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IMPACT ASSESSMENT

Accompanying the document

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

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Glossary

Term or acronym	*Meaning or definition*
AI	Artificial Intelligence
Charter	Charter of Fundamental Rights of the European Union
CSN	Consumer Safety Network
DSA	Digital Services Act
EEA	European Economic Area
EU	European Union
FIPD	Council Directive 87/357/EEC concerning the safety of food-imitating products
GPSD	Directive 2001/95/EC on the general safety of products (General Product Safety Directive)
ICT	Information and Communication Technology
IA	Impact Assessment
IoT	Internet of things
MSA	Market surveillance authority
OPC	Open Public Consultation
Pledge	Product Safety Pledge
REFIT	Regulatory fitness and performance check
Safety Gate/RAPEX	EU Rapid Alert System on dangerous consumer products
SME	Small and Medium Enterprise
Subgroup	Sub-group on AI, connected devices and other challenges for new technologies to the Consumer Safety Network
GPSD Study	The study commissioned by the Commission to support the evaluation and impact assessment of the GPSD revision and conducted by CIVIC consulting
TFEU	Treaty on the Functioning of the European Union

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

This report aims at assessing the impacts of a revision of the Directive 2001/95/EC on general product safety[1] (GPSD). It analyses also the impacts of a possible integration of the Directive 87/357/EEC[2] concerning the safety of food-imitating products (FIPD) into the GPSD.

The objective of the **GPSD** is to ensure EU consumers are protected from dangerous products and to ensure the proper functioning of the Single Market. The GPSD provides the general EU legal framework for the safety of non-food consumer products and requires that all products placed on the market be safe. The non-food consumer products include all products (including in the context of providing a service), which are not food stuff and are intended for consumers or are likely to be used by consumers, and are supplied or made available to them in the course of a commercial activity, be they new, used or reconditioned[3].

As illustrated in the Table 1, the **non-food product safety framework** is mainly made up of two sets of legislative instruments:

- **Union Harmonisation (hereinafter harmonised) legislation**: Regulation (EU) 2019/1020 on market surveillance and compliance of products together with the product-specific safety legislation, such as the toys or the machinery directive form 'harmonised legislation' (legislation setting common rules across the EU for specific sectors)
- **The GPSD**: As *lex generalis*, it applies to non-food consumer products to the extent that there are no specific provisions with the same objective in rules of Union law governing the safety of the products concerned, such as EU harmonised legislation for specific categories of products. Therefore it fully applies to non-harmonised consumer products and also partially to the consumer harmonised products for aspects not covered by the harmonised legislation. As such, it provides a "safety net" for consumers and aims to ensure that EU consumers are protected against any safety risks of consumer products, including future ones.

[1] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety
[2] Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers
[3] The definition of product in the GPSD excludes second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used.

Table 1: General overview of the Product Safety Framework

<table>
<tr><th colspan="5">Product Safety Framework</th></tr>
<tr><th rowspan="3">Areas \ Products</th><th colspan="3">Non-food</th><th>Food</th></tr>
<tr><th colspan="2">Non- Harmonised</th><th>Harmonised</th><th rowspan="4">General Food Law Regulation Regulation (EC) No 178/2002
and
Regulation (EC) 1935/2004 on food contact materials</th></tr>
<tr><th>Non-consumer</th><th colspan="2">Consumer</th><th>Non-consumer</th></tr>
<tr><td>Obligations of economic operators</td><td rowspan="3">National Law under the mutual recognition Regulation</td><td rowspan="3">GPSD</td><td>Sector specific Union harmonisation legislation
+ GPSD as safety net</td><td>Sector specific Union harmonisation legislation</td></tr>
<tr><td>Market surveillance on the internal market</td><td>Regulation (EU) 2019/1020
+Ability for market surveillance authorities to take “more specific measures” provided for in GPSD</td><td>Regulation (EU) 2019/1020</td></tr>
<tr><td>Safety Gate (RAPEX)</td><td>Regulation (EU) 2019/1020 and GPSD</td><td>Regulation (EU) 2019/1020 and GPSD</td></tr>
<tr><td>Customs control for products imported to the EU</td><td colspan="3">Regulation (EU) 2019/1020</td><td>Regulation (EU) 2017/625</td></tr>
</table>

The GPSD, as a safety net, is complementary to harmonised legislation in two ways. First, it applies in its entirety to consumer products falling outside the scope of harmonised legislation (e.g. furniture, childcare articles, clothes). Secondly, it applies partially to consumer products covered by harmonised legislation (e.g. toys or cars) as long as aspects of product safety covered by the GPSD are not covered in the harmonised legislation (for example, until very recently EU legislation for cars did not include provisions on product recalls, that were subject to the GPSD).

The concept of safety under the GPSD always covers levels of protection for the safety and health of persons, i.e. the dangerous product under the GPSD poses a risk to the health and safety of consumers. These risks can materialise in different ways but to be covered under the GPSD the risks always have to relate to health and safety of consumers. Other types of safety such as material damages are not covered unless they are linked to the safety and health of consumers.

Regarding **market surveillance**, there are also **two different systems** in place: one for harmonised products (Regulation (EU) 2019/1020) and another under the GPSD for non-harmonised products and risks falling under the scope of the GPSD.

The GPSD does not cover pharmaceuticals, medical devices and food products. The safety of food products is regulated separately under the General Food Law Regulation (EC) No 178/2002. The food products have their own regime, including an alert system (RASFF). However, the Regulation (EC) No 1935/2004 on food contact materials can interact with the GPSD when it comes to products containing such materials (e.g. reusable lunch boxes). Unsafe products containing food-contact materials products might be subject to safety alerts in both alert systems, RASFF for food and Safety Gate/RAPEX for non-food products.

The GPSD provides for the obligations of economic operators in the product safety field, in particular the general obligation for producers to place only safe products on the market. It contains rules on the power and obligations of Member States and on market

surveillance. The GPSD establishes provisions on the application of the general safety requirement and on the adoption of European safety standards supporting the legislation, which provide presumption of safety and therefore facilitate the compliance with the safety requirement under the GPSD. The GPSD includes obligations for Member States and the Commission to inform consumers about dangerous products and contains the legal basis for the EU Rapid Alert System (Safety Gate/RAPEX), which enables quick exchange of information between EU/EEA countries and the Commission on measures taken on unsafe non-food products posing a risk to consumers[4]. Finally, the GPSD also establishes cooperation on product safety between the Commission and Member States authorities competent for product safety in the context of the Consumer Product Safety Network 'CSN'.

Directive 87/357/EEC[5] (Food-Imitating Products Directive, 'FIPD') sets out rules for the safety of food-imitating products, i.e. products which can be confused with foodstuffs, while not being food-stuffs. The FIPD has been originally adopted to address divergence in national provisions on products which, appearing to be other than they are, endanger the safety or health of consumers[6]. The measures taken against unsafe food-imitating products by Member States are also notified in the Safety Gate/RAPEX.

The scope of this initiative covers therefore all non-harmonised consumer products, food-imitating products and also partially also harmonised products for aspects not covered by the harmonised legislation. However for some aspects the analysis also includes harmonised products, where data could not be dissociated between the harmonised and non-harmonised products.

The Commission has adopted **guidance** to clarify some of the aspects of the GPSD. The Commission Notice on the market surveillance of products sold online (2017/C 250/01)[7] provides guidance for the enforcement of EU legislation on the safety and compliance of non-food products sold online. The Notice also sets out good practices for the market surveillance of products sold online and for communication with businesses and consumers. On 9 November 2018, the Commission also revised the guidelines for the functioning of Safety Gate/RAPEX[8] (originally adopted in 2004 and revised for the first time in 2010).

ECJ Jurisprudence does not bring particular element helping interpreting the provisions of the GPSD, most of it being linked either to access to documents or to non-applicability in the presence of harmonised legislation.

At international level, very different approaches to product safety can be distinguished: Few jurisdictions, such as Canada and more recently Brazil (in 2019), have adopted a safety regulatory framework which includes a general safety requirement, similar to the EU "safety net". This approach is usually considered in international fora as the best way

[4] Regulation (EC) 765/2008 and the new Regulation (EU) 2019/1020 on market surveillance and compliance extends the scope of Safety Gate/RAPEX also to products to be used by professionals

[5] Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which, appearing to be other than they are, endanger the health or safety of consumers

[6] These pre-existing national provisions were differing in content, scope and field of application and therefore creating barriers to the free movement of goods and unequal competitive conditions on the market without ensuring effective protection for consumers, especially children.

[7] Commission Notice on the market surveillance of products sold online (2017/C 250/01) of 28 July 2017

[8] Decision 9 November 2018 laying down guidelines for the management of the Community Rapid Information System (RAPEX). According to Annex II, point 8 of GPSD, the Commission regularly update such guidelines. The new version of the guidelines updates the scope and purpose of safety Gate/RAPEX, integrates certain aspects of Regulation (EC) 765/2008 on market surveillance of harmonised products (inclusion of professional products and extension of the risks to risks other than those for the health and safety of consumers (e.g. environmental risks), includes a reference to new tools developed over the last years for the proper functioning of Safety Gate/RAPEX, clarifies notification criteria and enhances traceability, which is essential for follow up by countries in the Safety Gate/RAPEX network.

to ensure that regulators have an appropriate legal basis to order corrective measures against all types of dangerous products, notably when facing emerging safety issues that are not subject to any regulation yet[9].

In some jurisdictions such as the United States (US) or New Zealand, liability rules play a major role to complement product safety provisions and private enforcement is a key aspect of such systems. The US system also relies on a sophisticated injury data collection scheme and deterrent penalties incentivising businesses to inform as soon as possible the consumer product safety agency about dangerous products they are responsible for. In China, governmental approvals (be it certification, license, registration or individual approval) are required for many products and groups of products before they can be placed on the market.

Fora for multilateral product safety cooperation, such as the OECD and UNCTAD, provide opportunities to learn about and get inspiration from other jurisdictions' best practices and new regulatory developments.

Political context

The Commission announced the revision of the GPSD in its **Work Programme 2020** and confirmed it in the Adjusted Commission Work Programme 2020 published on 27 May 2020, as one of its REFIT (Regulatory Fitness and Performance Programme)[10] initiatives under the headline objective "A New Push for European Democracy". This revision is also one of the legislative proposals mentioned in the Communication of the Commission on New Consumer Agenda[11], published on 13 November 2020.

In the field of **new technologies** (including artificial intelligence 'AI'), the Commission published a Report on safety and liability implications of AI, the Internet of Things and Robotics[12] accompanying the White Paper on AI[13] in February 2020. The report highlights the need to include clear provisions in the EU product safety legislation, including the GPSD, to explicitly address safety risks linked to products incorporating new technologies (connected products and AI).

The other EU institutions have also highlighted the importance of product safety policy. The **European Parliament** adopted a resolution on addressing product safety in the Single Market on 25 November 2020[14] which also emphasised the need to revise the GPSD.

In its Presidency conclusions on The Charter of Fundamental Rights in the context of Artificial Intelligence and Digital Change[15], the **Council** stated that while these technologies may enhance the market surveillance of product safety on the EU market, they may also pose new challenges to consumer protection in the product safety area. The Council Conclusions on Shaping Europe's Digital Future[16] of 9 June 2020 mention that

[9] See for instance the OECD Recommendation on Consumer Product Safety from 17 July 2020, https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0459#mainText

[10] REFIT is the European Commission's regulatory fitness and performance programme established in 2012 to ensure that EU law is 'fit for purpose'. It is a process under which existing legislation and measures are analysed to make sure that the benefits of EU law are reached at least cost for stakeholders, citizens and public administrations and that regulatory costs are reduced, without affecting the policy objectives pursued by the initiative in question.

[11] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0696

[12] https://ec.europa.eu/info/publications/commission-report-safety-and-liability-implications-ai-internet-things-and-robotics_en

[13] https://ec.europa.eu/info/files/white-paper-artificial-intelligence-european-approach-excellence-and-trust_en

[14] https://www.europarl.europa.eu/doceo/document/TA-9-2020-0319_EN.html

[15] https://www.consilium.europa.eu/media/46496/st11481-en20.pdf

[16] https://www.consilium.europa.eu/media/44389/st08711-en20.pdf?utm_source=dsms-auto&utm_medium=email&utm_campaign=Shaping+Europe%e2%80%99s+digital+future+-+Council+adopts+conclusions

digital economy is to be characterised by a high degree of trust, security, safety and choice for consumers[17].

