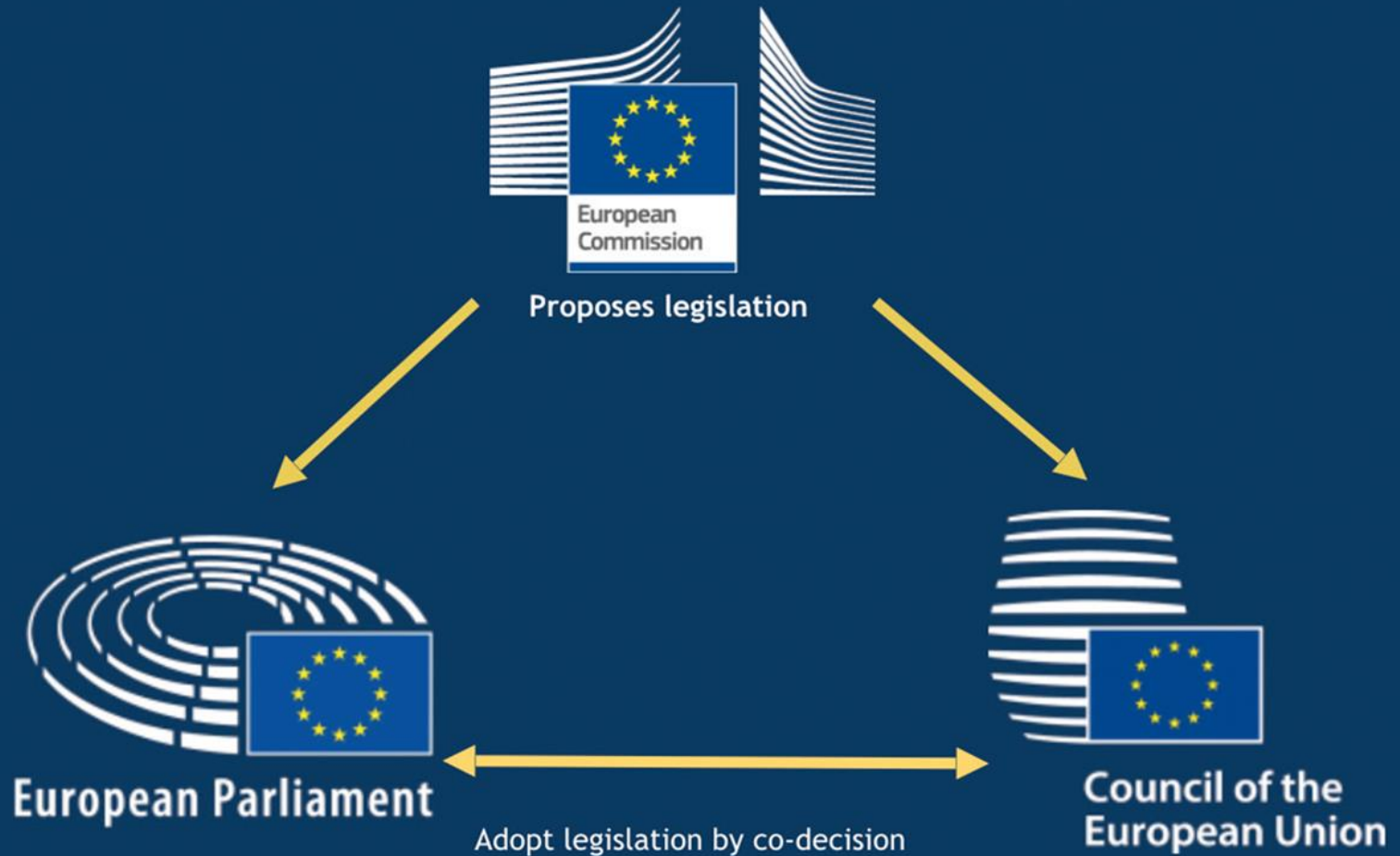
Toy Safety Regulation (TSR)

31 October 2023

A close-up photograph of a young child with light brown hair, smiling broadly. The child's face is partially framed by their hands, which are held up to their cheeks. The background is bright and out of focus. The text 'TSR PROPOSAL – ADOPTION PROCESS' is overlaid on the left side of the image.

