

# Updating the framework for the safety of non-food consumer products on the internal market

Impact assessment (SWD(2021) 168 final, SWD(2021) 169 final (summary)) accompanying a Commission 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 of the European Parliament and of the Council, COM(2021) 346

This briefing provides an initial analysis of the strengths and weaknesses of the European Commission's [impact assessment](#) (IA) accompanying the above-mentioned [proposal](#),<sup>1</sup> adopted on 30 June 2021 and referred to the European Parliament's Committee on Internal Market and Consumer Protection (IMCO). The proposal, a REFIT initiative included in the [adjusted Commission work programme 2020](#), aims to update the provisions currently set out in the General Product Safety [Directive 2001/95/EC](#) (GPSD) in order to address the product safety challenges of (non-food) consumer products linked to new technologies and online sales channels that might create a risk to the health and safety of consumers, and to tackle the ineffective procedures regarding the recall of unsafe products (IA, pp. 17-19). Additionally, the proposal seeks to create greater consistency between the rules on the market surveillance of the safety of *harmonised products* (i.e. products that are subject to the EU harmonisation legislation listed in Annex I of [Regulation \(EU\) 2019/1020](#), and those applicable to *non-harmonised products* (within the scope of the GPSD). Finally, the proposal seeks to address the inconsistent application of product safety rules regarding food-imitating products (i.e. products that can be confused with foodstuffs while not being such), resulting from the provisions set out in the Food-imitating Products [Directive 87/357/EEC](#) (FIPD), which includes rules on safety issues linked to food-imitating products, and those set out in the GPSD (adopted after the FIPD), which created the horizontal framework for the safety of all non-harmonised products.

## Problem definition

The IA identifies **one general problem: the EU legal framework does not ensure effective safety of all [non-food] consumer products on the EU market** (IA, Figure 1 – general problem tree, p. 22).

In addition, the IA identifies **five specific problems**:

1. **the GPSD does not address to a sufficient extent the product safety challenges linked to new technologies embedded in consumer products** (IA, pp. 12-15). According to the IA, when the GPSD was adopted, there were not many consumer products that incorporated new technologies. However, this is no longer the case and the IA states that the application of the GPSD to products such as connected devices or artificial intelligence-powered products is not entirely clear. In addition, the IA states that the GPSD does not explicitly address the fact that goods with digital elements (i.e. incorporating, or inter-connected with, digital content or a digital service) can impact product safety, and can bring new risks to consumers' health (e.g. mental health) and safety or change the way the existing risks could materialise (e.g. cybersecurity threats);
2. **the GPSD does not address to a sufficient extent the product safety challenges linked to online sales channels** (IA, pp. 15-17). According to the IA, while the GPSD applies to consumer products regardless of whether they are sold online or offline, the increased use of

- online platforms and online marketplaces, which facilitate the entering of products on the internal market from outside the EU, has negatively affected the relevance and effectiveness of the GPSD. According to the IA, the instruments under the GPSD are not effective enough for carrying out market surveillance of non-harmonised consumer products sold online as regards their safety. On the other hand, such instruments are available for the harmonised consumer products covered by the above-mentioned Regulation (EU) 2019/1020. In addition, while new online business models and actors (e.g. online marketplaces hosting third-party sellers) have become prominent, the GPSD establishes clear legal obligations regarding the safety of products only if made available by manufacturers, importers or distributors;
3. **the GPSD is not effective enough as regards the recall of unsafe products** (IA, pp. 17-19). According to the IA, the GPSD does not set any specific rules for the modalities of recalling unsafe products, and the recall procedure is not fully harmonised in the EU;
  4. **the market surveillance rules regarding product safety are complex and not fully effective** (IA, 19-21). According to the IA, this is due to the fact that there are two different sets of rules regarding the market surveillance of product safety, one for harmonised products and another one for non-harmonised products;
  5. **the FIPD product safety provisions on food-imitating products are not consistently applied**, due to differences in their interpretation/transposition (IA, pp. 21-22). According to the IA, the Member States have different positions in particular as to whether all food-imitating products should be banned as such, based on the 'primary interpretation' of the FIPD or, rather, the conformity of a product to the general safety requirement should be assessed by taking into account the elements set out in Article 3(3) of the GPSD, adopted later.

