Council of the European Union

Brussels, 10 March 2025
(OR. en)

6755/25

Interinstitutional File: 2023/0290(COD)

LIMITE

MI 118
ENT 27
CONSOM 34
SAN 79
COMPET 117
CHIMIE 11
ENV 118
CODEC 204

PUBLIC

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	12234/23 + ADD1 -5
Subject:	Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC - Preparation for the trilogue

I. INTRODUCTION

1. On 28 July 2023, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC[1].

2. The Proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU) and aims at further improving the protection of children from potential risks in toys, in particular from harmful chemicals, and strengthening enforcement, by requiring, among other things, that all toys to have a Digital Product Passport.

3. On 5 September 2023, the European Parliament's Committee on Internal Market and Consumer Protection (IMCO) appointed Mrs Marion Walsmann (EPP, DE) as rapporteur for the proposal. The Committee on the Environment, Public Health and Food Safety (ENVI) of

[1] ST 12234/23

the European Parliament delivered its opinion on the proposal on 12 February 2024. IMCO voted on its final report on the proposal on 13 February 2024, which was adopted in the plenary on 13 March 2024.

4. The European Economic and Social Committee gave an opinion on the proposal on 13 December 2023.

5. The Working Party on Technical Harmonisation (Safety of Toys) started the examination of the Proposal on 3 October 2023 under the Spanish Presidency. Since then, 16 additional Working Party meetings have taken place under the Spanish, Belgian, Hungarian and Polish presidencies.

6. Following the examination of the text under the Belgian Presidency, the Permanent Representatives Committee adopted the Council's mandate on 15 May 2024.

7. The main amendments in the Council's mandate aim at improving the provisions related to the obligations of the economic operators, aligning the provisions on the digital product passport with the framework for setting Ecodesign requirements for sustainable products (ESPR); striking a balance between ensuring a high level of protection of children from possible risks in toys, in particular from risks posed by harmful chemicals, and creating a predictable and well-founded situation for the industry by allowing for derogations from the generic prohibition for certain chemical substances in toys in justified circumstances.

II. INTERINSTITUTIONAL NEGOTIATIONS – STATE OF PLAY

8. The opening political trilogue was held under the Hungarian Presidency on 20 November 2024. The co-legislators presented their views on the main political issues and gave a broad mandate to the subsequent technical meetings to identify and make progress on areas of compromise. Thereafter, 11 technical meetings were organised, including 7 technical meetings under the Polish Presidency.

9. The Working Party on Technical Harmonisation (Safety of Toys) was convened on 6 and 12 December 2024, 21 January, 18 and 24 February 2025 to discuss the progress in the interinstitutional technical meetings and to prepare for the upcoming second trilogue.

10. The entire proposal has been discussed and considerable progress has been made at the technical level. Although many of the rows have been preliminary agreed, some provisions

could not be agreed and therefore require a substantive discussion at political level. Namely, the subject matter (Article 2(3a)), the product requirements, in particular requirements related to mental health (Article 5(2)), the obligations of economic operators, particularly of fulfilment service providers (Article 10a) and online market places (Article 10b), common specifications (Article 14), the digital product passport (Article 17), the references to substances of concern in the digital product passport (Articles 3, 17 and Annex VI), the selling-off period (Article 54 (1)), dates repeal and entry into application (Articles 53 and 56) and the chemicals provisions in the annexes, such as combined exposure to a substance or a mixture used in toys; conditions for derogation from the generic ban; potential ban of PFAS and bisphenols and fragrances in toys; non-intended presence of a substance or mixture (Annex II, point 19); limited time derogations from general prohibitions of banned chemicals (Article 46(7b)); cosmetic toys as well as slime, fingerpaint or modelling clay (Annex II, point 22) and their labelling based on Cosmetic Products Regulation; migration limits for 4 monomers: vinyl chloride, acrylonitrile, styrene, butadiene (Appendix Part A, point 3, Table 2).

