Council of the European Union

Brussels, 5 July 2021
(OR. en)

Interinstitutional File: 2021/0170(COD)

10381/21
ADD 4

CONSOM 147
MI 520
COMPET 526
CODEC 1020
DIGIT 83
CYBER 196
CHIMIE 65
JAI 818

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	1 July 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SEC (2021)280
Subject:	Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC - Regulatory Scrutiny Board Opinion: Impact assesment/Revision of the General Product Safety (Directive 2001/95/EC)

Delegations will find attached document SEC (2021)280.

Encl.: SEC (2021)280

EUROPEAN COMMISSION

22.1.2021

SEC(2021) 280

REGULATORY SCRUTINY BOARD OPINION

Proposal for a Regulation of the European Parliament and of the Council on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council, and repealing Council Directive 87/357/EEC and Directive 2001/95/EC

{COM(2021) 346}
{SWD(2021) 168}
{SWD(2021) 169}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB

Opinion

Title: Impact assessment / Revision of the General Product Safety (Directive 2001/95/EC)

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

The General Product Safety Directive (GPSD) came into effect in 2002. It aims to ensure safety for consumers for non-food products. It provides a "safety net" and applies when other specific rules do not exist. The Directive established the EU Rapid Alert System to facilitate exchange of information between EU/EEA Member States and the European Commission on dangerous non-food products posing a risk to consumers.

An evaluation concluded that the Directive is not fit for purpose. The revision of the Directive is a follow-up to a Commission proposal accompanying the 2013 Product Safety and Market Surveillance Package. It aims to respond to challenges related to e-commerce and the emergence of new technologies, better enforcement and the alignment of rules for harmonised and non-harmonised products.

(B) Summary of findings

The Board notes the additional useful information provided in advance of and during the meeting, and commitments to make necessary changes to the report.

However, the report still contains significant shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The report does not sufficiently explain how the horizontal and sectoral elements of the product safety framework interact with each other in a coherent manner. The fall-back function of the GPSD as safety net is not sufficiently elaborated. The links to recent safety related sectoral initiatives are not sufficiently clear.

(2) The available policy choices are not sufficiently clear. The report presents only a limited set of options and lacks detail on the content of the measures contained therein. It does not explain sufficiently why some options are discarded.

(3) The report does not explain in a convincing manner why the estimated costs for business under the integration option are much higher than those of the full legal

This opinion concerns a draft impact assessment which may differ from the final version.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 08/010. E-mail: regulatory-scrutiny-board@ec.europa.eu

revision option, although in terms of substance the options seem very similar.

(C) What to improve

(1) The report should explain upfront how the horizontal and sectoral elements of the product safety policy framework fit together and how the GPSD general safety net fall-back functions. It should better explain the coherence with Regulation 2019/1020 on market surveillance, and the relevance of the recent changes to that Regulation for the GPSD. It should better describe the links to recent initiatives, such as on digital platforms, cybersecurity, circular economy and artificial intelligence.

(2) The report should better present the scope of the initiative, especially on which consumer products are covered. In this sense, it may help to include a diagram presenting the product safety regulatory framework. The safety concept needs elaboration. It is not clear what types of risks and damages it covers, ranging from health to cyber issues. The report should detail the specific mechanisms it will use to identify future product risks to function as a safety net.

(3) The report should reinforce the problem analysis to better reflect the deficiencies and gaps the initiative wants to solve. It should clarify to what extent self-regulatory measures under the Product Safety Pledge have been effective and what lessons can be learned. It should explain to what extent the Pledge helped to get information on emerging risks of new technologies and improved recalls.

(4) The range of options analysed should be better linked with the specific objectives and the problems the initiative aims to tackle. The report should provide more detail on the content and functioning of the proposed policy measures under the various options. It should explore whether there are alternative policy choices to the substantive measures presented for each problem area under the preferred option. It should expand on how the self-regulatory elements could be strengthened. It should provide more details about discarded options and the reasons for their exclusion from the analysis.

(5) The full integration option comes with substantial additional costs as regards market surveillance for business although there seem to be no real substantive differences on new regulatory obligations, compared to the full legal revision option. The report should review the robustness and reliability of the costs estimates provided in the support study given their importance for the overall comparison and ranking of options.

(6) The report should provide greater clarity on how this initiative will tackle safety issues related to consumers' online purchase from third countries as well as software updates. It should explain how the sanction regime would work under the different options and clarify whether alternatives with different deterrence effects can be assessed. It should better describe how effective enforcement of the options will be ensured.

(7) The REFIT aspect should be clarified, explaining how the initiative would endeavour to keep regulatory burdens to the minimum necessary. More information is needed on how overlaps between *lex generalis* and *lex specialis* would be prevented.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

2

(D) Conclusion **The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.**	
Full title	Proposal for a revision of the Directive 2001/95/EC on general product safety
Reference number	PLAN/2019/6283
Submitted to RSB on	18 December 2020
Date of RSB meeting	20 January 2021

3

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Increased safety of non-harmonised products and reduced product safety risks covered by GPSD (and related reduction of number on injuries caused by unsafe products)	- Preventable detriment suffered by EU consumers and society due to product-related accidents estimated at EUR 11.5 billion per year. - the current cost of health care utilisation for product-related injuries in the EU is approximately EUR 6.7 billion per year, with hospitalisation accounting for the larger part of the total health care costs at about EUR 6.1 billion. These costs can be reduced under Option 3 Options 3 also expected to reduce consumer detriment estimated on the basis of the value of unsafe products by approximately **EUR 1.04 billion in the first year of implementation, increasing to approximately EUR 5.5 billion over the next decade**, This represents the decrease of financial costs for consumers since they would avoid buying unsafe products. The GPSD Study also showed that stakeholder consider that Option 3 provides 'moderate' to 'significant' benefits for consumers.	Main impact on EU consumers via broader coverage and greater effectiveness of the GPSD in protecting consumers from unsafe products, in particular in online sales and for risks of new technologies. Impact also on MS (positive impact on health care budget)