**TSR PROPOSAL – ADOPTION
PROCESS**

General



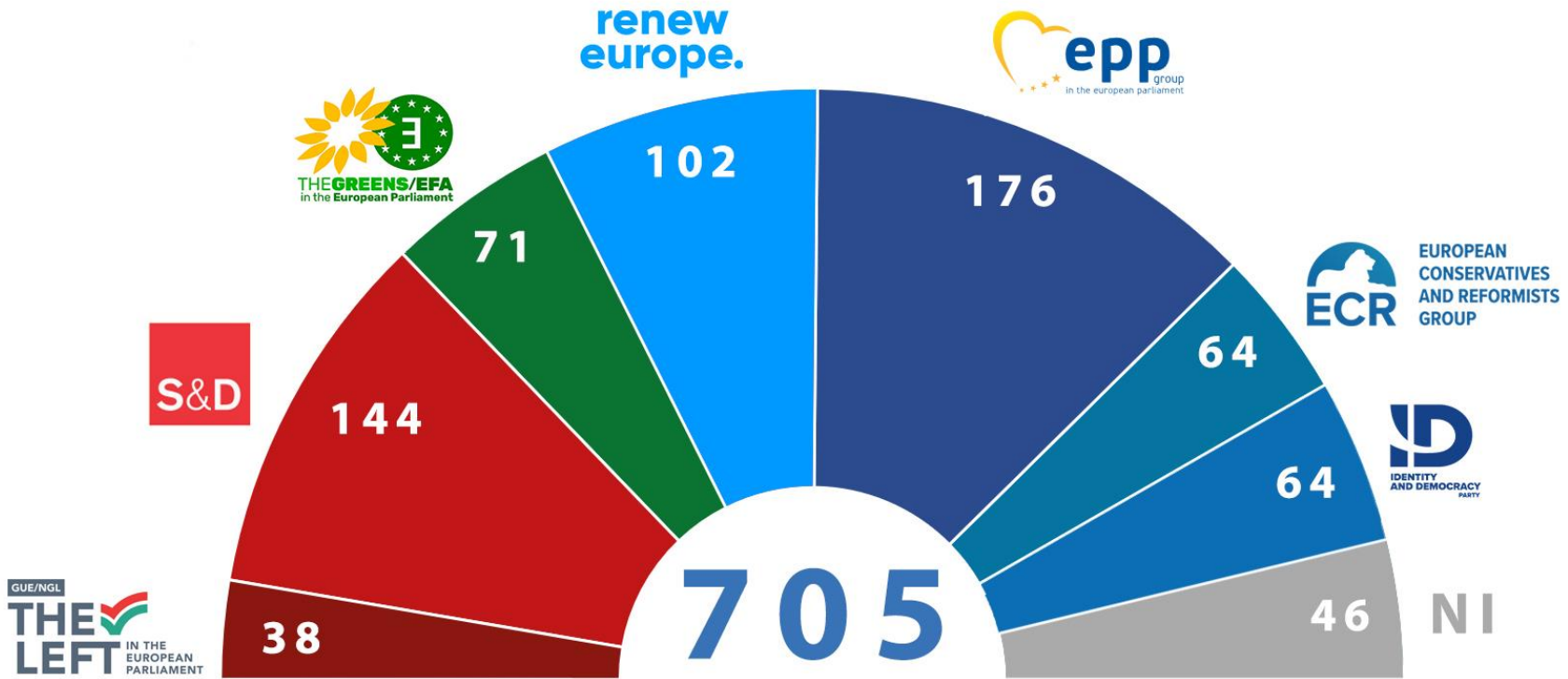
- The proposal from the European Commission was sent to the European Parliament & Council
- Both institutions will now work on an own position (make amendments) before negotiating a final text