According to the IA (pp. 24-25), without any intervention, problems 1 and 2, in particular, would likely get worse, e.g. due to the expected rise in online sales in western Europe by 16.9% in 2020 (IA, p. 32), and to an increase in the imports of consumer products from outside the EU, which has not been quantified. At the same time, the IA states that without any action by the EU, other problems, such as the complexity and ineffectiveness of the market surveillance rules, are likely to remain the same. For each problem, the IA identifies the underlying drivers, whose nature (market failure, regulatory failure, asymmetry of information, split markets, consumers' behavioural biases) is illustrated in Table 2 of the IA (pp. 23-24). Based on the text provided in the IA, the analysis illustrating the identified problems appears to be overall satisfactory, also in terms of providing evidence regarding the scale of some of the identified problems, while the description of how the problems would evolve without any EU intervention is very brief. As regards the underlying drivers, the analysis could have been developed in a clearer and more comprehensive way, as the explanations provided in Table 2 of the IA ('nature of problem drivers') appear to not always be clear enough, the reader having therefore to refer to other sections of the IA.

## Subsidiarity / proportionality

While the IA addresses subsidiarity in a dedicated chapter (IA, pp. 25-27), a subsidiarity grid is not included, although this was recommended in the 2018 [Report](#) of the Commission task force on subsidiarity, proportionality and 'doing less more efficiently'. The IA justifies EU action from both a Treaty and an added value perspective in a convincing way. It explains that the legal basis for the initiative is Article 114 of the Treaty on the Functioning of the European Union (TFEU), which, together with Article 115 TFEU allows the EU to regulate those elements of private law that create obstacles to trade in the internal market. Proportionality is mentioned a few times within the main text of the IA, for example, when illustrating the impacts of the preferred options, but it is not dealt with in a systematic and comprehensive way, and is only briefly illustrated in the proposal's explanatory memorandum (p. 8). No reasoned opinions were submitted by the EU-27 national parliaments at the time this briefing was completed, the deadline being set at 22 November.

## Objectives of the initiative

The IA states that **the proposal's general objective** is to **ensure EU consumers are protected from dangerous products and (to ensure) the proper functioning of the single market** (IA, p. 27). The IA identifies **five specific objectives** (Figure 2, p. 27 and pp. 27-28, Figure 4, p. 32), one for each identified problem: 1. Ensure that the EU legal framework provides for a safety net [general safety rules] for all [non-food] consumer products and risks, including products and risks linked to new technologies (although the associated description clarifies, as already indicated, that the proposal concerns *non-harmonised* consumer products); 2. Address product safety challenges in the online sales channels; 3. Make product recalls more effective and efficient to keep unsafe products away from consumers; 4. Enhance market surveillance and ensure better alignment of rules for harmonised and non-harmonised consumer products; and 5. Address safety issues related to food-imitating products. However, Table 3 (IA, p. 28) adds another specific objective (REFIT simplification and improving the efficiency of the existing legislation) that, in the afore-mentioned Figure 2, is not linked to the five problems identified, and is missing from the intervention logic of Figure 3 (IA, p. 29). In addition, Table 6 of the IA (p. 36) includes another objective regarding a digital solution in respect of the implementation of the proposed new rules and the reduction of the administrative burden. As regards the **operational objectives**, they are described after the preferred option was selected (IA, p. 77), although **they do not become entirely clear until** a later stage, **when the IA lists** in Table 26 (IA, pp. 81-82) **the monitoring indicators** selected for the operational objectives; these indicators appear to be specific, measurable, achievable and relevant, but not time-bound. Based on the text/tables included in the IA, the IA would have gained greater clarity if the text referring to the specific and operational objectives had been streamlined so as to avoid some inconsistencies in the way they have been described in the different sections of the report.

