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PAGE 2: Part I – General Information about Respondents

Q1: **Address**	
Contact name	Dominique BILLERET
Organisation/company	Toy Industries of Europe
Country	Belgium
Email Address	
Q2: **If you have a Transparency Register ID number, please provide it below. If your organisation is not registered, you have the opportunity to register now by following this link. If your entity responds without being registered, the Commission will consider its input as that of an individual/private person and, as such, will publish it separately.**	016371114093-01
Q3: **Received contributions may be published on the Commission's website, with the identity of the contributor. Please state your preference with regard to the publication of your contribution. Please note that regardless of the option chosen, your contribution may be subject to a request for access to documents under Regulation 1049/2001 on public access to European Parliament, Council and Commission documents. In such cases, the request will be assessed against the conditions set out in the Regulation and in accordance with applicable data protection rules.**	My contribution may be published under the name indicated; I declare that none of it is subject to copyright restrictions that prevent publication
Q4: **We might need to contact you to clarify some of your answers. Please state your preference below:**	I am available to be contacted
Q5: **Please indicate whether you are replying to this questionnaire as:**	An industry association
Q6: **If a business or industry association, please indicate your field(s) of interest or activity(ies) - the letters in between brackets correspond to NACE codes [multiple choice]:**	Manufacture of games and toys (C32.4)
Q7: **For businesses, please indicate the size of your business:The definition of small and medium-sized enterprises depends on the staff headcount and either the annual turnover or the balance sheet of the company. Please consult the following website: http://ec.europa.eu/growth/smes/business-friendly-environment/sme-definition/index_en.htm**	*Respondent skipped this question*

Q8: Please indicate the level at which your organisation is active:	EU

PAGE 3: Part II – General Questions

Q9: How important is it in your view that there is chemical and chemical-related legislation* at EU-level in order to achieve the following objectives? (1 = not important; 5= very important)*This comprises the chemical-related provisions in all legislation within the scope of this fitness check. It encompasses legislation governing hazard identification and classification, as well as risk management measures, including chemical-related aspects of legislation on worker safety, transport, environmental protection, chemicals controls and supporting legislation, excluding REACH. The full list of legislation can be found here.The internal market of the European Union (EU) is a single market in which the goods, services, capital and persons can move freely across borders. One of the key objectives of chemical and chemical-related legislation is to have a single market for chemical substances and mixtures, as well as products containing chemicals.**

Protecting human health	5
Protecting the environment	5
Ensuring a well-functioning internal market**	5
Stimulating competitiveness and innovation	5

Q10: Do you think the EU chemical and chemical-related legislation has been effective in achieving the following objectives? (1= not effective, 5= very effective). Please only consider chemical-related provisions in the legislation.

Protecting human health	5
Protecting the environment	5
Ensuring a well-functioning internal market	5
Stimulating competitiveness and innovation	5

Q11: If you think the EU chemical and chemical-related legislation is not effective (1) or only somewhat (2,3) effective, please indicate what you believe are the main reasons for this limited effectiveness in the following table:

Protecting human health	No opinion or not applicable
Protecting the environment	No opinion or not applicable
Ensuring a well-functioning internal market	No opinion or not applicable
Stimulating competitiveness and innovation	No opinion or not applicable

Q12: To what extent do you consider that EU chemical and chemical-related legislation has had an added value above what could have been achieved through action at a national level? (1= no value, 5= a very high added value)

EU-level legislation adds value to national level action	5

PAGE 4: Part III - Specific Questions

Q13: For businesses and industry associations - Please select the legislation that regulates or otherwise affects your sector's or your company's activities.For other stakeholders - Please select the legislation you are familiar with.	Classification, labelling and packaging (Regulation No (EC) 1272/2008) , REACH, Annex XIII (Regulation (EC) No 1907/2006) , Waste framework (Directive 2008/98/EC) and List of Waste , Restriction of the use of certain hazardous substances in electrical and electronic equipment (Directive 2011/65/EU) , Batteries (Directive 2006/66/EC), Packaging and Packaging Waste (Directive 94/62/EC) , Persistent organic pollutants (Regulation (EC) 850/2004) , Safety of toys (Directive 2009/48/EC) , Cosmetic products (Regulation (EC) No 1223/2009) , Food contact materials (Regulation (EC) No 10/2011 and Regulation (EC) No 450/2009) , General Product Safety (Directive 2001/95/EC)