11. The second political trilogue is scheduled for 18 March 2025 and the third trilogue is tentatively scheduled for 10 April 2025.

III. PREPARATION FOR THE SECOND TRILOGUE

12. Following the discussions at the Working Party meetings, the Presidency has identified a set of key issues where it seems necessary to adjust accordingly the mandate for further negotiations in trilogue in order to close the file as soon as possible. These issues are listed below in the order of individual articles.

13. The Presidency would like to invite COREPER to consider the following question and to express their views on possible areas of flexibility to reach a compromise.

(a) SUBJECT MATTER (Article 2(3a)) and PRODUCT REQUIREMENTS (Article 5(2))

14. The Parliament has indicated its strong preference to have both a reference to the precautionary principle in the operative part of the text in Article 2(3a) and to set mental health requirements as part of the essential safety requirements in Article 5. The Parliament has stressed throughout the negotiations the importance of including these considerations about mental health, especially for digitally connected toys, and has proposed additional

wording to this effect in rows 142a and 142b.

15. Taking into account the need to ensure that toys are designed and manufactured to the highest standard in order to protect the health and safety of children from potential risks in toys, the proposal from the Presidency would be to show flexibility towards the Parliament on the inclusion of the precautionary principle and to maintain the exclusion of mental health aspects in the product requirements, as set out in the Council mandate.

Could the delegations agree to such a compromise?

(b) OBLIGATIONS OF ECONOMIC OPERATORS (Articles 10a, 10b)

16. On Article 10a relating to obligations of fulfilment service providers, while Parliament has generally shown flexibility towards the inclusion of this Council addition, it has expressed resistance on paragraph 4 (row 234e). In Parliament's view, the wording of the Council text concerning the obligation to "not support the making available of the product on the market" is unclear in terms of what fulfilment service providers will be expected to do.

Could the delegations be flexible towards the Parliament and agree to delete this paragraph?

17. When it comes to the obligations of online marketplaces in Article 10b, the Presidency has strongly defended the Council's mandate throughout the negotiations and made it clear to the Parliament that this is a sensitive part of the text for the Council. The Presidency will continue to defend the Council mandate on this issue, while being open to moving Article 10b to new Chapter IIa as suggested by the Parliament, provided that the substance of the Council's text remains unchanged.

(c) COMMON SPECIFICATIONS (Article 14)

18. The main issue on this Article is the Parliament's insistence that common specifications for the essential safety requirements when there is no harmonized standard covering those requirements should be established by delegated act instead of implementing acts. The Presidency has strongly defended the Council's mandate to maintain implementing acts.

19. As a way forward, the Presidency could consider two last resort options. First option, in line with a similar provision in the new Construction Products Regulation (EU) 2024/3110, to include Parliament in the provision in Article 14(4) (row 256a) where Member States can raise objections to a common specification. This means that the Parliament would be able to raise objections to a common specification. The Council mandate would be maintained for the

rest of the provisions in Article 14. Alternatively, second option, the Presidency could propose to the Parliament that Article 14 be deleted relying instead entirely on the standardisation process.

Could the delegations be open to consider either the addition in Article 14(4) or the deletion of Article 14?

(d) DIGITAL PRODUCT PASSPORT (Article 17)

20. Considerable progress has been made throughout the negotiations to align the proposal to the final version of the Ecodesign for Sustainable Products Regulation (ESPR) text.

21. There are four main outstanding issues: the possibility for the Digital Product Passport (DPP) to replace Declarations of Conformity (DoC); the issue of differentiated access rights for the DPP; the reference to substances of concern in the DPP; and the Commission empowerment to set the technical requirements related to the DPP.

22. Regarding the possibility for the DPP to replace DoC, during discussions at the Working Party level, the legal risks of the proposed approach were raised. The Presidency therefore underlined to the Parliament the legal challenges that such an amendment would introduce. The Presidency understood that there could be some flexibility towards the principle of having the DPP replacing the DoC, on condition that legal certainty and clarity of such provisions would be ensured, and explored possible solutions with the Parliament.