Finally, the review builds on the results of the **Evaluation of the GPSD and the FIPD**, conducted back-to-back to this Impact Assessment ('IA') in order to assess the performance of GPSD in line with the Commission's Better Regulation rules (see Annex 5). The Evaluation showed the necessity to adapt the GPSD to address product challenges related to e-commerce as well as the rapid development of new technologies, and to ensure better enforcement and more efficient market surveillance for consumer products, including by aligning the systems for harmonised and non-harmonised products. Furthermore, the Evaluation also showed the necessity to modify some of the provisions of the GPSD to improve its effectiveness. For example, legislative changes are needed to improve the effectiveness of product recalls, as well as the treatment of food-imitating products.

The Commission already proposed to revise the GPSD with the **2013 Product Safety and Market Surveillance Package**. This 2013 Package - made up of two proposed Regulations, one on product safety (COM(2013)078), the other on market surveillance (COM(2013)075), aimed at enhancing product safety rules and creating a single set of market surveillance rules for harmonised and non-harmonised products. The 2013 Package was blocked in the inter-institutional process as the Council did not agree on a common position because of a proposed provision on the mandatory marking of the origin of industrial products (the "Made in" provision). The proposals were finally withdrawn by the Commission in September 2020.

Legal context

The legal framework relevant for the safety of consumer products has evolved with the adoption of several legal acts:

With the adoption of **Regulation (EU) 2019/1020**[18] **on market surveillance and compliance of products**, the legal framework for market surveillance of harmonised products has changed and has been adapted in particular to the challenges linked to the online sales. The market surveillance of non-harmonised products, also initially included in the 2013 Product Safety and Market Surveillance Package, remained unchanged. The differences between the two market surveillance frameworks have been therefore perpetuated with the adoption of Regulation (EU) 2019/1020, except for the provisions on products entering the EU market, which apply to all products covered by Union harmonisation law under Regulation (EU) 2019/1020. This Regulation widened the difference between the regime applicable to harmonised and non-harmonised products, in particular by envisaging new powers and cooperation instruments for market surveillance authorities ('MSAs') and introducing some new features such as the "responsible person", according to which any economic operators that wants to sell its products into the EU market has to be represented by an economic operator in the EU (applicable not to all harmonised products but only to some of them).

[17] Council stressed also that some AI applications can entail a number of risks, such as biased and opaque decisions affecting citizens' fundamental rights, such as the rights to safety and security. Concerning software, Council underlined the potential of safe, secure, sustainable and trusted hard- and software value chains to enable and establish trust in European digital technologies. Council also stressed the need to enhance citizens' safety and to protect their rights in the digital sphere across the Single Market and the need for effective and proportionate action against illegal activities and content online, including the distribution of dangerous goods.

[18] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011

In the standardisation area, the Commission adopted **Regulation (EU) 1025/2012**[19] on **European standardisation**, which provides the general framework for the adoption of European standards for products and services (to help assessing conformity with Union legislation), identifies Information and Communication Technology ('ICT') technical specifications, and allow financing for the European standardisation process. It also sets an obligation for European Standardisation Organisations (CEN, CENELEC, ETSI) and National Standardisation Bodies on transparency and participation.

The adoption of the new **Regulation (EU) 2019/515**[20] facilitates the application of the principle of **mutual recognition** according to which, where no harmonised rules exist at European level, products lawfully marketed in one Member State can be sold in other Member States regardless of complying or not with the national technical rules of these Member States.

Links with other legal initiatives

The GPSD initiative has the following links with other recent and ongoing proposals:

Digital Services Act (DSA)[21]: The DSA presented by the Commission on 15 December 2020 includes a new set of horizontal rules to regulate the responsibility of online intermediaries, including online marketplaces[22]. The DSA proposal aims to establish new obligations for online intermediaries inter alia in relation with how they handle all types of illegal content hosted on their websites (e.g. unsafe products, counterfeit products, hate speech, etc). The DSA establishes the general horizontal obligations for online intermediaries and leaves room for legislation in relation with specific types of illegal content (such as product safety) to be more specific. For example, the DSA provides the general framework for the notice-and-action system, but without providing the details on the timeframe or the procedure, which could then be set up in the revised GPSD (GPSD would provide a specific timeline and detailed procedure for such notices of unsafe products). The GPSD may also regulate other product safety aspects of online sales beyond the role of online intermediaries, such as the role of sellers and the powers of market surveillance authorities.

Artificial Intelligence (AI) horizontal framework: The new legislative proposal for AI horizontal framework lays down harmonised rules for the placing on the market, the putting into service and the use of artificial intelligence systems ('AI systems') in the Union, consistent with a high level of protection of the public interests, in particular health and safety, and fundamental rights and freedoms of persons. It lays down specific requirements with which high-risk AI systems must comply and imposes obligations on providers and users of such systems (for example, regulating inter alia safety aspects of AI applications in products such as machinery or lifts). Consequently, and with respect to product safety, it will establish specific requirements for certain AI applications, and the GPSD would apply as a safety net for products and safety aspects not covered by the AI horizontal legislation, and therefore complement it. The scope of the initiative is such that it is likely that some AI applications would remain not covered (e.g. some consumer

[19] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council

[20] Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008.

[21] https://eur-lex.europa.eu/legal-content/en/TXT/?qid=1608117147218&uri=COM%3A2020%3A825%3AFIN

[22] The DSA provides for several due diligence obligations relevant for the product safety area, namely obligations on notice & action, know your business customer, cooperation with authorities as well as clear terms and conditions including respect for consumer protection rights.

products such as vacuum cleaners). The revised GPSD would therefore need to provide a legal basis for withdrawing such products from the market to ensure an effective protection of consumers.

Delegated acts under the Radio Equipment Directive (RED): the RED establishes the possibility for the Commission of adopting delegated acts in relation with several aspects, including protection of personal data and fraud for specific categories of radio devices. The Commission is working on several delegated acts that might partially address the issue of products presenting cybersecurity risks. However, it will not be possible to cover all possible consumer products via delegated acts, for instance, devices connected by cable. Such gaps might be covered by a revised GPSD in its role of safety net.

Directive on Security of Network and Information Systems (NIS): The recent proposal for a NIS 2 Directive, presented by the Commission on 16 December 2020, lays down obligations for all Member States to adopt a national strategy on the security of network and information systems. However, it does not include minimum cybersecurity requirements for consumer products, so it does not provide any legal basis for authorities to take action against products presenting such risks. The **Cybersecurity Act** (**Regulation (EU) 2019/881)** introduces an EU-wide cybersecurity certification framework for ICT products, services and processes. However, it does not include minimum cybersecurity legal requirements for ICT products. The GPSD is therefore complementary to these initiatives to fill these gaps.

Circular Economy: According to the new Circular Economy Action Plan, products placed on the EU market should be more sustainable and designed therefore to last longer, to be easier to repair and upgrade, recycle and reuse. It is essential that repaired, upgraded, recycled or reused products continue to meet product safety requirements. According to the Eco-design directive (Directive 2009/125/EC), safety and health have to be taken into account in the choice of a specific design solution; however safety issues related to the end products are not specifically addressed. The Sustainable Product Policy Initiative (which intends to replace the Eco-design directive and extend its scope) will notably aim at correcting the fact that many products cannot be easily and safely reused, repaired or recycled. In case some safety aspects related to products in the circular economy (such as refurbished appliances or clothing made from recycled plastics) are not specifically addressed by initiatives from the Circular Economy Action Plan and do not fall under harmonised legislation, the safety net function of the GPSD comes into play.

2. PROBLEM DEFINITION

2.1. What are the problems?

The Evaluation and the stakeholder views show that the **GPSD appears overall to have met its objectives** of ensuring a high level of safety of consumers, while ensuring an effectively operating internal market for goods; however, **still too many unsafe products reach or remain in the hands of consumers**.

On the EU Single Market there should not be obstacles and barriers to the free movement of goods, which enables unsafe goods to circulate within the EU. Concerning the trend in the safety of products, the evaluation showed that the notifications of dangerous products by market surveillance authorities ('MSAs') in the Safety Gate/RAPEX increased, from 2005 to 2010, from around 540 to 2000 notifications/year and then fluctuated between 1 550 to 2 100 notifications/year (30% of which concerned non-harmonised products).

Also the number of follow-up measures[23] reported in Safety Gate/RAPEX has steadily increased since data started to be gathered in this respect by the European Commission in 2011. Some encouraging signs, such as improvements in product safety perceived by consumers and a plurality of stakeholders[24]can be observed; however, available data show that unsafe products are still available on the EU market. The share of dangerous products found by MSAs in inspections represents between 2% and 16% of total consumer products inspected, with a median value of 4%[25]. Unsafe products on the EU market affects consumers as well as economic operators that play by the rules as they suffer from lack of level playing field with "rogue operators" from inside and outside the EU not observing EU product safety rules.

Unsafe products represent an **important cost for consumers and society**. The GPSD Study supporting the GPSD Evaluation and IA (hereinafter 'GPSD Study')[26] estimates the consumer detriment due to unsafe products today in the following way:

- *Consumer detriment linked to product-related injuries and premature death:*

The total detriment to EU consumers and society from product-related injuries and premature death to be EUR 76.6 billion per year. This is the sum of detriment caused by non-fatal product-related injuries and the cost of premature death where a consumer product is involved (e.g. accident with tools, strangulation, electrocution, or fire) occurring outside of work-related locations[27]. This figure includes health care utilisation costs, productivity losses, loss of quality of life, cost of premature death linked to injuries due to consumer products (both harmonised and non-harmonised) in the EU.

The analysis based on previous research and interviews with product safety experts concluded that 15% is a reasonable and cautious estimate for the proportion of this total detriment that was caused by unsafe consumer products, or could have been prevented through better design, instruction or a safety device. These 15% of accidents could have been prevented if the products were safe. On this basis, the **preventable detriment** suffered by EU consumers and society due to product-related accidents can be **estimated at EUR 11.5 billion per year**[28].

- *Consumer detriment linked to the loss of value of unsafe products*

In addition to the above injury related detriment, the GPSD Study estimates that the consumers also suffered financial costs of a **total value of EUR 19.3 billion in 2019 arising from the fact they have purchased unsafe products** that they would not have

[23] Follow-ups can be defined as the feedback received from Member States participating in the Rapid Alert System on actions they have taken following up another country's alerts on their own market.
[24] Source: European Commission 2016 and 2018 survey of consumers' attitudes toward cross-border trade and consumer protection and the GPSD Implementation report
[25] Source: the GPSD Study. Member States inspections can be targeted so these figures cannot represent the proportion of all unsafe products on the EU market.
[26] Study to support the preparation of an evaluation of the General Product Safety Directive as well as of an impact assessment on its potential revision, prepared by Civic consulting, December 2020
https://ec.europa.eu/info/files/study-support-preparation-evaluation-gpsd-well-impact-assessment-its-revision-part-1-evaluation_en
https://ec.europa.eu/info/files/study-support-preparation-evaluation-gpsd-well-impact-assessment-its-revision-part-2-impact-assessment_en
[27] These estimates are based on the best possible approximation of product-related injuries and fatalities. The detriment cannot be estimated separately by categories of products and therefore include all consumer products, harmonised and non-harmonised products.
[28] 15% of EUR 76.6 billion per year. This is the part of the total injury detriment linked to the injuries/deaths caused by the unsafe aspect of the products. These accidents could have been prevented if the products were safe. The remaining EUR 65.1 billion are injuries/deaths where a product is involved but the accident is not caused by the unsafe aspect of the product (e.g. falling from a ladder is a product-related accident but it doesn't mean that the ladder itself is unsafe). This part cannot be prevented.

purchased if they knew these products were unsafe (hereinafter 'consumer detriment linked to the value of unsafe products'). The estimation is based on the fact that the value of unsafe non-harmonised products per year is estimated at EUR 3.9 billion for online sales channels, and EUR 15.4 billion for brick-and-mortar shops and other offline sales channels, for a total of EUR 19.3 billion. This detriment is reduced due to recalls (under current low recall effectiveness scenario) by approximately EUR 0.4 billion per year, assuming that consumers are compensated fully for all non-harmonised products they returned to producers in response to a product recall. This detriment relates to non-harmonised products covered by the GPSD and is based on the assumption that the loss in consumer welfare is at least the price to which the product was purchased.[29]

The presence of unsafe products on the EU market **affects** therefore both **EU consumers** (final users of products) who bear the risk of accidents, injury or death caused by dangerous products and related costs and **Member States** who bear increased health expenditure costs resulting from health treatment of injuries caused by dangerous products.