27 Member States:

- *Competitiveness Council*
- *Technical Harmonisation Working Party* (next meeting 20 November on digital product passport)

NL: Ministerie van Volksgezondheid, Welzijn en Sport

European Parliament



European Parliament

IMCO Committee (lead, except provisions on chemicals)



Antonius MANDERS

Lid
PPE
Nederland



Catharina RINZEMA

Plaatsvervanger
Renew
Nederland



Kim VAN SPARRENTAK

Lid
Verts/ALE
Nederland



Lara WOLTERS

Plaatsvervanger
S&D
Nederland

ENVI Committee (chemicals provisions)



Bas EICKHOUT

Ondervoorzitter
Verts/ALE
Nederland



Anja HAZEKAMP

Ondervoorzitter
The Left
Nederland



Mohammed CHAHIM

Lid
S&D
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Jan HUITEMA

Lid
Renew
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Esther de LANGE

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Robert ROOS

Plaatsvervanger
ECR
Nederland

TSR - Next Milestones



- Directorate-General For Internal Market, Industry, Entrepreneurship & SMEs (DG GROW) - Directorate F, Ecosystems I: Chemicals, Food, Retail, Unit F.2 Bioeconomy, chemicals, cosmetics
- Expert Group on Toy Safety



Committee responsible IMCO
Rapporteur: Marion **Walsmann** (EPP, DE)
Shadow Rapporteurs:
 Vlad-Marius **Botoș** (Renew, RO)
 Brando **Benifei** (S&D, IT)
 Katrin **Langensiepen** (Greens, DE)
 Alessandro **Basso** (ID, IT)

Associated Committee ENVI
Rapporteur: Sara **Cerdas** (S&D, PT)
Shadow Rapporteurs:
 Billy **Kelleher** (Renew, IE)



Competitiveness Council

- Working Party on Technical Harmonization

A close-up photograph of a young child with light brown hair, smiling broadly. The child's face is partially obscured by their hands, which are held up in front of their eyes and nose. The child is wearing a pink garment. The background is bright and out of focus.

TSR PROPOSAL – MAIN OBJECTIVES

TSR proposal – objectives

Strengthen the protection of children against possible risks in toys, in particular from chemicals

Improve compliance and enforcement of the Toy Safety rules

A close-up photograph of a young child with light brown hair, smiling broadly. The child's face is partially obscured by their hands, which are held up in front of them. The background is bright and out of focus. The text 'TSR PROPOSAL – SCOPE' is overlaid on the left side of the image.

TSR PROPOSAL – SCOPE

TSR proposal – scope

TSD article 2.1:

1. This Directive lays down rules on the safety of toys and on their free movement in the Community.

TSD article 3.29

29. ‘intended for use by’ means that a parent or supervisor shall reasonably be able to assume by virtue of the functions, dimensions and characteristics of a toy that it is intended for use by children of the stated age group.

TSR article 2.1:

1. This Regulation applies to products which are designed or intended, whether or not exclusively, for use in play by children under 14 years of age (‘toys’).

For the purposes of this Regulation, a product shall be considered to be intended for use in play by children under 14 years of age, or by children of any other specific age group below 14 years, where a parent or supervisor can reasonably assume, by virtue of the functions, dimensions and characteristics of that product, that it is intended for use in play by children of the relevant age group.

Several articles are moved/merged. In principle no change to current situation. NEW – power for Commission to decide if certain toys/categories are in scope!