PAGE 5: Effectiveness

Q14: In the EU legislative framework for chemicals, risk management measures are, in some cases, determined directly based on the identified hazard using generic risk considerations (e.g. widespread exposure or exposure of vulnerable groups), which justify the automatic adoption of such measures. In other cases, the risk management measures are determined by a specific risk assessment that assesses the probability of adverse health and environmental effects resulting from the specific exposure scenarios associated with the proposed use(s) of the chemical. In your view, do you think EU chemical and chemical-related legislation should, in general:	c. Remain as it is because the balance is more or less right (i.e. the legislation ensures appropriate application of specific risk assessments and generic risk considerations)

Q15: In your view, apart from the hazard and/or risk of a chemical substance or mixture, are all relevant considerations taken into account in regulatory decision making on risk management (e.g. whether there will be combined effects of chemicals, whether there are certain vulnerable groups, whether there will be impacts on jobs or on the competitiveness of EU industry, etc.)? Please explain your answer.	Yes

Q16: In your view, to what extent are the following elements of the overall EU legislative framework for chemicals satisfactory? (1= not satisfactory, 5= very satisfactory)

Transparency of procedures	4
Speed with which hazards/risks are identified	4
Speed with which identified risks are addressed	4
Time to allow duty holders to adapt	4
Predictability of the outcomes	2
Stability of the legal framework	4
Clarity of the legal texts	4
Guidance documents and implementation support	4
Effective implementation and enforcement across Member States	3
Consistent implementation and enforcement across Member States	2
Public awareness and outreach	3
International collaboration and harmonisation	4

Please explain your answers and list any other aspect you consider relevant. If you have specific legislation in mind, please specify it.	(Predictability of outcomes) Unfortunately, too often predictability of outcomes of EU decision-making is seriously undermined by political considerations and interferences which have nothing to do with sound science. When Member States disagree on a certain chemical restriction, we frequently see non-evidence based compromise decisions, which end up being a burden for our industry. This problem also affects the national level: In Member States such as France, we have also seen some attempts to impose diverging toy safety requirements which are often unscientific, breach EU legislation and its internal market, and can cause an enormous economic impact on industry without improving safety. Toy manufacturers believe that in these cases, the European Commission, which is the guardian of EU law, should take its responsibility and call Member States to order before it is too late. This would ensure predictability. (Consistent implementation and enforcement across Member States) We need more certainty and consistency of enforcement across the EU. We need harmonised risk assessments of products (If 2 countries make a risk assessment of the same product, this should be as standardised as possible and both should end up with the same conclusion). We see very often different interpretations of the same rules by national authorities. We understand market surveillance is a national competence, but toys are regulated by a harmonised directive and we are in the EU internal market. A number of toys not posing a severe hazard (just being not-compliant) still end up in RAPEX, classified as “serious risk”. The works of PROSAFE are highly valued by TIE, and actually this is why we actively contribute to it. For instance we find the e-Learning tool for controllers to have the same understanding of the rules very useful and we hope it will have positive results. The creation of an EU Referee could be a good idea to make sure in case of disagreements, official expert understanding of EU law prevails. [e.g. could the Commission be this referee? Or another independent party/expert?].

Q17: In your view, to what extent are the following elements of risk management satisfactory? (1= not satisfactory, 5= very satisfactory)

Hazard identification criteria	4
Risk assessment and characterisation	3
Hazard and risk communication measures to consumers (e.g. labels, pictograms, etc.)	3
Hazard and risk communication measures to workers (e.g. labels, pictograms, safety data sheets etc.)	I don't know
Risk management measures restricting or banning the use of chemicals	4
Risk management measures regulating the safe use of chemicals (e.g. packaging requirements or requirements for the use of personal protective equipment)	5
If you answered 1, 2 or 3 above and would like to provide further information (in particular on specific pieces of legislation), please explain your answers.	Q2: Chemicals regulation in the EU is essentially hazard based and does not take into account human relevant exposures in a lot of cases. The majority of data on which decisions are based is related to animal toxicity studies where the dose ranges are high and often approaching the maximum tolerated dose. There is also a lack of a mechanistic approach to determine if the effects in the animal studies are of human relevance. This also applies to carcinogenicity/genotoxicity studies where a binary hazard characterisation is made, when in fact there is often a threshold. There is a need for a) a better understanding of exposure and b) more regulatory acceptance of in vitro/mechanistic studies. The effect of not modifying the risk assessment approach will mean that a high proportion of potentially useful chemicals will be restricted or banned. Q3: The GHS pictograms in some instances are confusing for consumers. In particular the GHS05 symbol for serious eye damage is the same as skin corrosion and depicts a human hand. Where a substance or mixture is only classified as Eye Dam 1 and there is no equivalent hazard for skin contact this symbol could be considered to be inappropriate