The circulation of unsafe products on the EU market also creates a **problem for the Single Market**: it does not only contravene the principle of free circulation of goods (only safe goods are allowed to circulate in the Single Market), but it also risks to create distortions of competition on the EU Single Market. Economic operators compliant with EU product safety rules face compliance costs in comparison with non-complaint operators. At the same time, the presence of unsafe products on the EU market puts in danger the health and safety of EU consumers, which also undermines consumer's trust and confidence in the EU Single Market. Trust is an essential engine of consumers' consumption and therefore the growth of the EU economy[30]. The Eurobarometer data indicate a decrease between 2016 and 2018 in confidence of consumers in the safety of products sold in the EU[31].

Also, in the open public consultation ('OPC') a large majority of respondents (71%) expressed that current EU safety rules for non-food consumer products covered by the GPSD could be improved in specific areas to be more adequate to protect consumers[32].

2.1.1. Product safety challenges linked to new technologies

At the time of the adoption of the Directive the number of consumer products incorporating **new technologies** was scarce. This is not the case anymore. The scenario is likely to evolve with the increasing use of AI, impacting the whole EU market. Moreover, there were 14.2 billion connected devices in 2019 worldwide, a figure that is estimated to go up to 25 billion by 2025, of which 4.9 billion estimated to be in Europe[33].

The **application of the GPSD to new technology** products, such as connected devices or AI-powered products, is not crystal-clear and the safety of these products is not fully covered by other EU legislation. The GPSD does not explicitly address the fact that new

[29] This relates to non-harmonised consumer products covered by the GPSD. This is based on the assumption that willingness to pay (WTP) for a product depends on the utility of the product for the purchaser. WTP is equal or higher as the price for which a product is purchased by a consumer, as otherwise the transaction would not take place. It is very likely that WTP would be close to zero for an unsafe product (nobody wants to buy e.g., a dangerous childcare product) – so the loss in consumer welfare is at least the price to which the product was purchased.This calculation assumes that the consumers do not get reimbursed for the unsafe product.

[30]Consumer consumption represented 52,6% of the GDP of the EU in 2019. Source: https://ec.europa.eu/eurostat/statistics-explained/index.php/Household_consumption_by_purpose

[31] See European Commission 2016 and 2018 survey of consumers' attitudes toward cross-border trade and consumer protection.

[32] See Annex 11 on results of the OPC.

[33] Netherlands Entreprise Agency - https://www.cbi.eu/market-information/outsourcing-itobpo/intergrated-internet-things/market-potential

technologies, in particular AI and goods with digital elements[34], can impact product safety. In the OPC almost half the respondents considered the safety of products involving new technologies not to be adequately regulated (47%)[35]. The Evaluation showed that this can be problematic, as the development of new technologies mean that some of the provisions of the GPSD are not well adapted to respond to its objective of ensuring that all products (including those incorporating new technologies) must be safe for consumers.

As such, new technologies pose **challenges to the concepts and definitions** used under the GPSD. New technology-based products also bring **new risks** to consumers' health and safety or change the way the existing risks could materialise. These new risks, such as cybersecurity threats, might be possibly present in consumer products and this remains not explicitly covered in EU legislation for the moment. Besides, the applicability of software updates for product safety is still not regulated under EU legislation either (lack of clarify of the responsibilities of economic operators when for example an application is downloaded into a product modifying its safety features).

A typical example is when a product becomes dangerous by not possessing a minimum level of cybersecurity, leaving it open to hacking by a malicious party; that was the case of a passenger car notified in the Safety Gate/RAPEX[36]. The radio in the vehicle might have had certain software security gaps allowing unauthorised third party access to the interconnected control systems in the vehicle. If these software security gaps were exploited by a third party for malicious purposes, a road accident could have occurred. The Sub-group on AI, connected devices and other challenges for new technologies to the Consumer Safety Network ('the Subgroup') highlighted that the lack of explicit mention in the GPSD of cybersecurity risks affecting safety ('cybersafety') posed a challenge for the protection of consumers and legal certainty for businesses.

Another example relates to consumer's personal security that can be endangered by third party accessing their information, as illustrated in another notification in Safety Gate RAPEX of a smartwatch for children[37]. The Icelandic authority argued that this product would not cause a direct harm to the child wearing it, but lacking a minimum level of security, it can be easily used as a tool to have access to the location of the child. As one of the product's intended function is to keep children safe through localisation, a consumer would expect that it would not pose security threats to children that may affect their safety by them potentially being tracked and/or contacted by anyone. As measures regarding this product were notified to Safety Gate/RAPEX, authorities in the Member States took follow-up actions. However, the Evaluation showed that many of those authorities were unsure whether the GPSD[38] was applicable to such risks due to the lack of explicit provisions in this respect. The Sub-group also raised the fact that it is unclear under which legal or policy instrument such personal security risks should be tackled so that consumers are effectively protected against such threats.

In addition, the Subgroup stated that there is evidence that new technologies can have an impact on the **mental health** of consumers; e.g. connected products as a cause of

[34] As defined in Directive (EU) 2019/770 on certain aspects concerning contracts for the supply of digital content and digital services 'goods with digital elements' means any tangible movable items that incorporate, or are inter-connected with, digital content or a digital service in such a way that the absence of that digital content or digital service would prevent the goods from performing their functions.

[35] See Annex 11 on the results of the OPC

[36] RAPEX notification from Germany published in the EU Safety Gate (A12/1671/15) of a passenger car.

[37] Example RAPEX notification from Iceland published in the EU Safety Gate's website (A12/0157/19) of a smartwatch for children.

[38] The legal basis of this notification was the GPSD as at the moment there was no delegated acts under the RED which could cover this case.

depression, loss of sleep, altered brain function and myopia or early blindness in students[39] and children[40]. It was also noted however that some mental health challenges linked to products do not originate from new technologies, they were prevalent before digitalisation. The subgroup also expressed that it was unclear if mental health risks are covered under the current definition of safety of the Directive, and that mental health harm intrinsically caused by a product itself should be covered.

Moreover, it is not clearly stated to what extent the **definition of "product"** includes **software**, whether it is sold with the product or associated with the product later on. This might impact the safety assessment of the given product. New technologies also pose challenges related to the **notion of placing a product on the market**[41]. For example, products including new technologies can evolve and their safety features may change via software updates or machine learning after they have been placed on the market.

Many of the problems linked to new technologies are crosscutting, so the Commission has adopted or is working on a number of proposals in relation to those issues. In some cases specific risks linked to new technologies can be tackled by EU harmonised legislation. While such proposals may partially address the gaps identified, there are some aspects that remain or will remain not covered and for which action is still needed in the context of this initiative.

The Commission is currently developing a delegated act under the **Radio Equipment Directive** and assessing whether the provisions of that Directive referring to the combination of radio equipment and software should apply to certain categories of products covered by that Directive, as well as to standalone software uploaded onto connected products that communicate via certain radio modules. The Commission is also reviewing the **Machinery Directive** to address those types of risk having an impact on safety, for example protecting the machinery against malicious third parties or lack of connectivity. However, despite this, there are still some gaps in addressing safety risks of consumer products containing new technologies not already covered by other EU legislation. Home appliances connected to the Internet by cable e.g. will not be covered under the delegated acts of the Radio Equipment Directive, so cybersecurity risks of such products will not be covered by such delegated acts. In addition, in view of the highly innovative potential of the new technology sector, it is difficult to foresee the safety features and risks of these new technology products.

Finally, the Subgroup also mentioned that one of the common characteristics of AI and Internet of things ('IoT') products is the presence of software that can change/evolve over time. This challenges the traditional meaning of the concept of placing on the market of the GPSD. Therefore, the Subgroup recommended that a possible GPSD revision should clarify that products should be safe over their whole expected lifespan, and should explore the introduction of the concept of 'substantial modification' affecting the safety of the product after a product was once placed on the market.

This problem affects all consumers purchasing new technology products and causes particular difficulties to vulnerable consumers that are not familiar with new technologies, in particular small children and the elderly.

The lack of legal certainty regarding the application of consumer product safety rules to new technologies may create regulatory costs to businesses (especially SMEs) developing

[39] K. Demirci, M. Akgönül, A. Akpinar, 2015. Relationship of smartphone use severity with sleep quality, depression, and anxiety in university students. Journal of Behavioural Addictions, 4(2): 85–92.

[40] Dresp-Langley B. Children's Health in the Digital Age. Int J Environ Res Public Health. 2020 May 6;17(9):3240. doi: 10.3390/ijerph17093240. PMID: 32384728; PMCID: PMC7246471.

[41] The GPSD requires producers to place only safe products on the market (cf Article 3).

and producing new technology products and undermines their efforts to design innovative and cyber-safe products.

2.1.2. Product safety challenges in the online sales channels

While the GPSD applies to consumer products regardless if they are sold offline or online, the **increasing use of e-commerce has negatively influenced** the relevance and **effectiveness of the GPSD**, creating new challenges for the safety of consumers. Online sales increased steadily since the GPSD's adoption: in 2002 only 9% of Europeans purchased online, while over 70% of them shop online today[42]. Furthermore, one out of five companies in the EU nowadays sells online[43].This trend has been amplified by the COVID 19 crisis and related lockdowns: in the EU-27, retail sales via mail order houses or the Internet in April 2020 increased by 30% compared to April 2019, while total retail sales decreased by 17.9%[44] (see Evaluation Annex 5). In addition, many of dangerous COVID-19 related products (e.g. dangerous masks, hand sanitisers) have been found online (by 22 October 2020 they represented 16% of all COVID-19 notifications in Safety Gate/RAPEX from the beginning of the COVID-19 crisis). Furthermore, 39% of respondents in the OPC expressed that safety rules for products covered by the GPSD were not adapted to online trade and among respondents who experienced a product safety incident within the last 5 years, 70% bought this product online[45].

First, the GPSD **does not provide for sufficiently effective instruments for online market surveillance by MSAs**. They lack e.g. powers to acquire product samples under covert identity or block websites proposing dangerous products[46]. This creates inefficiencies in the market surveillance of non-harmonised products sold online, and therefore insufficient action against such products. This affects the consumer trust in online sales. While such instruments exist for the harmonised products covered by Regulation (EU) 2019/1020 on market surveillance, the fact that the latter is not applicable to non-harmonised products will create an uneven level-playing field between these two categories of consumer products in the Single Market once this Regulation will apply[47]. This means that an authority could be entitled to take more effective actions online against a toy bed (a toy being a harmonised product) as opposed to a baby's crib, which falls under the GPSD.

Second, **new online business models** and actors, such as online marketplaces hosting third party sellers, have become prominent and **product safety rules** for these economic operators are **unclear** under the current GPSD. Among European businesses selling goods online, 40% have been using online marketplaces to reach their customers in 2019[48].The GPSD does not establish clear legal obligations for product safety for business models that do not fall under the existing categories of producer, importer or distributor. The online marketplace does not fit to these categories. This affects both consumer protection and safety of products sold online and the related consumer's trust, creates inefficiencies in online market surveillance and creates an uneven level-playing field between the economic operators selling offline and those selling online in the EU.

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[42] Nestor Duch-Brown, 2015

[43] Eurostat (isoc_ec_eseln2), data for 2019.

[44] OECD - E-commerce in the time of COVID-19, http://www.oecd.org/coronavirus/policy-responses/e-commerce-in-the-time-of-covid-19-3a2b78e8/#biblio-d1e705

[45] See Annex 11 on results of the OPC.

[46] On 1st August 2017 the Commission issued a Notice on the market surveillance of products sold online to help public authorities with their market surveillance of online sales but this Notice doesn't create legal tools as such.

[47] The market surveillance provisions under Regulation (EU) 2019/102O will enter into force in July 2021.

[48] ESTAT https://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do See also (Eurobarometer - TNS, 2016) for more granular data based on a 2016 survey

This has been addressed partially through voluntary action: in 2018 several online marketplaces signed **voluntary commitments to improve the safety** of products sold online: **the Product Safety Pledge** (hereinafter 'the Pledge'). The current eleven signatories[49] committed, among others, to react within two days when a government informs them about an unsafe product offered on the platform, to cooperate with national authorities and to fight against repeat offenders. As the Evaluation has highlighted, while these voluntary commitments reflect some progress related to the cooperation between the signatories and authorities, it is challenging to analyse the effectiveness of the Pledge due to a suboptimal reporting system from the signatories. The Pledge has positive impacts, as it has set the grounds for an increased cooperation framework between online marketplaces and market surveillance authorities. However, authorities and stakeholders have signalled in the GPSD Study that as long as the Pledge remains voluntary, the infringement of those commitments cannot be penalised by authorities. It is also challenging to analyse how effective the Pledge is in appropriately ensuring the safety of products sold online, since the Key Performance Indicators (KPIs) are calculated only on certain commitments. From this aspect, the Pledge did not help to get information on specific issues such as on emerging risks of new technologies or improved recalls. The monitoring reports also showed that there has been a divergence in the way online marketplaces calculated the KPIs, making it difficult to extract conclusions from those numbers and properly monitor the effectiveness of the commitments of the Pledge. Finally, there are also many players on the market that have not decided to adhere to the voluntary commitments, creating an uneven level-playing field between online marketplaces targeting EU consumers. Therefore, while the Pledge sets out a very useful mean of cooperation between online marketplaces and national authorities, its effectiveness is limited by the limited range of signatories and by its voluntary nature, limiting enforcement.