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TSR PROPOSAL – PRODUCT REQUIREMENTS

TSR proposal – product requirements

TSD article 10:

- 1. Member States shall take all measures necessary to ensure that toys may not be placed on the market unless they comply with the essential safety requirements set out, as far as the general safety requirement is concerned, in paragraph 2, and, as far as the particular safety requirements are concerned, in Annex II.
- 2. Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

TSR article 5:

- 1. Toys shall only be placed on the market if they comply with the essential safety requirements which include the safety requirement set out in paragraph 2 (the ‘general safety requirement’) and the safety requirements set out in Annex II (the ‘particular safety requirements’)
- 2. Toys shall not present a risk to the safety or health of users or third parties, including the psychological and mental health, well-being and cognitive development of children, when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

This general safety requirement is not matched by specific requirements

TSR proposal – particular safety requirements

TSD Annex II

Part I: Physical and mechanical properties

10) Toys **which are designed to emit a sound** shall be designed and manufactured in such a way in terms of the maximum values for impulse noise and continuous noise that the sound from them is not able to impair children's hearing.

TSR Annex II:

Part I: Physical and mechanical properties

10) **Toys** shall be designed and manufactured in such a way, in terms of the maximum values for impulse noise and continuous noise, that the sound from them is not able to impair children's hearing.

The TSR wording suggests to extend the current TSD acoustic requirements from toys designed to emit sound to all toys generating unintended sounds. These would be for example mechanical sounds generated by:



Wind-up toys



Hammer and pegs



Clicks from toy guns

Does this also include sounds generated when a child is playing with marbles or kicks a ball?

TSR proposal – particular safety requirements

TSD Annex II

Part III: Chemical properties

1. Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in the first subparagraph of Article 10(2).

TSR Annex II:

Part III: Chemical properties

1. Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain, when the toys are used as specified in Article 5(2), first subparagraph.

No change to the general requirement, the « exposure concept » remains.

TSR proposal – particular safety requirements

TSD Annex II

Part III: Chemical properties

3. Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys

TSR Annex II:

Part III: Chemical properties

4. The use in toys, components of toys or micro-structurally distinct parts of toys, of substances or mixtures classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 in any of the following categories is prohibited:

- (a) carcinogenicity, germ cell mutagenicity or reproductive toxicity (CMR) category 1A, 1B or 2;
- (b) endocrine disruption category 1 or 2;
- (c) specific target organ toxicity category 1, either in single exposure or in repeated exposure;
- (d) respiratory sensitisation category 1

The TSR extends the TSD CMR ban to endocrine disruptors (EDs), STOT and respiratory sensitisers cat 1.

TSR proposal – particular safety requirements

TSD Annex II

Part III: Chemical properties

4. By way of derogation from point 3, substances or mixtures classified as CMR ... may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:

(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in CLP

A major change is introduced in the TSR, CLP thresholds are replaced by non-intended presence of substances (such as impurities, residues such as monomers) and which are technically unavoidable. This change requires more knowledge on substances in toy materials (CMRs, EDs, STOT, RE) through safety datasheets and/or extensive/expensive testing.

It is not only limited to knowledge of chemicals content in materials, but it also requires to assess compliance with the general safety requirement (article 5 par. 2). In other words, evaluation of potential exposure (ingestion, dermal, inhalation, etc.) e.g. via migration and risk assessment (e.g. by a toxicologist) needs to be carried out.

TSR Annex II:

Part III: Chemical properties

5. The non-intended presence of a substance or mixture referred to in point 4 that stems from impurities of natural or synthetic ingredients, or from the manufacturing process and that is technically unavoidable in good manufacturing practice, shall be permitted provided that, despite such presence, toys remain in conformity with the general safety requirement.

TSR proposal – particular safety requirements

TSD Annex II

Part III: Chemical properties

4. By way of derogation from point 3, substances or mixtures classified as CMR ... may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:

(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2);

TSR Annex II:

Part III: Chemical properties

7. Points 4 to 6 shall not apply to:

(b) batteries in toys; or

(c) toy components necessary for electronic or electric functions of the toy where the substance or mixture is fully inaccessible to children, including by inhalation.

The TSD inaccessibility derogation is replaced in the TSR by derogation for electric/electronic components and batteries. This implies that for all other cases (inaccessible internal mechanism, inaccessible components on top of a climbing frame , etc.), the new CMR /EDs/STOT/RE rules and the specific substances restrictions (current TSD Appendix C) will apply.