## Range of options considered

In addition to the baseline option of no change, the IA retains, for assessment purposes, **four options** (see Table 1) which derive logically from the general and specific objectives, one of which envisages non-legislative action (Option 1) and three envisage legislative action (Options 2-4). As regards the FIPD, its provisions are to be revised under all four options, with two related sub-options being considered. A further policy option was discarded at an early stage, i.e. the complete repeal of the GPSD, because its evaluation showed that it is still relevant, effective, efficient, and coherent, bringing an EU added value. In addition, the IA states that *alternatives measures* to some of those finally chosen for the retained options were initially considered (e.g. the introduction of the 'made in' labelling clause for products) but subsequently discarded for the reasons concisely illustrated (IA, pp. 42-43). According to the IA (p. 42), during the consultation process, stakeholders did not suggest 'any other new real alternatives' to the envisaged options.

Table 1 – Range of retained options (the preferred option is highlighted in light grey)

	OPTION 0 BASELINE	OPTION 1 ENHANCED ENFORCEMENT	OPTION 2 TARGETED REVISION	OPTION 3 FULL REVISION	OPTION 4 NEW REGULATION
PROBLEM					
Product safety challenges linked to new technologies being incorporated in consumer products	NO CHANGE	<ul style="list-style-type: none"> <li>develop guidance for economic operators on the safety of new technologies [to clarify that the GPSD already encompasses protection against new risks, e.g. cybersecurity threats, and other risks related to new technologies potentially affecting the physical or mental health]</li> </ul>	<ul style="list-style-type: none"> <li>make explicit how the scope of the legal framework and its definitions apply to risks posed by new technologies through revising the GPSD (i.e. revising the definition of safety in the GPSD in a way similar to what is envisaged under Option 1) but <i>without extending</i> the definition for 'product' to standalone software (i.e. the definition for 'product'</li> </ul>	<ul style="list-style-type: none"> <li>Option 2 + clarify software-related rules (e.g. as regards software updates)</li> </ul>	<ul style="list-style-type: none"> <li>Option 3</li> </ul>

	OPTION 0 BASELINE	OPTION 1 ENHANCED ENFORCEMENT	OPTION 2 TARGETED REVISION	OPTION 3 FULL REVISION	OPTION 4 NEW REGULATION
PROBLEM		<ul style="list-style-type: none"> <li>use of European standards to address new risks</li> </ul>	in the GPSD would not be changed)		
Product safety challenges linked to online sales channels	NO CHANGE	<ul style="list-style-type: none"> <li>update the <a href="#">Product Safety Pledge</a> and promote it in order to encourage further online marketplaces to sign it</li> </ul>	<ul style="list-style-type: none"> <li>add requirements for online marketplaces by making most provisions of the Product Safety Pledge legally binding</li> </ul>	<ul style="list-style-type: none"> <li>Option 2 + include additional requirements for online operators across the supply chain</li> </ul>	<ul style="list-style-type: none"> <li>Option 3</li> </ul>
Recall (of unsafe products) effectiveness	NO CHANGE	<ul style="list-style-type: none"> <li>develop guidance on product recalls for market surveillance authorities and economic operators</li> </ul>	<ul style="list-style-type: none"> <li>add requirements for enhancing the effectiveness of product recalls (e.g. create the legal basis to allow economic operators to use available customer contact details to notify the owners of recalled products; define mandatory elements that are to be included in every recall notice)</li> </ul>	<ul style="list-style-type: none"> <li>Option 2 + introduce additional mandatory requirements (e.g. right to effective, cost-free and timely remedy, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Option 3</li> </ul>
Market surveillance rules on product safety are complex and not fully effective	NO CHANGE	<ul style="list-style-type: none"> <li>provide increased funding for joint market surveillance activities among Member States, including the joint testing of consumer products</li> </ul>	<ul style="list-style-type: none"> <li>align the existing rules on market surveillance and product traceability for non-harmonised products with those provided for harmonised products by Regulation (EU) 2019/1020</li> <li>simplify standardisation procedures (under the GPSD) at the Commission level</li> </ul>	<ul style="list-style-type: none"> <li>Option 2 + introduce stronger enforcement powers for Member States + introduce an arbitration mechanism in case Member States have diverging product safety risk assessments + possibility for Member States to set further requirements for traceability systems</li> </ul>	<ul style="list-style-type: none"> <li>Option 3 + integrate the legal instruments regarding market surveillance provided for by the GPSD and Regulation (EU) 2019/1020</li> </ul>
Inconsistent application of product safety provisions on food-imitating products	NO CHANGE	<ul style="list-style-type: none"> <li>keep the FISD but clarify its scope. Two sub-options:                             <ol style="list-style-type: none"> <li>general (full) ban of food-imitating products (FIPs);</li> <li>apply a product safety risk-assessment to FIPs on a case-by-case basis</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>merge the provisions of the FIPD into the GPSD. Two sub-options:                             <ol style="list-style-type: none"> <li>maintain dedicated provisions on FIPs (recast and integration) with a general (full) ban of FIPs;</li> <li>abandon any dedicated provisions on FIPs (repeal) and rely on general provisions for risk-assessment approach of FIPs</li> </ol> </li> </ul>	<ul style="list-style-type: none"> <li>Option 2 (including the two sub-options)</li> </ul>	<ul style="list-style-type: none"> <li>Option 3</li> </ul>