Q18: Safety data for chemicals is subject to quality requirements, notably Good Laboratory Practice (GLP), aimed at ensuring the reliability and reproducibility of the data. Do you consider these requirements to be appropriate?	Yes

PAGE 6: Efficiency

Q19: In your view, what are the most significant benefits generated for EU society by the EU chemical and chemical related legislation? (one or more answers possible)	Reducing the exposure of consumers and of citizens in general to toxic chemicals and, therefore, avoiding healthcare costs, lost productivity, etc. , Reducing the damage to the environment and to eco-systems and, therefore, avoiding the costs of treating contaminated water, restoring impacted fisheries, cleaning-up of contaminated land, compensating for reduced crop pollinisation, etc. , Stimulating competition and trade within the EU single market , Stimulating international trade between the EU and other countries
Q20: In your view, what are the most significant costs incurred by EU society due to EU chemical and chemical related legislation? (one or more answers possible)	Costs for authorities at national level, Costs for small and medium sized enterprises, Costs for large enterprises
Q21: In your view, do any of the following requirements in the legislative framework lead to significant costs for companies?	Understanding and keeping up-to-date with changes in legal requirements , Training staff to ensure compliance with legal requirements , Inspections and administrative requirements, Other (please specify) Misinterpretation of existing rules, and new rules which are not based on sound evidence may also lead to significant costs for companies. When Member States disagree on a certain chemical restriction, we frequently see non-evidence based compromise decisions, which end up being a burden for our industry. This problem also affects the national level: In Member States such as France, we have also seen some attempts to impose diverging toy safety requirements which are often unscientific, breach EU legislation and its internal market, and can cause an enormous economic impact on industry without improving safety. For example, trying to impose a 'zero limit' of a certain substance may lead to the ban of all products on the market, as it is completely impossible to guarantee the total absence of traces of that substances when these are below detection limits.

Q22: Are there specific requirements in the EU chemicals legislative framework which lead to particularly significant costs for authorities?	Yes, If you answered yes, please indicate what these are. Proper and exhaustive market surveillance and enforcement of existing requirements to able to stop all (or a majority of) dangerous toys entering the EU market would certainly be costly for authorities.

PAGE 7: Relevance

Q23: To what extent has the EU legislative framework for chemicals contributed to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives? (1= no contribution, 5= a large contribution)

Framework has led to a reduction in the number and/or use of hazardous chemicals and/or their substitution with safer alternatives	5

Q24: To what extent does the existing EU legislative framework sufficiently address emerging areas of concern, e.g. arising from advances in science and technology? (1= emerging areas of concern are not sufficiently addressed, 5 = emerging areas of concern are sufficiently addressed)

Novel areas of concern sufficiently addressed by framework	5
Please comment	Should new scientific evidence show a certain substance needs to be restricted, the Toy Safety Directive (TSD) allows for additional restrictions whenever necessary. Also, toy manufacturers have the obligation to carry out mandatory safety (incl. chemical) assessments, which allow operators to identify potential new hazards. The TSD also covers internet sales, which is one of the main emerging areas 'of concern'. Toy safety requirements also apply to toys sold online. The TSD Explanatory Guidance Document also refers to how warnings, markings and other information should be displayed on websites. However, it is clear that market surveillance here is more difficult, and it is important that authorities enforce the Directive also by checking internet channels.

PAGE 8: Coherence

Q25: Please indicate the extent to which you agree with the following statements relating to the EU chemicals legislation framework overall

The EU chemicals legislation framework contains gaps and missing links	Neutral
The EU chemicals legislation framework has overlaps	Neutral
The EU chemicals legislation framework is internally inconsistent	Neutral

Q26: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between the different pieces of legislation which are under the scope of this fitness check. Please only consider aspects related to hazard identification, risk assessment and risk management of chemicals. The legislation covered by this fitness check can be found here.