4

Higher return rates during recalls of unsafe products	Reduced number of deaths and injuries caused by products staying in hands of consumers due to delayed and badly managed recalls. Reduced amount of consumer detriment. Reduced consumer detriment related to the value of unsafe products which were not effectively recalled by **EUR 410 million per year.** Examples from ineffective recalls: faulty Takata airbags (estimated to have cause 35 deaths and 300 injuries worldwide) and Fisher-Price rock 'n play baby sleepers (associated with 59 baby deaths in the US).	Main impact on EU consumers via lower exposure to unsafe products and on MS (positive impact on health care budget).
Level playing field and a better functioning EU internal market	These potential benefits were assessed as being 'moderate' to 'significant' in the Study's survey	Mainly via alignment of the market surveillance rules for all products, a clearer legal framework and deterrent effect on rogue traders. Main impact on EU businesses.
Reduced regulatory costs and burdens for businesses	Cost reductions for all businesses and in particular for the 42% of businesses who reported additional costs related to the diverging implementation of the GPSD. **Cost savings for businesses** of around **EUR 59 million annually (**EUR 34 million saved by EU SMEs and 26 million EUR saved by EU large businesses respectively) through more harmonised implementation. Study showed that companies and business associations estimate the benefits between 'minor' and 'moderate' and MSAs and other stakeholders to be mostly considerably more than 'moderate' and close to 'significant'.	Main impact on businesses via: -legally binding clarifications and choice of Regulation as instrument will reduce regulatory uncertainty and even implementation -aligning the general market surveillance and safety requirements for harmonise and non-harmonised products will reduce implementation differences and improve the traceability of supply chain
Efficiency gains in market surveillance and enforcement	Cost reductions for all MSAs and in particular for the16% of MSAs who reported related additional costs to the diverging legal frameworks between harmonised and	Main impact on MSAs due to aligning market surveillance provisions between harmonised and non-harmonised products, more aligned enforcement

5

	non-harmonised products. **Cost savings for MSAs** estimated at **EUR 0.7 million per year** across the EU.	powers, increased deterrent effect and arbitration mechanism.
Reduced administrative burden of the standardisation process	Not quantifiable	Via the simplification of the standardisation process will streamline the related EU process. As it would accelerate standardisation work, it would increase legal certainty for companies on the standards to comply with. Main impact on MSs and EC
Indirect benefits		
Positive spill-over effects on consumer trust, demand, production and employment	Not quantifiable	Via increased safety of products and free movement of goods in the Single Market. Beneficial for all undertakings
Improved companies' competitiveness	Additional competitiveness gains expected to be very moderate as companies' current compliance costs with consumer product safety legislation are already relatively low and additional regulatory requirements would level potential cost reductions.	Via a more harmonised regulatory level-playing field within the EU Main impact on EU businesses
Positive impacts on competition-driven innovation	Not quantifiable	Via a greater degree of harmonisation and greater legal certainty (e.g. development of new innovative information and traceability systems).

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
New general due diligence measures of economic operators	Direct costs	-	-	Familiarisation costs, adaptation costs to regulatory changes Total costs of businesses in the EU27 in the	Additional regulatory compliance costs, related to staff and additional resources (more for	Only relatively moderate one-off adaptation and implementation costs.	total additional recurrent costs of MSAs in EU27 of approx. **EUR 6.7 million**

for product safety				first year of implementation are estimated at **EUR 196.6 million** (one-off + recurrent costs in the first year), equivalent to **0.02% of turnover of EU companies** for manufacturing, wholesale and retail of non-harmonised consumer products.	manufacturers to adjust different stages of the value-adding process to new regulatory requirements) Recurrent costs amount to **EUR 177.8 million** (0,02% of companies' turnover)		**annually**
	Indirect costs	-	Potential impact on consumer prices in the EU, expected to be negligible (potentially for low-income consumers). No significant or negative impact on consumer choice in the EU expected	-	-	-	-
Duty of care obligations for online marketplaces	Direct costs	-	-	Costs estimation included in the total above	Additional regulatory compliance costs, for all online marketplaces and in particular for non-signatory of the Pledge, but likely less efforts than those of brick and mortar distributors for fulfilling their obligations today. Costs estimation included in the total above	-	-
	Indirect costs	-	-	-	-	-	-
All safety information is provided	Direct costs	-	-	-	Costs to be very limited for both online platforms and	-	-

7

online in the same vein as it is required "offline"					online sellers (information already available and does not go beyond what is indicated on the packaging)		
	Indirect costs	-	-	-	-	-	-
New requirements on recalls	Direct costs	Reduced cost of recall (improved remedy)	-	Higher administrative burden for recalls and registration systems. Costs mainly limited to situations when recall occurs (unsafe product placed on the market) and in any case operators should already carry out effective recalls.	-		
	Indirect costs	-	-	-	-	-	-
Integration of food-imitating products into GPSD	Direct costs	-	-	-	Minimal effect on producers of food-imitating products, and in any case not exceeding costs supported by other producers	-	Potentially some costs for MSAs which were applying a ban per se of these products and will have to do a risk assessment. Considered as minor in view of the limited amount of these products
	Indirect costs	-	-	-		-	-

8

This opinion concerns a draft impact assessment which may differ from the final version.