Data source: Author's own compilation, based on the IA (Tables 5 and 6, pp. 33-37, and pp. 38-42) and the [study](#) supporting the IA (Table 10, p. 72)

**Option 0 – baseline** (IA, pp. 29-32): the IA states that, in the absence of action at EU level, no new legislative or non-legislative action targeting *specifically* the safety of non-food consumer products would be developed (IA, p.29). According to the IA, the baseline scenario takes into account recently adopted legislative proposals that include aspects linked to this proposal, e.g. the [proposal](#) for a regulation on a single market for digital services (digital services act), which envisages [new responsibilities](#) for online intermediaries (including online marketplaces). During the time horizon

considered for the baseline scenario (10 years), the Commission would continue, inter alia, to finance coordinated market surveillance activities on product safety and to adopt safety standards giving the presumption of safety for non-harmonised consumer products (IA, pp. 29-30). The IA includes an estimate of the costs that would be incurred to ensure compliance with the GPSD for businesses, disaggregated by company size, associated to the baseline (IA, Table 4, p. 30). These costs would amount to €1.1 billion per year. The IA also includes cost estimates for SMEs, for the Member States (related to the market surveillance of non-harmonised consumer products), and an estimate of the consumer detriment (due to ineffective recalls), calculated as the value of recalled products that remain with consumers, amounting to about €1.3 billion per year (IA, pp. 30-31). Finally, the IA analyses briefly the impacts of the coronavirus pandemic under the baseline scenario (IA, pp. 31-32).