Finally, via online sales, EU consumers also **purchase more frequently products offered directly by operators established outside the EU**: the proportion of purchases from sellers outside the EU increased from 17% in 2014 to 27% in 2019[50]. Around 150 million small consignments are imported free of VAT into the EU each year[51]. In 2017 there were 150.000 private consignments coming from China to individual EU consumers per day[52]. This is problematic: first, direct imports make it more complicated to control the safety of the product before it enters the EU market since it is directly delivered in individual packages to the consumer without possibly being handled by any economic operator in the EU subject to products safety obligations under the GPSD[53]. Second, national authorities have difficulties to engage with the trader in case of safety concerns, if the trader is not represented in the EU but is based in a third country. Article 4 of Regulation (EU) 2019/1020 on market surveillance creates an obligation, in case a product is sold in the EU, to have an economic operator in the EU for certain tasks linked to market surveillance of products' safety and compliance, but its applicability is limited to certain categories of harmonised products. If the product safety is not evenly enforced between EU and non-EU operators, this creates an uneven level-playing field between these operators. A study provided by Eurocommerce indicates that the cost difference between products produced in accordance with EU rules and standards, and produced

[49] AliExpress, Allegro, Amazon, Bol.com, C-discount, Ebay, eMAG, Etsy, Joom, Rakuten France, Wish.com
[50] Eurostat https://ec.europa.eu/eurostat/statistics-explained/index.php?title=E_commerce_statistics_for_individuals#E-shopping_from_other_EU_countries
[51] European Commission , Memo 2017 - Modernising VAT for e-commerce https://ec.europa.eu/commission/presscorner/detail/en/MEMO_16_3746
[52] Eurocommerce – Creating a level-playing field for retail in Europe – August 2019
[53] Pure postal and delivery services are exempted from product safety obligations.

without taking account of the EU rules may be important for some products[54]. While these conclusions cannot be extrapolated to the overall market or to all products, they give an indication of the possible detriment due to the presence of rogue traders from third countries.

The Evaluation has also compiled evidence pointing to the fact that the **control of the safety of products sold online is more problematic** than the one for unsafe products found in brick-and-mortar shops. For example, data coming from the Safety Gate/RAPEX for the period 2018-2019 show that the share of notifications of unsafe products in which one of the four traceability information items[55] was missing was between 29,2% and 57,3% (depending on the item) for products 'sold online' and considerably lower (between 12,6% and 35,7%) for products sold offline. None of the traceability information was found in 12,8% notifications of products sold online, while it was only 0,5% for the unsafe products sold offline.

These **problems affect also economic operators**. EU producers face an uneven playing field between them and non-EU producers if those do not comply with EU safety rules and therefore do not bear the compliance costs of the EU product safety legislation. Online marketplaces targeting EU consumers also do not have a level-playing field since the signatories of the Pledge bear additional costs and administrative burden compared to non-signatories that do not take the steps outlined in the Pledge.

In the area of online sales, the product safety obligations of online market places are not spelled out in any EU legislation and current market surveillance provisions relating to products imported from outside the EU are tackled only for certain harmonised products under Regulation (EU) 2019/1020.

Besides, there are also traceability problems with products offered online (the traceability of the online chain is often deficient and there is a gap between the product information available to the consumer for a product sold online and offline). The DSA aims to partly tackle these issues by introducing the "Know-Your-Business-Customer" principle (KYBC) and traceability provisions when it comes to the online sales via certain online marketplaces, leaving scope to the revised GPSD to tackle traceability issues for all online sales.

2.1.3. Ineffective product recalls

Article 5 of the GPSD requires that when a product already sold to consumers turns out to be dangerous, it needs to be recalled (as a **measure of last resort**) to protect EU consumers. But the **GPSD does not set any specific rules regarding the modalities of recalling unsafe products** and evidence suggests that the proportion of products successfully recovered from consumers remains generally low, as recognised by a recent OECD report[56] (even though it varies considerably depending on factors such as channel of sale[57] and product type[58]). For instance, one Member State indicated that the return rate rarely exceeds 10%, except when products have been purchased online[59]. Another national authority estimated that around 80% of products that have relatively low value and short lifespan remain in consumers' hands[60].

[54]Eurocommerce - Creating a level-playing field for retail in Europe – August 2019.
[55] Indication of: manufacturer, brand, type/model, batch number/barcode
[56] OECD (2018), Enhancing Product Recall Effectiveness Globally, p. 5.
[57] Recalls tend to be more effective if the product was bought online because it's easier to identify and directly contact the buyers.
[58] Recall effectiveness increases with product price and expected lifespan and decreases with product age.
[59] Idem, p. 17.
[60] European Commission, 2021, Behavioural study on strategies to increase the effectiveness of product recalls.

The EU-wide societal cost of recalled products remaining in consumers' hands have been estimated at approximately €378 million in 2019 due to healthcare costs, productivity losses and losses of quality of life[61]. The GPSD Study also estimated that the value of recalled products that remain with consumers is today EUR 1.3 billion.

The consequences of delayed and ineffective recalls are also exemplified by the deaths and injuries caused by recent examples of recalled products such as faulty airbags (estimated to have caused 35 deaths and 300 injuries worldwide[62]) and baby sleepers (associated with 59 baby deaths in the US[63]).

The **recall procedure** is **not fully harmonised** in the EU, which leads to different practices, depending on national provisions and economic operators involved. As an example, fewer than half of EU/EEA countries have established codes of good practice or guidelines on recalls, and only few of these documents set out requirements as to the content and channels of recall information or remedies for consumers. The evaluation has identified this as a significant shortcoming, suggesting that existing requirements are in themselves currently not sufficient to ensure effective recalls, leading to two problem areas.

First, **many EU consumers** are **not aware** of **ongoing recalls** of products they own. It is often difficult to reach the owners of the recalled product. Apart from motor vehicles (whose registration with public authorities is mandatory), registration schemes are only available for few higher-value product categories like domestic electric appliances and communication devices, and even there no link is typically made between registration and safety[64]. In addition, economic operators are hesitant about using customers' information collected for other purposes (e.g. in the context of online sales or loyalty programmes) in the event of a recall because of legal uncertainty about the compliance with the General Data Protection Regulation.[65] Also, there are no comprehensive public sources of recall information for consumers. For instance, in most EU/EEA countries, the recalling company has no obligation to put the recall notice on their website or social media and not all Member States' authorities publish recall information on their websites, in addition to reporting recalls to the Safety Gate/RAPEX[66].

Second, consumers **may not return** a recalled product **even if they are aware** of the recall. According to recent surveys, more than a third of EU consumers continue using a recalled product despite seeing a recall notice[67]. This may be caused by recall notices being unclear and/or minimising consumers' perception of risk. For instance, the analysis of existing recall announcements showed that over half of them used terms and expressions, which could downplay risk, such as 'voluntary/precautionary recall', 'potential concern/problem', 'in rare cases/in specific conditions' or highlighting that

[61] Idem
[62] https://www.consumerreports.org/car-recalls-defects/takata-airbag-recall-everything-you-need-to-know/
[63] https://www.washingtonpost.com/gdpr-consent/?next_url=https%3a%2f%2fwww.washingtonpost.com%2fbusiness%2f2019%2f10%2f17%2fstudy-concludes-design-rock-n-play-other-infant-sleepers-led-deaths%2f
[64] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.
[65] European Commission, Notes from EU Workshop on strategies to maximise the effectiveness of product recalls, 23rd October 2019, p. 2.
[66] However, not all recalls need to be notified to Safety Gate/RAPEX. As regards products posing a less than serious risk, notification is encouraged but not mandatory in the case of voluntary measures taken against products covered by the GPSD and in the case of both voluntary and compulsory measures taken against products subject to EU harmonised legislation. In addition, Member States are not required to notify corrective measures in cases where the effects of the product risk cannot go beyond the territory of the Member State.
[67] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls, European Commission, 2019, Survey on consumer behaviour and product recalls effectiveness. Final Report https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/ Product.Recall.pdf

there have been no reported injuries. Also the procedure for consumers to return the recalled product may be complex and burdensome and the remedies offered may not be sufficiently attractive and timely. In a recent consumer survey, recall process taking too much time and effort was the second-top reason for not responding to a recall (after the product being cheap)[68].

The stakeholders especially affected by insufficient recall effectiveness are socially disadvantaged, younger and less safety-conscious consumers (who have shown to be less responsive to product recalls and less likely to register their products[69]) as well as consumers living in remote areas (for whom returning the recalled product can be costly). Diverging national requirements (e.g. on recall communication and remedies) also result in an uneven level-playing field for companies.

2.1.4. Market surveillance rules are complex and not fully effective

Following the adoption of Regulation (EU) 2019/1020, the **market surveillance rules differ for harmonised and non-harmonised products**. This Regulation is applicable to the non-harmonised area under GPSD only regarding the provisions for customs controls. The market surveillance rules under this Regulation apply only to harmonised products and differ from those for non-harmonised products in several aspects: responsible operator in the EU for products entering the EU market, online market surveillance tools (mystery shopping, blocking websites), strengthened market surveillance rules (e.g. Single Liaison Office, cross-border mutual assistance).

The Evaluation has also identified coherence problems resulting from the fact that there are **two different sets of market surveillance rules**, for harmonised and non-harmonised products. One good example is toys (e.g. doll's bed) and childcare articles (e.g. baby's bed), that might be conceptually very close and targeting the same consumers, but are however regulated differently: a toy is a harmonised product regulated by Directive 2009/48/EC, a baby's bed is a childcare article, which is a non-harmonised product, falling under the scope of application of the GPSD. Therefore, market surveillance authorities have different powers for these two products: for example they can carry out online investigations under covered identity for a doll's bed, but not for a baby's bed, as explained above.[70]

This has also clear implications for the effectiveness and efficiency of the GPSD[71] as it may lead to market surveillance inefficiencies and thus higher presence of unsafe products on the EU market in the non-harmonised area. Ensuring coherence between these rules is important both for market surveillance authorities (they have difficulties to apply different rules according to the products, e.g. since they do not have the same market surveillance tools for harmonised and non-harmonised products in online sales) and for economic operator who might deal, at the same time, with both types of products: different rules complicate and make more expensive the business activity.

The Evaluation identified also several **additional problems for market surveillance** of product safety:

[68] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls

[69] Idem, European Commission, 2019, Survey on consumer behaviour and product recalls effectiveness. Final Report https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/ Product.Recall.pdf

[70] Regulation 2019(1020) creates e.g. obligation to designate a responsible economic operator in the EU, possibility to use specific tools for online market surveillance (mystery shopping, blocking websites), etc.

[71] This leads to asymmetrical obligations for the different actors based on whether they are dealing with harmonised or non-harmonised products, leading to administrative burden and complexities for EU businesses.

- Market surveillance and customs authorities lack appropriate instruments to enforce product safety rules for non-harmonised products, in particular in online sales, such as blocking websites, mystery shopping.
- Products are difficult to trace throughout the supply chain. In particular, products such as laser pointers, lighters, jewellery, or decorative articles, that fall within the scope of GPSD and are not subject to sector-specific harmonisation rules, are more likely to lack relevant information items that are essential to trace them in case they are notified to Safety Gate/RAPEX.
- The process for adopting voluntary safety standards for the GPSD products is complex and not sufficiently efficient. It requires a three step process involving comitology. This could be simplified and streamlined.
- There are differences in the GPSD implementation across Member States. (e.g. the traceability requirements differ between Member States).
- There is a lack of a mechanism at EU level to solve divergent positions of Member States regarding the risk assessment of a specific product, which causes a difference in the treatment of some consumer products inside the Single Market. The number of notifications to the Safety Gate/RAPEX that were subject to disputes between Member States has been on average 30 per year.
- The deterrent effect of the GPSD might not be effective enough. A plausible explanation for this suggested by several stakeholders might be that the sanctions and penalties for product safety infringements, that are not harmonised across Member States, remain low. This creates a problem in the context where all products cannot be controlled by the national authorities, in view of their huge volumes and need to facilitate trade and free movement of goods.
- The market surveillance system under the GPSD appears to be operating under considerable resource constraints[72]. Market surveillance authorities have indicated limited staff/financial resources for market surveillance and enforcement most frequently as a key factor influencing negatively the level of achievement of their tasks.
- The difficulty of taking enforcement actions against economic operators outside the EU. This is particularly relevant as the growth of online sales [73] have resulted in an increase of direct imports; around 150 million small consignments are imported free of VAT into the EU each year[74].