23. Regarding the issue of differentiated access rights to the DPP in row 280a, the Parliament insists on its position because it does not accept Council's position in row 293a to have the access rights set through implementing acts. The Parliament's argument is based on the fact that in the ESPR access rights are set through delegated acts. Council's position is based on the Machinery Regulation (2023/1230).

Could the delegations consider showing flexibility and accept Parliament's position in row 280a?

24. On the references to substances of concern in the DPP in rows 286, 135 and 810, the Council kept these references in its mandate for the purposes of aligning the text with the ESPR framework. The Parliament has pointed out during the negotiations that the effect of maintaining these references would introduce additional unnecessary burden on economic operators by imposing a wide-ranging requirement to report on any substance of concern that

PUBLIC

is present in the toy.

25. Parliament strongly argued that the sustainability requirements should be addressed though the implementing legislation under ESPR and that ESPR requirements should not take effect before the Toys Safety Regulation is included in the scope of the ESPR. It should be noted that such requirement in the Toys Safety Regulation would in any case be replaced by an upcoming delegated act setting those information requirements under the ESPR framework. The Presidency would therefore suggest letting ESPR set those requirements.

Could the delegations show flexibility towards the Parliament's position and agree to drop the references to substances of concerns?

26. Regarding the Commission empowerment to set the technical requirements related to the DPP in row 288, during the discussions at Working Party level, the delegations showed openness regarding the Parliament's idea to impose a deadline for the adoption by the Commission of implementing legislation setting the technical requirements related to the DPP. Such a deadline would tentatively be of 18 months after the entry into force of Toys Safety Regulation. The question of whether such technical requirements should be set through delegated or implementing acts is still open. The Presidency would suggest showing flexibility on this point in order to maintain the Council mandate in other parts of the text.

Could the delegations show flexibility towards the Parliament's position and agree to have delegated acts here?

(e) TRANSITIONAL PROVISIONS (Article 54), REPEAL (Article 53) and ENTRY INTO APPLICATION (Article 56)

27. Regarding the selling off period in Article 54(1), the Parliament has expressed the concerns that such a provision does not exist in other product legislations and that it would be questionable to exclude from the circulation toys that have been placed on the market under Directive 2009/48/EC. According to the Parliament, such a selling off period would most probably create huge number of toys, which at some point should be treated as waste, creating both financial consequences to the industry and risk to the environment.

28. As a way forward, it is suggested to delete time limit for the selling off period, which would mean that toys that have been placed on the market under Directive 2009/48/EC could still be

in market circulation without any time constraints (instead of 5 years in the Commission proposal).

Could the delegation show flexibility towards the Presidency's above-mentioned proposal?

29. The Council set the date of the repeal of the Toys Safety Directive and the date of application for the new rules at 54 months after the date of entry into force of the Toys Safety Regulation, while the Parliament kept the deadline of the Commission proposal: 30 months. In Parliament's view a shorter date of application is needed to ensure swift application of the new rules stemming from Toys Safety Regulation and to better protection of children.

Could the delegation show flexibility towards reducing the period for date of entry into application and the date of repeal of the current rules? Can we meet with the Parliament in the halfway and accept 42 months?

(f) CHEMICAL PROVISIONS IN THE ANNEXES

30. When it comes to the overall discussion on the chemical provisions, good progress has been made at the technical level, where the Parliament has showed considerable flexibility so far. However, a number of issues remain open and require discussion at political level to obtain guidance on the way forward.

31. There are seven main outstanding issues relating to the chemical provisions of the text: combined exposure to a substance or a mixture used in toys (Article 46(7a)); conditions for derogation from the generic ban (Article 46(7)); potential ban of PFAS, bisphenols and fragrances in toys; non-intended presence of a substance or mixture (Annex II, point 19); limited time derogations from general prohibitions of banned chemicals (Article 46(7b)); cosmetic toys as well as slime, fingerpaint or modelling clay (Annex II, point 22) and their labelling based on Cosmetic Products Regulation; migration limits for 4 monomers: vinyl chloride, acrylonitrile, styrene, butadiene (Appendix Part A, point 3, Table 2).