TSR proposal – particular safety requirements

TSD Annex II

Part III: Chemical properties

4. By way of derogation from point 3, substances or mixtures classified as CMR ... may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:

(c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

TSR Article 46 (7) indicates that the use in toys of a substance or mixture prohibited under Part III, point 4, of Annex II may only be permitted when all of the following conditions are met:

- (a) it has been found to be safe by the European Chemicals Agency (ECHA), in particular in view of exposure, including the overall exposure from other sources, and taking particular account of the vulnerability of children;
- (b) there are no suitable alternative substances or mixtures available, as established by ECHA based on an analysis of alternatives;
- (c) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

TSR Annex II:

Part III: Chemical properties

6. By way of derogation from point 4, substances or mixtures prohibited under that point may be used in toys if they are listed in Part C of the Appendix, under the conditions specified therein.

TSR proposal – particular safety requirements

TSD Annex II

Part III: Chemical properties

7. Points 3, 4 and 5 shall not apply to materials that comply with the specific limit values set out in Appendix C.

TSR Annex II:

Part III: Chemical properties

7. Points 4 to 6 shall not apply to:
(a) materials that comply with the conditions set out for specific substances in Part A of the Appendix, as regards those substances;

The TSR rules on CMRs, Eds, STOT, RE will not apply to:

- Toy materials complying with the migration limits (when they apply)
- Toy materials in scope of the nitrosamines/nitrosable substances restriction
- Toy materials further restricted through Appendix A (“equivalent” to TSD Appendix C) under the condition specified (e.g. migration, emission, content) for these substances
- Toy materials complying with the fragrances ban

TSD Annex II

Part III: Chemical properties

8. Without prejudice to the application of points 3 and 4, nitrosamines and nitrosable substances shall be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances.

TSR Appendix to Annex II

Part A: Substances subject to specific limit values

2. Nitrosamines and nitrosable substances are prohibited in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth where the migration of those substances is equal to or higher than 0,01 mg/kg for nitrosamines and 0,1 mg/kg for nitrosable substances.

The TSR introduces a change that drastically reduces the limits for all toys in scope (including finger paints and balloons).

TSD Appendix C

Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth

Table containing current TSD Appendix C restrictions

TSR Appendix to Annex II

Part A: Substances subject to specific limit values

Table containing current TSD Appendix C restrictions but extended to all toys

The TSR extension of the current TSD Appendix C restrictions to all toys.

It shall be noted that:

- the current BPA restriction has been removed from the TSR due to the EFSA opinion
- The formaldehyde emission limit has been reduced to align with the new REACH Annex XVII restriction that will apply August 2026.

A close-up photograph of a young child with light brown hair, smiling broadly. The child's face is partially framed by their hands, which are held up to their cheeks. The background is bright and out of focus. The text 'TSR PROPOSAL – DIGITAL PRODUCT PASSPORT' is overlaid on the left side of the image.

**TSR PROPOSAL – DIGITAL PRODUCT
PASSPORT**

TSR proposal – product passport

- the **EU declaration of conformity** = similar information (but also more, e.g. ‘substances of concern’)
- Requirements:
 - *all relevant **information on the toy**: identification of the toy, economic operators, legislation and standards*
 - *corresponds to a **toy model**,*
 - *must be kept **up to date** and be **accessible for 10 years***
 - ***Language(s)** of the Member State where the toy is made available*
 - ***Technical requirements** to be laid down in an **implementing act**: types of data carrier, layout data carrier, technical elements and actors that can add information*
 - ***Interoperability** with other product passports*
- Linked with a **data carrier** affixed to the toy
- **Compliance information directly accessible to market surveillance and customs authorities (efficiency gains)**

TSR proposal – product passport

- Prerequisite for placing on the market : Reference of the unique product and operator identifiers to be included in a Commission central registry
- Customs controls on the product passport: Prior to release for free circulation: verification at customs that the information on the unique product identifier in the Commission registry is matching the information provided in the customs declaration