Uneven and, in some cases, insufficient enforcement actions can harm EU consumers, since they are exposed to more dangerous products, but also risk to distort competition for EU businesses and create obstacles to free movement of goods. National market surveillance authorities suffer from higher administrative costs as a consequence of cross-border inefficiencies and investigation costs if the relevant operator or the product to be traced are difficult to find. Discrepancies in the GPSD implementation create an uneven playing field between Member States and additional regulatory burden for businesses active across the EU.

The fragmentation of the market surveillance rules between harmonised and non-harmonised products may also create regulatory burden both for national administrations and EU businesses. The complexity of the market surveillance legislation creates higher

[72] See Annex 11 on the results of the OPC. When asked about the main challenges for enforcement half of the respondents considered as problematic that Member States' authorities did not have enough resources (49%), followed by the difficulty of taking enforcement actions against economic operators outside the EU (46%).
[73] Idem
[74] European Commission , Memo 2017 - Modernising VAT for e-commerce
https://ec.europa.eu/commission/presscorner/detail/en/MEMO_16_3746

costs for economic operators (additional costs of complying with different national market surveillance and product safety rules for businesses operating in more than one Member State). The current standardisation process for non-harmonised products also creates unnecessary administrative burden at EU level and undermines the efficiency of the standardisation process under the GPSD.

2.1.5. Inconsistent application of product safety rules for food-imitating products

The legal framework providing rules on safety issues linked to food imitating products is set out in **Directive 87/357/EEC (FIPD)**. This Directive was adopted before the GPSD was created the horizontal legal framework for safety of all non-harmonised products, and it aimed at harmonising the divergent pre-existing national rules on food imitating products[75]. Such separation of rules according to a specific aspect of a product creates **regulatory complexity** for national administrations and economic operators.

As reflected in the Evaluation, the number of Safety Gate/RAPEX notifications of food imitating products is a small percentage of the total. Between 2005 and 2015, a total of 258 notifications (around 17 per year on average) relate to food imitating products. Moreover, it seems that the product category "Food-imitating products" was only used up to 2015; afterwards, the products have been categorised according to their use (cosmetics, clothing, etc.): since 2015, 71 notifications mentioning products not complying with the FIPD have been submitted under other categories such as cosmetics, kitchen/cooking accessories, stationery, or decorative articles. Despite that, the number of notification for food-imitating products remain low. The aspects related to the imitating nature of the product were incorporated in the risk assessment of the product itself, but not in a systematic manner by all Member States.

Indeed, the safety provisions of the FIPD are **applied differently between Member States**, which have diverging positions on substantial issues, in particular whether all food-imitating products should be banned per se or measures against these products should be based on a risk assessment under this Directive. Indeed, the FIPD was adopted before the GPSD, which sets out the principle of the necessity of risk assessment before taking appropriate measures against dangerous products and some Member States started to apply to food-imitating products the GPSD logic while others maintained the primary interpretation of the FIPD as a ban of these products.

Such different application of this Directive leads to an uneven treatment of these products across the EU and risks to create distortions of competition in the Single Market. The stakeholders impacted by this problem are businesses producing such products, due to the lack of clarity of rules, and also European consumers, who are differently protected against these products. National market surveillance authorities also suffer from higher administrative costs due to complexity of the rules. The low number of notifications related to food-imitating products in the Safety Gate/RAPEX also raises a question whether a separate legal regime for these products remains justified.

2.1.6. Problems related to the legal form

The current legal form, a **Directive, creates several problems linked especially to the implementation and national differences** regarding the date and/or manner of transposition. Several problems have been encountered in the application of the GPSD, such as the application of provision on the corrective measures to be adopted in case of a dangerous product found on the market (Article 8 of the GPSD): the measures to be

[75] The first version of the GPSD was the Council Directive 92/59/EEC of 29 June 1992 on general product safety

adopted and the type can vary consistently among Member States national transposition legislation entailing different treatments in different Member States, bringing eventually to fragmentation in the internal market. Even more relevant, in practice, is the different transposition of the provision on traceability (Article 5 of the GPSD): the requirements contained in this article are transposed differently, for example as far as the indication of the batch of a product or the way and location of the identity and details of the producer are concerned.

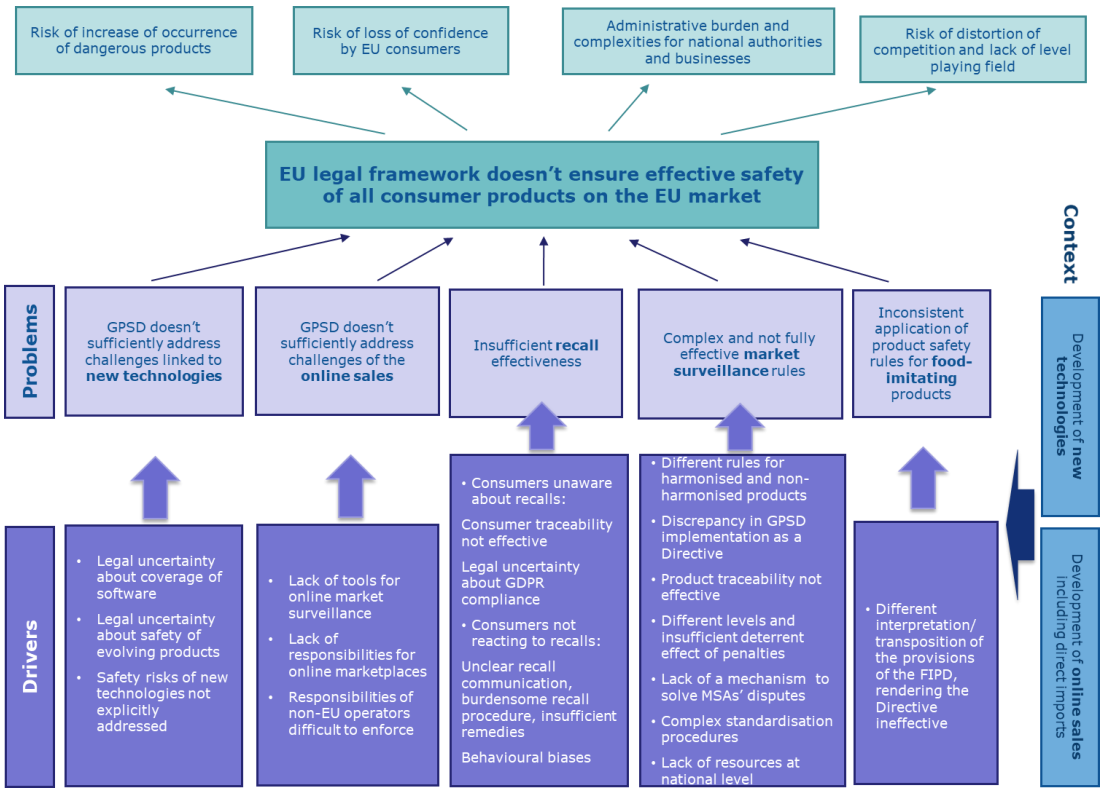
2.1.7. Regulatory burden and costs of the GPSD (REFIT problem)

To summarise, several of the aspects of the current GPSD developed above create unnecessary regulatory burden for MSAs and companies: discrepancies between market surveillance procedures for harmonised products and non-harmonised products, market surveillance inefficiencies between Member States due to diverging assessments and actions taken against products, lack of clarity inter alia about the scope of GPSD, sub-efficient standardisation procedures, different implementation of safety rules for food-imitating products, differences in GPSD implementation, and lack of resources for MSAs to implement the rules.

2.2. What are the problem drivers?

The figure below summarises the main drivers for the general problem and the five specific problems identified above:

Figure 1: GPSD General problem tree



The underlying drivers (causes) for the identified problems are multifaceted:

Table 2: Nature of problem drivers

Problem area	Drivers nature	Drivers' action
General problem of unsafe products occurring on the market	Market failure	Under classical economic rationale, the producer's objective is profit maximisation and therefore to produce the given product at the best price; in the absence of any safety regulation, it may tend to sacrifice the product quality and safety by choosing cheaper components and undergoing less safety verifications. The market price of a dangerous product does not reflect the real cost for the consumer and for the society, in particular the costs of injuries linked to a dangerous product. Therefore, the market does not take into account the negative externalities of dangerous products in terms of reduced public health and increased public health expenses and such market outcome is therefore not optimal for the society. However it also has to be taken into account that it is important for some companies to produce products that are safe for consumers, as their reputation is at stake and they may lose the consumers' trust in their brand.
	Asymmetry of information	Information is needed for markets to operate efficiently. Buyers need to know about the quality and safety of the product to assess its value. The consumer does not know exactly in which way the product has been produced and its exact components, while the safety of a product can be verified including by undergoing a proper laboratory test, which is of course impossible for an individual consumer to do in advance. Consequently, most of the times consumers cannot verify the product safety when buying a product and take this into consideration in their choice; therefore they may make the wrong choice and buy unsafe products, which leads to sub-optimal societal outcomes.
	Split markets	In the markets where actors have different and not aligned objectives and the information is imperfect (as explained above), socially desirable actions are not undertaken and regulation can then redefine the characteristics of products to be placed on the market, as it is the case for product safety legislation.
New technologies	Regulatory failures	The GPSD does not provide enough legal certainty about the coverage of the specific features of new technology products, such as software updates or the evolving nature of some products. Some new types of risks linked to new technologies (such as cybersecurity risks affecting safety) are not explicitly covered, which leads to legal uncertainty. Consequently, the current GPSD does not efficiently play its role of safety net for new technology products.
Online sales	Regulatory failures	When the GPSD was developed, online sales were still at an early stage and therefore the GPSD's provisions do not properly address the challenges of the current online environment. The GPSD does not set out specific obligations related to product safety for the online marketplaces, while these play today an important role in the online sales. Also, the GPSD does not provide for effective investigation tools for online sales. Finally, E-commerce allows for an important increase of direct imports from economic operators located outside the EU. While the GPSD creates product safety obligations for any products being placed on the EU market, regardless of their place of origin, it is very difficult to enforce against traders established outside the Union and offering their products to EU consumers. There are therefore enforcement difficulties allowing the entering of non-harmonised consumer products on the EU market without having an economic operator responsible for these products in the EU.
Recalls	Regulatory failures	Recall procedure as such is not defined under the GPSD. In particular, there are no minimum requirements on the content and channels or recall communication or remedies that consumers are entitled to. In some countries, requirements are more prescriptive than in others, leading to varying levels of consumer protection. One major deficiency is the lack of legal basis for using existing customers' data for recall purposes.
	Market failures (companies fail to act	Companies may **fear the negative reputational impact** and other costs created by a recall and thus avoid communicating clearly about possible safety issues and delay recall measures and/or underplay the risk when the product turns out to be dangerous[76]. Almost half (47%) of industry respondents to a European Commission's survey indicated that they

[76]An analysis of existing product registration schemes indicated that very few companies make a link between registration and safety, while a similar analysis of recall announcements showed that over half of them used terms and expressions, which could reduce consumers' perceptions of risk European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

	effectively)	did not have a written procedure in place in case the product needs to be recalled (even though safety-conscious companies were likely overrepresented in the survey)[77]. Also marketing literature suggests that most companies engage in a passive recall strategy rather than a proactive one[78].
	Behavioural biases (consumer inertia)	Consumers do **not always act in a rational way** in response to recalls. Biases such as information overload and framing effects mean that if recall notices are lengthy and unclear, consumers may ignore them, especially if they are time poor. Over-optimism may result in consumers underweighting the risk posed by a recalled product, while inertia and endowment effect[79] relate to the fact that consumers have an inherent preference for status-quo, which in the case of recalls means keeping the product.
Market surveillance	Regulatory failures	At EU level, the market surveillance rules for harmonised and non-harmonised products are not only set up in two different legal texts, but also the **applicable rules differ** in several aspects for these two categories of products, which creates regulatory complexity for national administrations and businesses. Furthermore, implementation issues stem from the fact that the GPSD is a Directive and as such is not directly applicable in the EU and, as the Evaluation shows, is transposed differently across EU Member States. The GPSD also does not sufficiently harmonise the provisions on the product traceability, which are therefore defined at national level and prove to be insufficient. The GPSD does not tackle the disputes on the risk assessment between Member States, and the standardisation procedure under the GPSD is not efficient enough. At national level, the main driver for enforcement problems is **lack of resources** dedicated to market surveillance by Member States. Also, the current level of penalties and sanctions does not create a sufficient deterrent effect for economic operators to prevent the placing of unsafe products on the market.
Food-imitating products	Regulatory failures	The **uneven application** of product safety rules for **food-imitating products** stems from the fact that the rules are formulated in such a way that it allows a very different application across EU Member States, some categorically banning all food imitating products, some others performing a risk assessment before deciding on the measure. The fact that these rules are set out in another piece of legislation than the rest of the product safety rules creates unnecessary regulatory complexity for national administrations and businesses and leads to incoherent measures on the Single Market.