**Option 1 – enhanced enforcement** (IA, p.38): this option would aim to improve the implementation and enforcement of the GPSD, without revising it, by implementing the measures listed in the above Table 2. **Option 2 – targeted revision** (IA, pp. 38-40): this option would require a targeted legal revision of the GPSD, which would remain a directive or become a regulation that would include the measures listed in the above Table 1. **Option 3 – full revision** (IA, pp. 40-41): this option would repeal the directive, recasting it as a regulation in order to ensure the even application of its implementation in the Member States. This option would include all measures envisaged under Option 2, in addition to the other measures listed in the above Table 1. **Option 4 – a new regulation** (IA, pp. 41-42): this option would provide for a new legal instrument including all measures envisaged under Option 3, in addition to merging the market surveillance provisions of the GPSD and those of Regulation (EU) 2019/1020, so that one single set of rules would apply to both harmonised and non-harmonised consumer products. The content of the individual measures envisaged under each option is clearly presented with a good level of detail, also considering the additional information included in Table 6 ('option package') of the IA (pp. 35-36). The IA provides three tables summarising how options 1-3 compare to the baseline scenario in terms of their effectiveness in achieving the specific objectives identified (IA, Table 7 p. 44, Table 8 pp. 48-49, and Table 10 pp. 55-56, respectively), while for Option 4 the IA explains why a similar table is missing (pp. 61-62). The IA does not appear to have succeeded in explaining how the options compare in terms of coherence with other EU policy objectives (IA, pp. 72-73), nor does it include any comparison of the options in terms of efficiency and proportionality as required by the Better Regulation Guidelines. However, proportionality is mentioned when discussing the impacts of the options. According to the IA, the options were ranked based on a comparison of their impacts (IA, pp. 64-71), and not by using a multi-criteria analysis (MCA). At the same time, it states that 'the MCA was tested on the criteria (impacts) in the comparison table' (IA, p. 75). It is therefore unclear what role, if any, the MCA played in the ranking of the options and how the MCA was performed. Based on the analysis carried out in the IA, **Option 3 is selected as the preferred option** (IA, pp. 76-78), **with sub-option b** being selected as **the preferred approach to deal with food-imitating products** (IA, p. 74). However, the statement that Option 3 addresses all identified problems and objectives in the most effective, efficient and proportionate way appears to be substantiated only with regard to its effectiveness. In addition, the IA would have benefited from describing more clearly the alternatives considered for treating food-imitating products, also because the text provided is somehow inconsistent, initially mentioning two sub-options (IA, p. 33) and later on three (IA, p. 74).

## Assessment of impacts

The IA mainly focuses on economic and social impacts, while environmental ones are mentioned only briefly. Estimates are provided for the costs for ensuring the (regulatory) compliance of EU companies, detailed for three company sizes, resulting from implementing Options 2-4 (IA, Table 9 p. 50, Table 11 p. 57, and Table 12, p. 62, respectively). The IA also estimates the benefits for businesses linked to savings in costs caused by differences in the national implementation of the GPSD (IA, Table 15, p. 65), which are quantified. The impact on the Member States is quantified for the additional recurrent costs to be sustained by their MSAs, estimated at about €6.7 million annually for the preferred Option 3, with cost savings due to the alignment of market surveillance

provisions for non-harmonised and harmonised consumer products, estimated at €0.7 million per year (IA, p. 60). Administrative simplification is mentioned but not quantified. An impact on fundamental rights is also mentioned (IA, p. 48, p. 55, p. 61, and p. 64), e.g. regarding the freedom to conduct a business. As for social impacts, the IA focuses on the potentially positive impacts on healthcare costs due to product-related injuries in the EU, which would be reduced by a certain unquantified amount, to the extent that unsafe products available on the market would cause a lower number of injuries (IA, p. 54). The broader coverage and greater effectiveness of the GPSD in protecting consumers from unsafe products resulting from Option 3 is expected to reduce the detriment to consumers resulting from unsafe products by €1.0 billion in the first year of implementation, and by €5.5 billion over the chosen time-frame of 10 years. Environmental impacts are mentioned only briefly, which seems reasonable in light of the problem definition and the objectives of the legislative proposal, and are assessed qualitatively. The impact of the sub-options for food-imitating products is also dealt with by the IA (p. 69). The IA includes some helpful tables providing an overview of the qualitative/quantitative impacts considered for the options retained for assessment (IA, pp. 64-68). Based on the conducted analysis, the IA appears to have performed a satisfactory analysis of the main impacts of the options retained for assessment, providing estimates for some of them, and the limited qualitative analysis regarding a few other impacts appears to be justified.

