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**NOTE**

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From:	Presidency
To:	Working Party on Technical Harmonisation (Safety of Toys)
Subject:	Proposal for Regulation on the safety of toys : mental health

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## Draft compromise proposal for mental health

# Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the safety of toys and repealing Directive 2009/48/EC (Text with EEA relevance) 2023/0290(COD)

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Recital 14				
23	<p>(14) Relying on digital technologies has led to new hazards in toys. Radio toys are to comply with essential requirements for the protection of privacy and internet-connected toys are to incorporate safeguards towards cybersecurity and protection from fraud in accordance with Directive 2014/53/EU of the European Parliament and of the Council<sup>1</sup>. Toys which include artificial intelligence are to comply with Regulation (EU) .../...[P.O. insert serial number for Regulation laying down harmonised rules on artificial intelligence]<sup>2</sup>. Therefore, particular safety requirements regarding cybersecurity, protection of personal data and privacy</p>	<p>(14) Relying on digital technologies has led to new hazards in toys. Radio toys are to comply with essential requirements for the protection of privacy and internet-connected toys are to incorporate safeguards towards cybersecurity and protection from fraud in accordance with Directive 2014/53/EU of the European Parliament and of the Council<sup>430</sup>. Toys which include artificial intelligence are to comply with Regulation (EU) .../...[P.O. insert serial number for Regulation laying down harmonised rules on artificial intelligence]<sup>231</sup>. Therefore, <u>such toys should comply with standards of safety, security and privacy by design</u>. Particular safety</p>	<p>(14) Relying on digital technologies has led to new hazards in toys. Radio toys are to comply with essential requirements for the protection of privacy and internet-connected toys are to incorporate safeguards towards cybersecurity and protection from fraud in accordance with Directive 2014/53/EU of the European Parliament and of the Council<sup>1</sup>. Toys <b>with digital elements are to comply with Regulation (EU) .../...[P.O. insert serial number for Regulation on horizontal cybersecurity requirements for products with digital elements]</b>. Toys which include artificial intelligence are to comply with Regulation (EU) .../...[P.O. insert</p>	<p>(14) Relying on digital technologies has led to new hazards in toys. Radio toys are to comply with essential requirements for the protection of privacy and internet-connected toys are to incorporate safeguards towards cybersecurity and protection from fraud in accordance with Directive 2014/53/EU of the European Parliament and of the Council<sup>1</sup>. Toys <b>with digital elements are to comply with Regulation (EU) .../...[P.O. insert serial number for Regulation on horizontal cybersecurity requirements for products with digital elements]</b>. Toys which include artificial intelligence are to comply with Regulation (EU) .../...[P.O. insert</p>

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	<p>or other hazards stemming from the incorporation of artificial intelligence in toys should not be set out. However, protecting the health of children should not merely ensure the absence of disease or infirmity and relying on digital technologies may pose risks to children which go beyond their physical health. To ensure that children are protected from any risk coming from the use of digital technologies in toys, the general safety requirement should ensure the psychological and mental health, as well as the well-being and cognitive development, of children.</p> <p>1. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).</p> <p>2. PO: Please insert in the text the number of the Regulation and insert the number, date, title and OJ reference of that Regulation in the footnote.</p>	<p>requirements regarding cybersecurity, protection of personal data and privacy or other hazards stemming from the incorporation of artificial intelligence in toys should <del>not be set out.</del>  <del>However, protecting the health of children should not merely ensure the absence of disease or infirmity and relying on digital technologies may pose risks to children which go beyond their physical health</del><u>be dealt with within the specific legislation.</u>  <del>To ensure that children are protected from any risk coming from the use of digital technologies in toys, the general safety requirement should ensure the psychological and mental health, as well as the well-being and cognitive development, of children.</del></p> <p><del>1. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).</del></p>	<p>serial number for Regulation laying down harmonised rules on artificial intelligence]<sup>2</sup>. Therefore, <b>this Regulation should not lay down</b> particular safety requirements regarding cybersecurity, protection of personal data and privacy or other hazards stemming from the incorporation of artificial intelligence in toys should not be set out. However, protecting the health of children should not merely ensure the absence of disease or infirmity and relying on digital technologies may pose risks to children which go beyond their physical health. To ensure that children are protected from any risk coming from the use of digital technologies in toys, the general safety requirement should ensure the psychological and mental health, as well as the well-being and cognitive development, of children..</p> <p>1. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of</p>	<p><del>serial number for Regulation laying down harmonised rules on artificial intelligence]<sup>2</sup>. Therefore, <b>this Regulation should not lay down</b> particular safety requirements regarding cybersecurity, protection of personal data and privacy or other hazards stemming from the incorporation of artificial intelligence in toys should not be set out. However, protecting the health of children should not merely ensure the absence of disease or infirmity and relying on digital technologies may pose risks to children which go beyond their physical health. To ensure that children are protected from any risk coming from the use of digital technologies in toys, the general safety requirement should ensure the psychological and mental health, as well as the well-being and cognitive development, of children..</del></p> <p>1. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of</p>

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Recital 14b					
R	23b	<u><i>(14b) The safety assessment should take into account the health risk posed by digitally connected toys, where appropriate, including any risk posed to mental health. Therefore, when assessing the safety of digitally connected toys likely to have an impact on children, manufacturers should ensure that the products they make available on the market meet the highest standards of safety, security and privacy by design, in the best interests of children.</i></u>		<u><i>(14b) The safety assessment should take into account the health risk posed by digitally connected toys, where appropriate, including any risk posed to mental health. Therefore, when assessing the safety of digitally connected toys likely to have an impact on children, manufacturers should ensure that the products they make available on the market meet the highest standards of safety, security and privacy by design, in the best interests of children.</i></u>	R
Recital 55a					
R	64a		<b>(55a) The safety assessment should take into account the health risk posed by digitally connected products, including the risk to mental health. Therefore, when assessing the safety</b>	Deleted – covered in EP recital in row 23b	R

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			of digitally connected products likely to have an impact on children, manufacturers should ensure that the products they make available on the market meet the highest standards of safety, security and privacy by design, in the best interests of children.		
Article 5(2), first subparagraph					
Y	142	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.	2.Toys shall not present a risk to the safety or health of users or third parties; <del>including the psychological and mental health, well-being and cognitive development of children,</del> when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.	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.	2.Toys shall not present a risk to the safety or health of users or third parties; <del>including the psychological and mental health, well-being and cognitive development of children,</del> when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.
Article 5(2), first subparagraph a					
R	142a		<u>When assessing the risk referred to in the first subparagraph, a manufacturer of digitally connected toys shall, where appropriate, according to reasonable best efforts, also take into account any risk posed to mental health, as well as the cognitive development, of children, that may arise</u>	Draft compromise proposal:  <i>Furthermore, digitally connected toys shall not present a risk to mental health or the cognitive development of children when used as intended and shall, for that purpose, meet the highest standards for safety, security and privacy by design</i>	

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		<u>when such toys are used in accordance with their intended use.</u>		<i>applicable to such toys, taking account of the vulnerabilities of children, in accordance with Regulation (EU) 2024/1689 on artificial intelligence, Regulation (EU) 2024/2847 on the Cyber Resilience Act and Regulation (EU) 2016/679 on general data protection.</i>	
Article 5(2), first subparagraph b					
R	142b	<u>A manufacturer shall apply the second subparagraph in a manner that is proportionate to its capability in relation to adequately assessing those risks.</u>		Delete	R