2.3. How will the problem evolve?

Some of the identified problems will remain and even likely get worse: in particular those linked to online sales and new technologies. There is a clear increasing trend in online sales in the EU. The COVID-19 crisis and the repetitive lockdowns are accelerating e-commerce, as well as imports of consumer products from outside the EU. There is also an increase of new technology consumer products being available on the EU market. Therefore, the magnitude of problems linked to these new digital challenges is likely to increase.

At the same time, digital developments offer also opportunities for more efficient market surveillance by using new technology tools, for example to identify already recalled products online. Online sales may ease the identification of customers, which is particularly important in recalls. Also, connected products may be easier to recall and fix or switch off remotely.

[77] Idem.

[78] Chen, Yubo & Ganesan, Shankar & Liu, Yong. (2009). Does a Firm's Product-Recall Strategy Affect Its Financial Value? An Examination of Strategic Alternatives During Product-Harm Crises. Journal of Marketing American Marketing Association ISSN. 73. 214-226. 10.1509/jmkg.73.6.214
Mukherjee, U., Ball, G., Wowak, K., Natarajan, K. and Miller, J (2021), Hiding in the Herd: The Product Recall Clustering Phenomenon, Manufacturing & Service Operations Management, https://doi.org/10.1287/msom.2020.0937
Kalaignanam, Kartik & Kushwaha, Tarun & Eilert, Meike. (2012). The Impact of Product Recalls on Future Product Reliability and Future Accidents: Evidence from the Automobile Industry. Journal of Marketing. 77. 10.2307/23487412

[79] In behavioural economics the endowment effect is he finding that people are more likely to retain an object they own than acquire that same object when they do not own it

The new Regulation (EU) 2019/1020 will only have a limited effect on the market surveillance for products and risks covered by GPSD since only its provisions on customs (Chapter VII of this Regulation) apply to these products.

Some other problems will also continue to exist and are likely to remain the same or of the same magnitude in the absence of EU action, in particular the fragmentation, complexity and ineffectiveness identified in the market surveillance rules. These problems are mainly linked to regulatory failures of the legal framework itself and would get worse only if there is an increased trend of non-harmonised consumer products circulating on the EU market. Problems linked to lack of resources mostly relates to the political priorities and resources of the Member States.

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

The legal basis for this initiative is Article 114, with due regard to Article 169[80], of the TFEU. The GPSD has for object ensuring product safety and improving the functioning of the internal market. GPSD aims at ensuring a high level of consumer protection, by contributing to protect the health, safety of European consumers and promoting their right to information[81].

The EU has no exclusive competence on product safety, which is a shared competence. Therefore, the subsidiarity principle does apply.

3.2. Subsidiarity: Necessity of EU action

The GPSD harmonises the general product safety requirement in the EU. Ensuring safety of products in the Single Market cannot be achieved sufficiently by Member States acting alone for the following reasons:

- Data show unsafe products are spread across the EU: unsafe products can be found in all Member States[82].
- Products circulate freely across the Single Market, including the dangerous ones. When a dangerous product is identified in a certain country it is very likely that the same product could be found in other Member States too, not least following the exponential growth of online selling. This is demonstrated by the number of follow-up actions taken by Member States in their country after the notification of a dangerous product in the RAPEX/Safety Gate; while in 2011 there were 2100 follow-up measures, in 2019 more than 4400 of such measures were notified to Safety Gate/RAPEX.
- Different rules on product safety at national level can create uneven costs for businesses to comply with product safety legislation and therefore can cause distortions of the internal market when /if companies want to operate across borders.
- According to Article 169 of TFEU, in order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health and safety of consumers. If there are different rules concerning product

[80] Article 169 make reference to Article 114 to achieve its objectives.
[81] Also, product safety is part of the high level of consumer protection that Union policies ensure (see Article 38 of the Charter of Fundamental Rights of the European Union) and therefore one of the pillars of the EU consumer protection policy.
[82] See Safety Gate/RAPEX annual report – https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/docs/RAPEX.2019.Factsheet.EN.pdf

safety and its market surveillance, EU consumers will not be protected against dangerous products in the same way across the Member States.
- The identified problem drivers mostly do not have any national or sub-national specificities (problems linked to digital challenges, recalls and food-imitating products). Problem drivers for market surveillance have partly a national dimension concerning the lack of resources, level of penalties and availability of market surveillance tools, which can differ from one Member State to another.

The objective of products safety cannot be sufficiently achieved by the Member States acting alone, given the need for a very high degree of cooperation, interaction and coherent action of all the competent authorities in all Member States across the Single Market to ensure the same high level of protection of consumers and enable effective action on the Single Market where products circulate freely. Member States cannot ensure cooperation and coordination by acting independently.

The GPSD establishes the cooperation and coordination between Member States: via the EU Safety Gate/RAPEX, Member States inform each other about measures taken against dangerous products. They also take follow-up actions in their territory if the product alerted is present there. Moreover, authorities consider the implementation of EU coordinated market surveillance activities on product safety extremely useful, as economies of scale and the funding provided by the Commission have allowed them to carry out inspections for some priority categories of products.

The measures under this initiative would not affect the Member States' competences in market surveillance or assessment of risks, neither would they interfere with national enforcement or judicial systems, nor would they affect the internal division of competences among authorities at national level. In the product safety field, Member States can act first independently to notify the corrective measures taken against dangerous products, but then follow-up actions are required from all other Member States.

3.3. Subsidiarity: Added value of EU action

EU level action in product safety for non-harmonised products has clear benefits demonstrated by the GPSD evaluation:

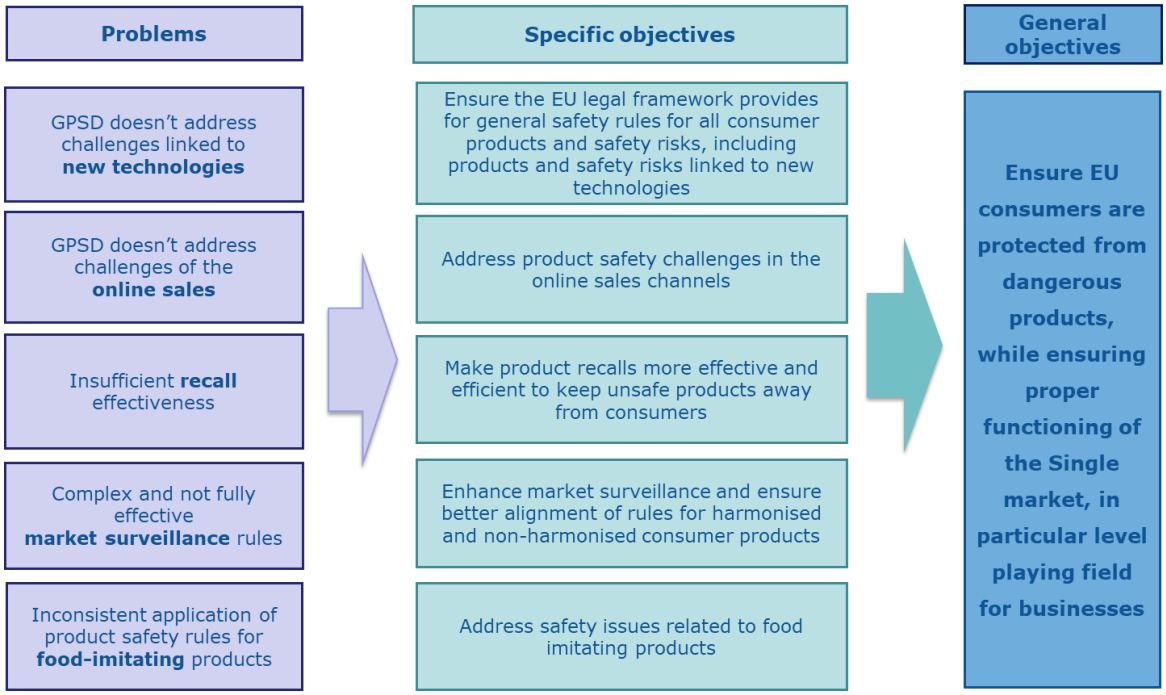
- Common Union rules allow economy of scale in market surveillance, in particular nowadays with the exponential development of online selling which intensifies sales across the EU and direct imports from outside the EU. Sharing costs of market surveillance occurs also by performing joint market surveillance actions among EU countries and exchange information.
- EU action allows faster and more efficient circulation of information, in particular via the Safety Gate/Rapex, thus ensuring fast actions against dangerous products across the EU and also level playing field.
- Common rules for product safety at EU level have benefits in term of costs savings and lower administrative burden and complexities for businesses by avoiding them having to comply with heterogeneous sets of national rules. This enables also free circulation of goods in the EU and allows for closer cooperation between Member States.
- Common Union rules enable developing EU product safety standards, which by giving EU-wide presumption of safety facilitate product safety compliance for businesses (and potentially decrease the related costs).
- At international level the common set of provisions established by the GPSD has also allowed the EU to be stronger in promoting high level of safety with international actors, thus tackling the increasingly high circulation of goods from third countries via online selling.

The functioning of the internal market will be improved by EU level action since common product safety and market surveillance rules across the EU will ensure a more even treatment of businesses and therefore less likely distort competition on the EU Single Market. Better market surveillance and enhanced coordination between Member States will lead to higher detection of unsafe products, and thus to higher consumer protection and trust.

The food-imitating product directive is currently subject to very different interpretations between Member States, ranging from a ban of such products to the inclusion of the food-imitating aspect in the elements taken into account in the risk assessment. This leads to a fragmentation of the internal market regarding such products, a more unified approach of food-imitating products is therefore needed at the EU level, requiring Union action.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

Figure 2: Schematic overview of problems and objectives



4.1. General objectives

The general objective of the GPSD is to ensure EU consumers are protected from dangerous products and to ensure the proper functioning of the Single Market. These two main objectives of the GPSD are interlinked: if the same high level of safety requirements applies to all economic operators, it ensures the health and protection of EU consumers and also level-playing field for all businesses operating on the EU market.