### SMEs/ Competitiveness

The IA illustrates in its Annex 7 (pp. 104-107 – pp. 188-191 of the file, as the numbering of the report is not sequential) the results of the SMEs Test (Better Regulation Guidelines, [tool#22](#)). According to the IA (p. 31), the current annual costs needed for SMEs to comply with the GPSD are estimated at €428 million per year (companies with < 50 employees) and €226 million per year (companies with 50 to 249 employees). Based on these estimates, the IA states that SMEs account for 59 % of the total EU compliance costs related to the GPSD. Compliance costs for SMEs are also estimated for each of the retained options (IA, pp. 29-32, p. 50, pp. 56-59, pp. 65-66, pp. 78-79, pp. 105-106), bearing in mind that the net impact on SMEs would depend on the benefits resulting from a greater level of regulatory harmonisation envisaged under each option, which are quantified. According to the IA, under options 2 to 4, the effects of additional compliance costs are considered to be moderate when measured against the benefits that would result from a greater level of regulatory harmonisation. As regards competitiveness, the IA states (p. 59) that under Option 3, no significant distortions in competition and international trade would be expected in light of the relatively low additional costs for businesses, representing 0.02 % of their annual turnover in the first year of implementation. Additional competitiveness gains are expected to be very moderate (IA, p. 98). The analysis regarding the impact on SMEs appears to be well developed and quantitatively supported, while the analysis on competitiveness appears to be quite succinct.

### Simplification and other regulatory implications

Being a REFIT initiative, the IA has analysed how the current legal framework could be simplified in order to improve efficiency and decrease the administrative burden. The outcome of the preferred Option 3 is shown in Table 24 ('REFIT cost savings') of the IA (pp. 78-79), which lists the results obtained for the different measures envisaged under this Option, although only the impact of two measures is quantified. However, the table mentions two measures not previously mentioned under Option 3 when comparing the options retained for assessment, namely: (the reduced/lower administrative burden deriving from) the potential future introduction of improved digital solutions for product traceability through delegated acts; and the digital interlinks between existing market surveillance systems at EU and national level (including customs).

### Monitoring and evaluation

The IA states that the Commission would monitor the implementation of the revised GPSD, its identified policy objectives and the operational objectives, in addition to including, in the legislative proposal, a commitment for evaluating the impacts of the new legislative act. According to the IA

(p.80), the monitoring would be based, whenever possible, on existing data sources, and the legislative proposal would introduce reporting obligations for the Member States. The IA provides two tables detailing the monitoring indicators for the policy objectives (Table 25, pp. 80-81), and the monitoring indicators for the operational objectives (Table 26, pp. 81-82). The two tables identify the data sources and/or the data collection methods, specifying whether the data are already collected and who is responsible for their collection. Enforcement indicators would be further defined by a study, while a methodological study to design them is ongoing but not referenced. Based on the information given in the IA, the envisaged monitoring framework appears to be convincing, although some necessary data are not currently collected and the enforcement indicators would be defined at a later stage.

## Stakeholder consultation

The Commission held a wide consultation (IA, Annex 2, pp. 87-95), including several workshops, an international product safety week with more than 500 participants from 73 countries, a European consumer summit, in addition to the standard 12-week open public consultation – OPC (30 June-6 October 2020) that gathered the views of the public about [four initiatives](#) on EU consumer policy, including the review of the GPSD, which fed into the evaluation and the impact assessment of the Directive. The majority of the 257 respondents were business associations (26%), EU citizens (26%), and company/business organisations (15%). Annex 5 of the IA (pp.42-89) provides a very comprehensive and detailed report of the OPC, focused on aspects of the evaluation of the GPSD (relevance, effectiveness, efficiency, coherence and EU added value). Annexes 11 and 12 of the IA (pp. 129-146) include those replies to the OPC that appear to be mainly focused on supporting the IA, e.g. the stakeholders' views about the benefits of the different policy options. Annexes 13 and 14 (IA, pp. 146-159) complete the already extensive report on the OPC by providing the minutes from two workshops on addressing the sale of illegal goods online and on strategies to maximise the effectiveness of consumer products recalls, a topic that is extensively discussed in a dedicated Annex of the IA (Annex 8, pp. 108-124). The IA specifically refers to the feedback received in several parts of the report; as regards the retained options, the IA states that in the OPC, the stakeholders showed clear support for certain proposed provisions under Options 2, 3 and 4 (IA, p. 73).