TSR proposal – product passport (content)

ANNEX VI - PRODUCT PASSPORT

Part I – Information to be included in the product passport

- (a) unique product identifier of the toy;
- (b) name and address of the manufacturer or of the manufacturer's authorised representative , as well as the unique operator identifier;
- (c) name and address of the economic operator responsible for carrying out the tasks set out in Article 4 of Regulation (EU) 2019/1020 , as well as the unique operator identifier;
- (d) object of the passport (identification of toy allowing traceability, including a colour image of sufficient clarity to enable the identification of the toy);
- (e) the commodity code under which the toy is classified at the moment the passport is created, as set out in Council Regulation (EEC) No 2658/87;
- (f) references to all Union legislation that the toy complies with;
- (g) references to the relevant harmonised standards used, or references to common specifications in relation to which conformity is declared;
- (h) where applicable: the notified body name and number which has intervened in the conformity assessment procedure and issued a certificate, as well as the reference to the certificate ;
- (i) the CE marking;
- (j) a list of allergenic fragrances that are present in the toy and that are subject to specific labelling requirements as set out in Part B, point 1, of the Appendix to Annex II;
- (k) any substance of concern that is present in the toy.

A close-up photograph of a young child with light brown hair, smiling broadly. The child's eyes are covered by their hands, which are held up in front of their face. The child is wearing a pink garment. The background is bright and out of focus.

**TSR PROPOSAL – WARNING
LABELLING**

TSR proposal – warning labelling

TSD article 17:

- [...]The warnings shall be preceded by the words ‘Warning’ or ‘Warnings’, as the case may be. [...]

TSR ANNEX III:

- 1. All warnings shall be preceded by the word ‘Warning’ or, alternatively, by a generic pictogram such as the following:.



TSR proposal – warning labelling

TSD article 11:

- [...] Warnings which determine the decision to purchase the toy, such as those specifying the minimum and maximum ages for users and the other applicable warnings set out in Annex V, shall appear on the consumer packaging or be otherwise clearly visible to the consumer before the purchase, including in cases where the purchase is made on-line.
- . [...]

TSR Article 6:

- [...] Warnings shall be clearly visible to the consumer before the purchase, including in cases where the purchase is made through distance sales. Warnings shall be of sufficient size to ensure their visibility. [...]

In the TSR, all warnings need to be clearly visible to the consumer before purchase. Not only warnings that determine the decision to purchase

A close-up photograph of a young child with light brown hair, smiling broadly. The child's face is partially framed by their hands, which are held up to their cheeks. A large, semi-transparent white circle is overlaid on the left side of the image, partially obscuring the child's face. The background is bright and out of focus.

**TSR PROPOSAL – TRANSITION
PERIOD & TIMING**

TSR proposal – transition period

Article 54 TSR – Transitional provisions

1. Toys placed on the market in conformity with Directive 2009/48/EC before ... [OP please insert the date = the first day of the month following 30 months after the date of entry into force of this Regulation] may continue to be made available on the market until ... [OP please insert the date = the first day of the month following 42 months after the date of entry into force of this Regulation].

This means that toys compliant with the TSD can only be sold for one year after the TSR applies. This is highly problematic. Such a provision is very unusual!

The transition period might be challenging:

- **Need for updates of standards**
- **Need for establishing Digital product passport (standards, delegated acts, IT development, roll-out....)**
- **Need to request derogations for certain chemicals**

We estimate that the new Regulation will apply by mid-2027:

- **Publication in the EU's Official Journal by end-2024**
- **30 months transition period**

However, this is for sure subject to change: the file might be adopted later and the transition period can also still be amended by the Parliament & Council

A close-up photograph of a young child with light brown hair, smiling broadly. The child's face is partially obscured by their hands, which are held up in front of them. The background is bright and out of focus. The text "THANK YOU" is overlaid on the image in a bold, dark blue font.

THANK YOU