4.2. Specific objectives

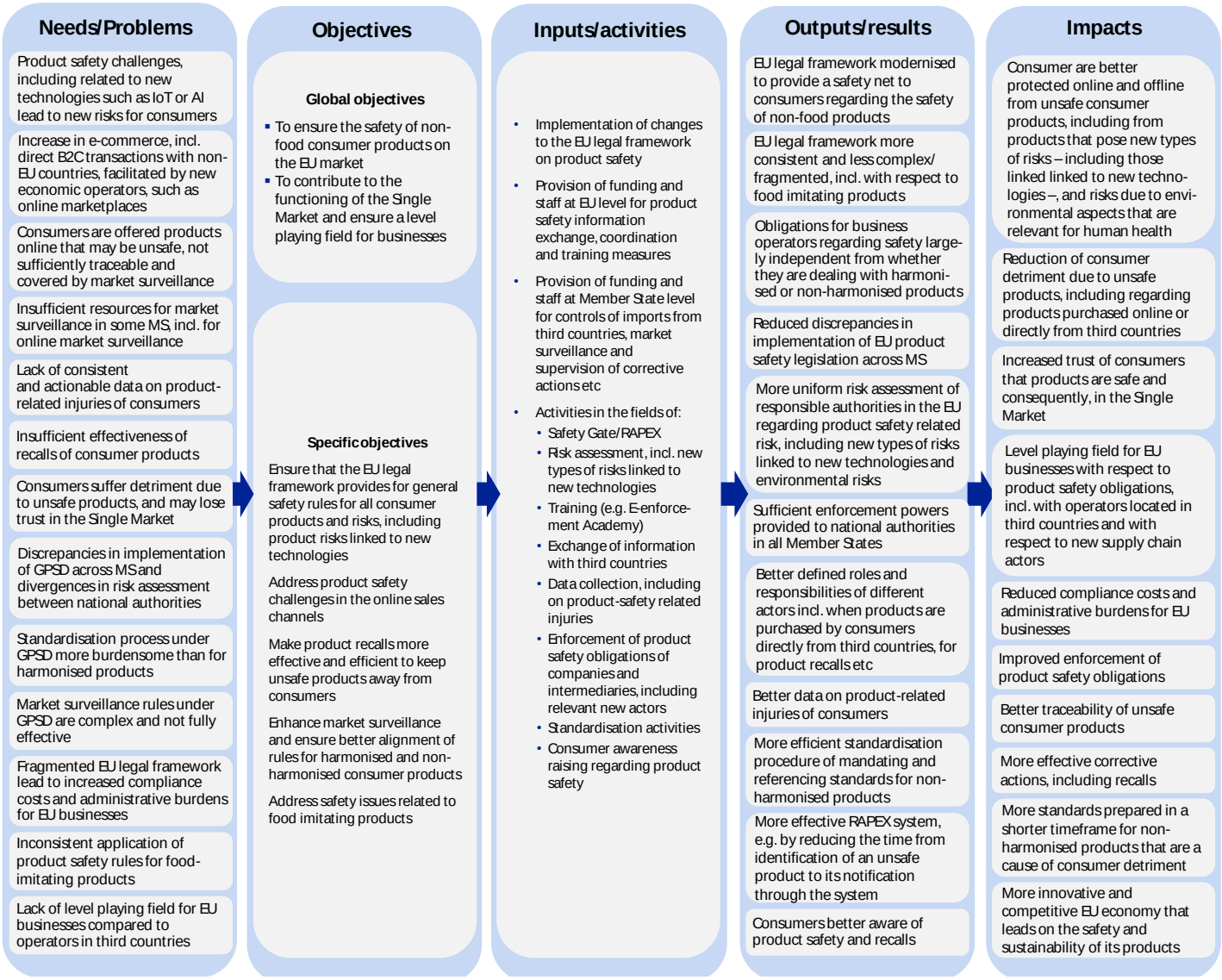
This initiative has five specific objectives linked to the five problems identified; it also seeks to simplify legislation and reduce the administrative burden of the current acts under consideration (REFIT objective):

Table 3: Specific objectives

Specific objectives	Description
Ensure that the EU legal framework provides for a safety net for all consumer products and risks, including products and risks linked to new technologies	This initiative aims to make sure that the GPSD ensures the safety of all non-harmonised products and addresses relevant risks. In view of the development of new technologies, there is a need to ensure legal certainty regarding the legal coverage of new technology products such as connected products and AI, and to be able to address new products safety risks for health and safety of consumers related to these new technologies, when not already covered by sectoral legislation. The aim is to preserve the role of the GPSD as a safety net for consumers. The initiative does not aim to regulate all risks related to new technologies in general but only when they create risks to health and safety of consumers (e.g. cybersecurity can entail risks for privacy or data protection, which are not covered by the GPSD; the GPSD would only cover the risks related to health and safety (e.g. physical incident) created by e.g. lack of sufficient cybersecurity features)
Address product safety challenges in the online sales channels	There is also a need to adapt the GPSD to the new challenges of e-commerce. Product safety must be ensured irrespectively of the modalities of the supply chain: rules for new online business models need to be clarified and provisions for market surveillance of imported products improved to enable appropriate consumer protection and level-playing field for businesses. Also national market surveillance authorities need to have efficient tools to perform market surveillance of online sales and the product traceability in the online sales needs to be improved.
Make product recalls more effective and efficient to keep unsafe products away from consumers	Product recalls play an important role to ensure the safety of EU consumers, since they are the last resort to keep dangerous products away from them. This initiative aims to increase the effectiveness and efficiency of recalls by improving the channels and content of recall information, making recall procedure less burdensome for EU consumers and ensuring their right to an effective remedy. The initiative takes into account the identified behavioural biases to increase consumer response. The initiative also aims to ensure effective monitoring of recall actions.
Enhance market surveillance and ensure better alignment of rules for harmonised and non-harmonised consumer products	This initiative aims to ensure better enforcement of product safety rules by contributing to more efficient market surveillance. The objective is to improve product traceability so that dangerous product can be effectively eliminated, the deterrent effect of the legislation for economic operators not complying with the rules, and to tackle possible discrepancies about risk assessment between Member States. The aim is also to simplify the procedures leading up to referencing standards in the Official Journal of the EU for non-harmonised products. Following the recent adoption of Regulation (EU) 2019/1020, there is a need to align the market surveillance legislative framework for non-harmonised products with the one for harmonised products, the definitions of the GPSD with product harmonisation legislation and ensure equal treatment for all products and businesses. The objective is also to ensure more efficient and coherent enforcement and implementation of the product safety rules across the EU and to monitor that sufficient resources are dedicated to market surveillance at national level.
Address safety issues related to food-imitating products	This initiative aims to ensure a consistent application of product safety rules for food-imitating products by simplifying and clarifying those rules.
REFIT Simplification and improving the efficiency of the existing legislation	This initiative aims also to simplify and reduce the regulatory burden of the current GPSD.

Figure 3 presents the intervention logic for this initiative:

Figure 3: Intervention logic



Source: GPSD Study

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. What is the baseline from which options are assessed?

In the baseline scenario, no new legislative or non-legislative actions specifically targeting the safety of consumer products will be developed at EU or national level. This scenario includes several EU-level and national policies and measures which are assumed to continue being in force or will enter into force in the future:

At **EU level**, the Commission has recently adopted a proposal for a **Digital Services Act** which, if adopted by the co-legislators and once entered into force, should set up new responsibilities for online intermediaries, including online marketplaces. Also, the Commission has recently announced its intention to propose **new legislative initiatives** linked to **new technologies and artificial intelligence**, namely the proposal for a horizontal instrument on AI and the proposal for the revision of the **Machinery Directive**, which will clarify certain sectorial safety aspects of new technologies. The new customs provisions applicable for GPSD products under the new **Regulation (EU) 2019/1020** will start to apply in 2021. The Commission will continue, in the frame of the allocated EU budget, to **finance coordinated market surveillance activities** on product

safety (see Annex 9). The Commission is expected to continue its advocacy policy on product safety, in the form of **information campaigns** and other promotion initiatives such as the Product Safety Award[83]. The Commission will also continue its **coordination role** in product safety as Chair of the **Consumer Safety Network** ('CSN')[84]. In the area of product safety in the online sales, the baseline scenario takes into account that the Commission will continue the cooperation with and steering the commitments of the online market places in the context of the Product Safety Pledge. Finally, the Commission will continue **adopting safety standards** giving presumption of safety for non-harmonised products under the current procedure, and also its international cooperation activities.

At **national level**, it is assumed that Member States will also continue their measures supporting product safety policy, such as information and promotion campaigns, under the constraints of the national budgets, and their current market surveillance activities.

Several **expected socio-economic developments** are also relevant for the product safety area. Important technological developments bring an increasing number of AI-driven consumer products and connected products on the EU market. Also the increasing digitalisation of online sales, dramatically accelerated during the current COVID-19 crisis, will increase the number of products sold online and also those imported directly from outside the EU. Demographic changes can also have an impact on the safety of consumers, as for example older people have specific consumption-related needs[85].

The **time horizon** for this baseline scenario, which will be used for the assessment of impacts of the different options is a 10 years' horizon. This takes into account the likely lifetime of any individual option and on the need to allow for impacts to be realised.

The GPSD Study estimated the **costs** associated with this baseline scenario for businesses and Member States as following:

Table 4: Estimated annual cost for businesses to comply with the GPSD, by company size class, in million EUR

	Cost by company size			Total costs
Company size (employees)	**From 0 to 49**	**50 – 249**	**250 or more**	**All size categories**
Total of manufacturing	79	101	163	**343**
Total of wholesale	118	81	122	**321**
Total of retail	232	44	163	**439**
Total	428	226	448	**1 102**

Source: The survey conducted in the context of the GPSD Study

The estimated **costs for businesses to comply with the GPSD in its current form amount to EUR 1.1 billion per year**[86].

Consumer detriment linked to the unsafe products is expected to grow in the mid-term in the baseline scenario, due to increasing consumption and a continuing shift to e-commerce: the GPSD Study evaluates that **consumers suffer financial costs of EUR 19.3 billion in 2019** arising from the fact that they have purchased unsafe products that

[83] Since 2019 the Product Safety Award rewards every two years businesses going the extra mile for product safety, beyond their legal requirements.
[84] CSN is a network of authorities of the Member States competent for product safety. See Annex 9.
[85] COM(2020) 696 final - New Consumer Agenda - Strengthening consumer resilience for sustainable recovery
[86] Product safety-related costs that companies would incur anyway (i.e. even in absence of product safety legislation, e.g. because these costs relate to due diligence) are deducted.

they would not have purchased if they knew these products are unsafe. This consumer detriment in the EU due to unsafe non-harmonised products is estimated on the basis that the product value is EUR 3.9 billion for the online sales channels, and EUR 15.4 billion for brick-and-mortar shops and other offline sales channels, for a total of EUR 19.3 billion per year. This estimated baseline consumer detriment in the EU related to unsafe non-harmonised products is currently reduced due to recalls by approximately EUR 0.4 billion per year[87]. This consumer detriment due to the loss of value of unsafe products is expected to reach **EUR 20.8 billion by 2025 and almost EUR 22 billion by 2034 in the baseline scenario[88].**

The **cost estimation for Member States** takes into account the different organisational approaches of Member States to market surveillance and is based on staff data for surveillance of non-harmonised consumer products at national level. The GPSD Study concluded that the total EU27 staff-related costs for market surveillance of non-harmonised consumer product amount to approximately **EUR 122.4 million per year**[89]. Also, four in ten MSAs reported incurring costs other than staff costs (e.g. testing of products), estimated at most at **0.34% of total staff costs**.

The GPSD Study identified that (minor to significant) **additional costs** due to differences in the safety requirements in Member States, caused by **differences in the national implementation of the GPSD** (e.g. regarding traceability requirements) **or legislative fragmentation** between harmonised and non-harmonised products, currently affect 42% of surveyed companies and 16% of MSAs. These costs are estimated for **MSAs** to amount to **EUR 0.7 million annually** (total for the EU27) and to **EUR 119 million annually for businesses**.

On the **benefits** side of the baseline, the interviews carried out in the context of the GPSD Study identified that authorities and businesses see moderate to significant benefits resulting from the GPSD across the board, and in particular through better information on unsafe products and measures taken by authorities provided through the Safety Gate/RAPEX, a better functioning internal market and increased consumer trust. 90% respondents that expressed an opinion considered the costs due to the product safety requirements of the GPSD to be at least "moderately proportionate" to the resulting benefits. Close to 60% of respondents that had an opinion even found these costs to be "largely proportionate" or "very proportionate", including respondents from companies and business associations.

For **SMEs**, the estimated annual **costs to comply with the GPSD** (after subtraction of business-as-usual costs) are **EUR 428 million per year** (companies < 50 employees) and **EUR 226 million per year** (companies 50 to 249 employees). The median value for consumer product safety-related costs in proportion of the total annual turnover appears to decrease with the company's size/turnover. This is likely due to scale effects. This general pattern is confirmed by SMEs' replies to the business stakeholder survey. Accordingly, SMEs account for 59% of the total of GPSD-related compliance costs in the EU, in line with their overall share in the market.

The GPSD Study also analysed the **impacts of the COVID 19 crisis on the baseline scenario**. It shows that while the confinement measures have serious expected impacts on GDP, total retail quickly recovered after the first crisis wave, but new measures in the

[87] The GPSD Study estimated the total consumer detriment under the baseline scenario with low recall effectiveness to be about EUR 1.3 billion per year (calculated as a value of recalled products that remain with consumers).
[88] The GPSD Study could estimate the impact of options on the consumer detriment taking as assumption that the detriment incurred by consumers in case of an unsafe product is equivalent to at least its purchase price.
[89] Monetised on basis of population size, number of person hours per year and average wage.

current second wave are likely to again lead to substantial impacts on retail and therefore sales of products. The decline in overall retail sales has been accompanied by a rise of e-commerce sales that are expected to increase by 16.9% in 2020 in Western Europe[90]. The boost in new spending is expected to leave e-commerce permanently ahead of its previous pace.