Inconsistencies	The risk assessment principles between the implementation of the Toy Safety Directive and the Cosmetics Product Regulation differ in approach with regard to the treatment of children. The SCCS Opinion that covers risk assessment for children indicates that in general no additional safety factors are employed during the risk assessment process. The Toy Safety Directive however requires that an additional safety factor of 10 times or more is used to account for other exposures. This can lead to a potential compliance issue when borderline products that may include cosmetic toys are subject to a safety assessment.

Q27: Please indicate any incoherence (gaps or missing links, overlaps, inconsistencies etc.) between legislation which are covered by this fitness check and any other legislation you consider relevant as regards the regulation and risk management of chemicals.

Sometimes, EU proposals under REACH (eg. CMRs in textile articles), overlap and conflict with requirements under the Toy Safety Directive. In this concrete case, certain proposed limits are less strict than the ones set by the TSD, and even by REACH, for the same chemical substances (for example, the proposed limits are 10 times less strict in the case of TCEP and benzene). Certain proposed restricted substances are already specifically regulated by REACH for toys (phthalates, benzene). And very often REACH restrictions (or proposed restrictions) are unscientific and set arbitrary total content limits. Unlike the TSD, this approach ignores whether there is any real life exposure to the chemical substance.
A 2012 study into the scope of REACH and its overlaps with product-specific legislation commissioned by the European Commission concluded, inter alia, that “in the interest of legal certainty it could be more appropriate to bring all toy-specific restrictions related to substances into the specific sectoral legislation. (…) It is recommended to delete those [existing] restrictions which refer to toys from Annex XVII of REACH and integrate them instead into the Toy Safety Directive”. It also concludes that “the process of setting essential requirements and of developing standards for toys presumably involves assessing the risks related to a particular product type and the product characteristics needed to manage that risk”.

PAGE 9: Part IV: Specific questions on the CLP Regulation

Q28: CLP communicates hazards to workers and consumers through various label elements, including danger words, pictograms, hazard statements and precautionary statements. (1= not effective; 5= very effective)

To what extent are CLP labels effective in communicating hazards to workers?	I don't know
To what extent are CLP labels effective in communicating hazards to consumers?	3

Q29: Do the hazard classes in the CLP Regulation cover all relevant hazards?

Environmental	I don't know
Physical	Yes
Human health	Yes

Q30: How effective is the support to companies through formal guidance documents and national helpdesks? (1= not effective; 5= very effective)	
Guidance documents	4
Helpdesks	4
Industry association guidance and materials	4
Other (training, conferences, etc.)	No experience
Q31: To what extent is CLP enforced in a harmonised manner across Member States?	I don't know
Q32: To what extent are the current elements relating to the CLP classification criteria satisfactory? (1= not satisfactory; 5= very satisfactory)	
Ease of implementation for duty holders	4
Appropriateness of classification criteria and methods for substances	4
Appropriateness of classification criteria and methods for mixtures	4
International harmonisation through the Globally Harmonised System (GHS)	4
Q33: CLP is revised on a regular basis through adaptations to technical progress. Do transitional periods allow sufficient time to implement new or revised classification criteria?	Transition period is sufficient
Q34: To what extent are the current elements of the procedures for harmonised classification & labelling (CLH) satisfactory? (1= not satisfactory; 5= very satisfactory)	
Transparency of the procedures	4
Involvement of stakeholders	4
Quality of scientific data and related information	4
Speed of the procedure	4

PAGE 10: Part V: Additional comments

Q35: In case you have any additional comments with relevance for this public consultation, please insert them here.	Apart from the big risk that the EU or Member States are undertaking by adopting some political and non-evidence based decisions (as explained above), it is important to insist that enforcement of existing requirements is absolutely key. As expressed by the previous European Commissioner for Industry, the EU toy safety requirements are the strictest in the world. However, strict European rules become useless without proper enforcement. RAPEX statistics show that around 96% of the RAPEX notifications of toys come from rogue traders who will always try to circumvent the rules regardless of how strict these are.