32. On the combined exposure, the Commission has proposed a way forward where the known combined exposure would have to be taken into account by manufacturers during the safety assessment based on the information on self-classified substances that comes from suppliers. The compromise was presented to the delegations at the Working Party on 24 February 2025.

33. As part of the overall package on the conditions for derogations for generic ban in Article 46, the Parliament has showed openness to drop their amendments in Article 46 and move

towards the Council text in Annex II, Part 3. The Parliament is however insisting that the prohibited substances can only be permitted if there are no suitable alternatives available, including via design changes, and that the ECHA assessment should prioritise the safety of any alternatives identified, and also consider its technical feasibility and availability.

Could the delegation show flexibility towards this package as described here above?

34. On the general prohibition of PFAS, bisphenols and fragrances in row 645g, the situation is complex as there are three different elements to be considered. The Presidency has so far defended the Council mandate on these points. Regarding PFAS, the Parliament has insisted that this is a key point for them in the whole Regulation. The Parliament is proposing to introduce a temporary ban on PFAS (similar to what can be found in the Packaging and Packaging Waste Regulation) that would be replaced by the horizontal ban on PFAS which is supposed to be adopted as restriction under REACH Regulation (EC) No 1907/2006.

35. On bisphenols, the Parliament has indicated that it could accept to reduce the scope of its proposed ban and limit it to only the 34 bisphenols that have already been identified by ECHA as dangerous.

36. On the fragrances, the Parliament signalled that it could accept to reduce the scope of its ban and limit it to a full ban only for those fragrances that are under the labelling obligation (Table 4).

37. Considering the need to reach a compromise on these provisions, the Presidency would propose to consider them as a package where flexibility could be offered on bisphenols and fragrances, but the Council mandate on PFAS would be maintained.

Could the delegation show flexibility towards the Presidency's above-mentioned proposal?

38. On the 100 mg/kg threshold for the non-intended presence in row 646, the Parliament has insisted that the Council mandate is not acceptable to them. The Parliament considers the threshold of 100 mg/kg as too high for the impurities.

Could the delegation show flexibility towards moving back to the original Commission proposal in order to reach a compromise?

39. On the question of the labelling of toys that are themselves substances or mixtures in row 639, the Parliament has insisted on its amendment requiring such toys to be subjected to the

labelling requirements under the Cosmetic Products Regulation ((EC) 1223/2009). The Presidency will continue to defend the Council position that these toys are not cosmetics and should not fall under the scope of the Cosmetic Products Regulation.

40. As regards migration limits for 4 monomers (vinyl chloride, acrylonitrile, styrene, butadiene (Appendix Part A, point 3, Table 2)), the Parliament has showed openness towards the Council position in Table 2. The Presidency will continue to defend the Council position on this issue.

In case further conciliations are needed to reach a compromise, could the delegation show flexibility towards the Parliament's position on the labelling of toys being substances or mixtures and on the 4 monomers?

41. Following the discussions at technical level, the Parliament has signalled its readiness to drop the time-limited derogations from generic bans but insisted that there should be an obligation for industry to submit data to ECHA, when ECHA so requests. The possible compromise was presented to the Working Party on 24 February 2025 and received broad support.

IV. CONCLUSION

42. The Permanent Representatives Committee is invited to reflect on the abovementioned questions and to express its views on possible areas of flexibility in order to engage in negotiations with the European Parliament at the next informal trilogue on 18 March 2025.

43. The Permanent Representatives Committee is therefore invited:

- to confirm the preliminary agreement reached at the technical level on the part of the text proposal, which is set out in document WK 2492/2025;
- to approve the revision of the Council mandate for negotiating with the Parliament on the issues listed above.

PUBLIC