## Supporting data and analytical methods used

The analysis performed in the IA is supported by a [study](#) on the assessment of the impacts of the potential revision of the GPSD, and by a very comprehensive [study](#) supporting both the evaluation of the relevant provisions contained in the GPSD and the analysis regarding the implementation of the FIPD (Annex 5, pp. 30-89, and Appendix 4, pp. 99-101). However, the evaluation and the IA were done in parallel ('back to back'), rather than sequentially, as should normally be the case in line with the 'evaluate first' principle enshrined in the Better Regulation Guidelines ([Chapter VI](#), pp. 50-66). In addition, the analysis was supported by complementary studies and research that were only partially referenced (IA, Annex 5, p. 42), and benefited from the feedback received during the stakeholder consultation (IA, Annex 2, pp. 87-95). Finally, the IA states (p. 42) that the analysis builds also on the conclusions of the IA – [SWD\(2013\) 33](#) – accompanying the (withdrawn) [product safety and market surveillance package 2013](#) (IA, p. 8). Annex 4 of the IA (pp.101-112) provides an overview of the analytical methods and techniques used for making various estimates, and the data sources used. Appendix 2 of the evaluation report (IA, Annex 5, pp.92-96) illustrates the analytical methods *additionally* used for making the evaluation. The IA transparently acknowledges (Annex 5, p. 43) one important limitation of the evaluation regarding the 'difficulty to differentiate data gathered between harmonised and non-harmonised products', and that 'data coming from the safety Gate/RAPEX should be interpreted cautiously'. The IA states that a multi-criteria analysis (MCA) was used in comparing the options, but it is unclear how the MCA was performed. The evidence gathered and sources used are listed on p. 86 of the IA, although the bibliography is described as being 'selective'. Overall, the analysis carried out in the IA appears to be well grounded, especially thanks to the comprehensive supporting studies. In addition, the description of the steps used for obtaining the different estimates given in Annex 4 (IA, pp. 101-112) is very clear.

## Follow-up to the opinion of the Commission Regulatory Scrutiny Board

On 22 January 2021, the Commission Regulatory Scrutiny Board (RSB) adopted a [positive opinion](#) with reservations on a draft version of the IA submitted on 18 December 2020, recommending improvements in several respects, for instance by: better explaining how the horizontal and sectoral elements of the product safety framework [see IA, Table 1, p. 5] interact with each other in a coherent manner, and giving greater clarity on how they link with recent safety-related sectoral initiatives; better linking the range of analysed options with the specific objectives and the problems the initiative aims to tackle; providing more details regarding the discarded options and the reasons for their exclusion from the analysis; reviewing the robustness and the reliability of the cost estimates provided in the support study in light of their importance for comparing the options; and clarifying the REFIT aspects, i.e. how the initiative would endeavour to keep regulatory burdens to the minimum necessary. The IA explains in its Annex 1 (pp. 83-85) how the comments included in the RSB's opinion were addressed. Overall, the IA appears to have addressed the RSB's comments.

## Coherence between the Commission's legislative proposal and IA

Overall, the proposal appears to be largely consistent with the analysis provided in the IA.

The IA defines clearly the problems to be addressed and their analysis appears to be satisfactory, while the analysis regarding the underlying drivers could have been developed in a more comprehensive way. The description of how the problems would evolve without any EU intervention is very limited. The IA compares the four retained options against the criterion of effectiveness in meeting the policy objectives, but does not include any comparison in terms of efficiency and proportionality, contrary to what the Better Regulation Guidelines require. The IA appears to have done a convincing analysis of the economic and social impacts of the options retained for assessment and provided estimates for some of them. Moreover, the qualitative analysis of other impacts appears to be justified by the problem definition and the objectives of the proposal. The IA includes a very comprehensive report of the consultations held, specifically referring to the received feedback in several parts of the report. Overall, the analysis done in the IA appears to be well grounded. The IA appears to have addressed the RSB's comments and the proposal appears to be largely consistent with the analysis provided in the IA.

## ENDNOTES

<sup>1</sup> See N. Šajn, [General product safety regulation](#), EPRS, European Parliament, 2021. See also E. Binder, [Revision of the General Product Safety Directive](#), EPRS, European Parliament, 2021.

This briefing, prepared for the IMCO committee, analyses whether the principal criteria laid down in the Commission's own Better Regulation Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal.

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