In general terms, product safety processes at companies including with respect to related supply chain management appear to remain largely unchanged in the COVID-19 context, except with the increasing reliance on electronic communication instead of physical meetings (this may pose issues to product assessments). Companies also confirmed the switch to online sales channels to offer products.

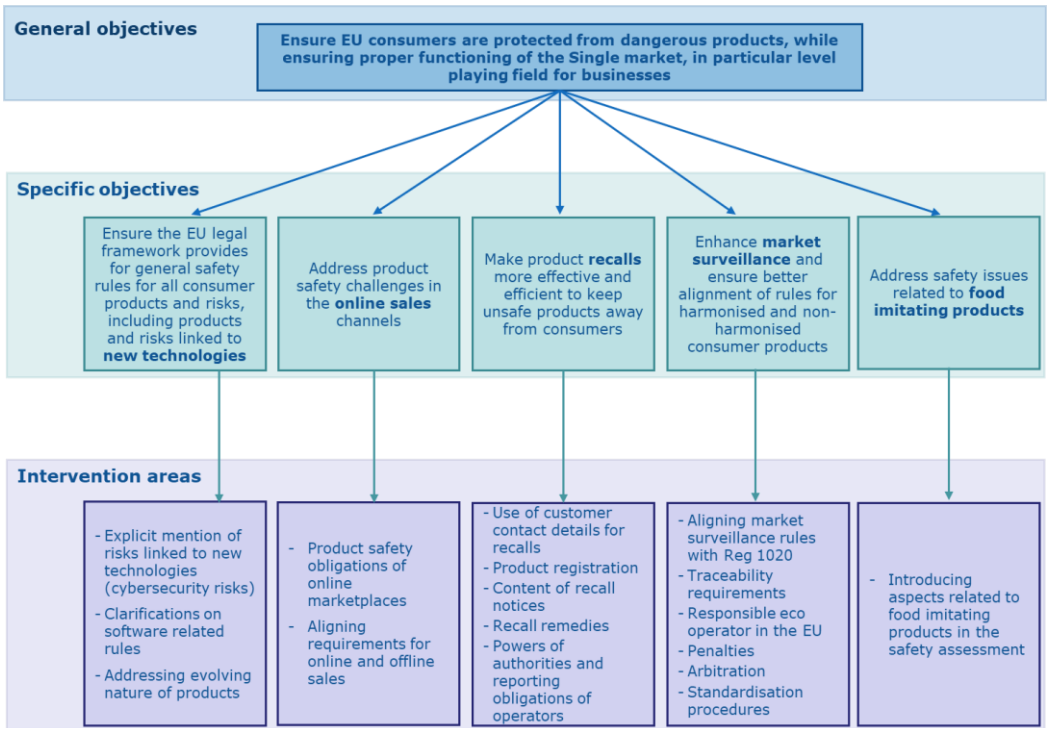
Moreover this crisis required increased market surveillance of COVID-19-related products, in particular face-covering products (other than the medical or personal protective equipment devices).Until 1 December 2020, 16 Member States notified in the Safety Gate/RAPEX 174 alerts (mainly safety masks, some disinfecting gels and UV lamps).

Finally, there is a **strong political commitment** for a strong product safety policy at EU level. This has been recognised by the recently adopted Consumer Agenda[91] and several Council conclusions as explained above. The GPSD evaluation confirms the validity of the GPSD, but at the same time considers the need for its revision. The European Parliament has also highlighted the need to revise the GPSD in its resolution on addressing product safety in the Single Market[92]. This also has been largely recognised by the stakeholders in the consultation process.

5.2. Description of the policy options

To address the objectives developed above, the initiative will intervene on the following areas:

Figure 4: Interventions to improve the GPSD's effectiveness



[90] https://www.emarketer.com/content/western-europe-see-10-83-billion-more-ecommerce-sales-than-expected
[91] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0696
[92] https://www.europarl.europa.eu/doceo/document/TA-9-2020-0319_EN.html

Beyond the baseline scenario ('Status quo') not involving any new actions, the identified policy options to address the different specific objectives are:

- **Option 1**. **Improved implementation** and **enforcement** of the existing legal framework, without legal revision of the GPSD (only FIPD revised);
- **Option 2**. **Targeted revision** of the GPSD (Directive or Regulation);
- **Option 3**. **Full revision** of the GPSD and recasting as Regulation;
- **Option 4. Integration of more legal instruments**

The range of options includes non-legislative (Option 1) and legislative actions (Options 2, 3 and 4) to address the different specific objectives. All the options defined in the report propose specific actions to address all five problems identified, but differ in the level of ambition.

The **substantive provisions of the Food-imitating Product Directive** were considered to be revised **under all options 1 to 4** with **two possible sub-options**: (a) a full ban of food-imitating products *per se* and (b) application of a product safety risk-assessment on a case by case basis to this category of products.

Table 5: Overview of the policy options and addressees of the measures

	Option 0 Baseline	Option 1 Enhanced enforcement	Option 2 Targeted legal revision	Option 3 Full legal revision	Option 4 Integration of rules	Most relevant stakeholders
New technologies	No change	• **Guidance** for economic operators • Use of **standards** for new risks	• **Coverage of new risks** • **No clarifications** on **software** related rules	• **Coverage of new risks** • **Clarify software** related rules	**Option 3** + **Integration of the legal instruments on market surveillance** (GPSD market surveillance provisions and Regulation 2019/1020)	Businesses (for consumer products incorporating new technologies) and MSAs
Online sales	No change	Reform, promotion and expansion of the **Product Safety Pledge**	• Making **most provisions inspired by the Product Safety Pledge legally binding**	Obligations for economic operators **going beyond the Product Safety Pledge** (e.g. display same information online as it is with the product offline, duty of care as for distributors)		Online marketplaces, online retailers, and MSAs
Recall effectiveness	No change	**Guidance** on product recalls	• **Mandatory requirements** on product **recalls** • **Legal basis** to use **customers' data for recalls** • **Mandatory elements of recall notice**	**Option 2** **+ Some additional mandatory requirements** (e.g. on product registration, template for recall notice, right to remedy and monitoring)		Businesses (harmonised and non-harmonised consumer products), MSAs
Market surveillance	No change	Increased **funding of joint market surveillance activities**	• **Alignment** with market surveillance and traceability rules of **harmonised products** • **Simplifying standardisation procedures**	**Option 2** **+ stronger enforcement powers to Member States** (penalties) , **arbitration mechanism** and **increased traceability** (delegated acts)		MSAs and businesses (in particular businesses of non-harmonised consumer products)
Food-Imitating Products	No change	**Separate revision of the FIPD** to ensure its even interpretation **2 sub-options** for treatment of food-imitating products: **(a) full ban *per se*.**	**Integration of** the FIP provisions **into the GPSD** **2 sub-options** for treatment of food-imitating products: **(a) Maintaining dedicated provision on**	**Idem Option 2**		Producers of food imitating products and MSAs

		(b) risk-assessment approach	**FIP (recast and integration) with a full ban *per se* (b) Abandoning any dedicated provision (repeal) and reliance on general provisions for risk-assessment approach**			
Instrument	**Directive**	**Directive**	**Directive or Regulation**	**Regulation**	**Regulation**	

Businesses and MSAs are the most affected stakeholders by the measures as detailed in the Table 5. The **SMEs and micro-SMEs are not exempted** from any of the obligations foreseen under the different options. EU product safety legislation does not allow for "lighter" regimes for SMEs since a consumer product must be safe whatever the characteristics of its supply chain to meet the general objective of product safety and consumer protection. However provisions are foreseen in the EU legislation e.g. to facilitate access for SMEs to EU safety standards including those adopted under the GPSD (see Article 6 of Regulation (EU) 1025/2012).

The detailed description of the actions under the different options, as well as their time horizon, potential for simplification and reduction of regulatory burden and digital solutions envisaged to increase efficiency, are developed in the Table 6.

Table 6: Option packages

Objectives	Option 0 Baseline	Option 1 Enhanced enforcement	Option 2 Targeted legal revision	Option 3 Full legal revision	Option 4 Integration of market surveillance rules
Ensure the EU legal framework provides for general safety rules for all consumer products and risks, including products and risks linked to new technologies	No change	• **Guidance** for businesses that cyber-security threats and other risks of **new technologies** affecting physical or mental health. • Exploring use of **European Standards for new risks**	• **New risks** (cyber-security and other risks of new technologies affecting physical or mental health) **explicitly covered** through legal revision of product safety definition	**Option 2** **+ Clarify software related rules**: Explain how software can impact the safety of product and clarify responsibilities to ensure consumer safety	**Option 3** **+** **Integration of the legal instruments on market surveillance** (GPSD market surveillance provisions merged with Regulation 2019/1020 into one Regulation on market surveillance
Address product safety challenges in the online sales channels	No change	• Review, promotion and expansion of the **Product Safety Pledge**	**Making most provisions of the Product Safety Pledge legally binding for all online marketplaces**, such as: • to **consult information on recalled/dangerous products available** on Safety Gate/RAPEX and from other sources and react quickly; • to take **appropriate action** in respect to recalled/dangerous products, when they can be identified • to provide **single contact points for EU MSA**s and to **cooperate** with them • to have an **internal mechanism for notice and action** procedure with specific provisions for unsafe products (e.g. timeframes for action) and other requirements	**Option 2 + additional requirements for online operators:** • to display of **all safety information online** that is also required to be provided offline; online marketplaces required to make sure that sellers on their platform provide this information together with the product offer • a **duty of care** to help ensure compliance with the safety requirements for online marketplaces (in the same vein as the classical distributors have today: stop supplying unsafe products, participate in market monitoring, keeping traceability information, cooperation in corrective actions, cooperate with MSAs**,** making efforts to identify dangerous product offers already removed from their websites but that keep reappearing. That duty of care would be different than for distributors as they do not have physical contact with the product, so their role will focus on doing their most to ensure that their websites do not offer dangerous products, and if they do, they cooperate with authorities for corrective actions. This duty of care would be complementary to the obligations of actual sellers on the online marketplaces)	
Make product recalls more effective and efficient to keep unsafe products away from consumers	No change	• **Guidance on product recalls**	**Mandatory requirements on product recalls:** • Legal basis to **use available customer contact details** for recalls • Operators need to **disseminate recall announcements on their website, social media, newsletters, retail outlets** and other appropriate channels to ensure the widest possible reach. • **Mandatory key elements for recall notices** (product description + photo, description of hazard, instructions on what to do, description of remedy, contact details for queries) • **Prohibition to use terms decreasing the perception of risk** in recall notices	**Option 2 + Further measures to enhance recall effectiveness,** for example: • Obligation for economic operators **to notify consumers directly** whenever possible • Economic operators who already offer product registration systems or loyalty programmes should **offer consumers the possibility to register their contact details specifically to receive safety notifications** • Possibility to **set further requirements for registration of specific categories of products** through delegated act • **Mandatory template** for recall notices to be set through implementing act	

				• Consumers' right to an effective, cost-free and timely **remedy** for the recalled product (repair, replacement or refund) • Less burdensome recall procedure for consumers (returning a product should not incur any financial costs, non-portable items to be collected by the operator)Obligation for businesses to **register voluntary recalls in an EU public database** and to **monitor recall effectiveness**. Power for authorities to request monitoring data from operators and decide if the case can be closed.	
Enhance market surveillance and ensure better alignment of rules for harmonised and non-harmonised consumer products	No change	• **Increased funding** of EU joint market surveillance activities among EU Member States	**Legal revision of the GPSD to align with market surveillance and traceability rules for harmonised products**: • The **market surveillance rules aligned with Regulation (EU) 2019/1020** • Additional requirements for businesses in line with Regulation (EU) 2019/1020 (notably regarding the requirement of an **EU representative**) and other harmonisation legislation, in particular **traceability** requirements from Decision No 768/2008/EC **+ Simplifying standardisation procedures** (streamlining the EU process for elaborating safety requirements and the standardisation request, e.g. by combining them in one Commission Decision)	**Option 2** **+** • More stringent rules on **penalties** to strengthen their deterrent effect beyond Regulation (EU) 2019/1020 • **Arbitration mechanism** in case Member States have diverging product safety risk assessments (either a group of Member States or the Commission are called to arbitrate) • **Possibility to set further requirements for traceability systems** through delegated acts, for example regarding chemicals in childcare articles.	
Address safety issues related to food-imitating products	No change	**Separate revision of the FIPD**, **2 sub-options** for treatment of food-imitating products: **(a) full ban *per se*** **(b) risk-assessment approach**	**Integration of the FIP** the provisions **into the GPSD**. **2 sub-options** for treatment of food-imitating products: **(a) Maintaining dedicated provision on FIP (recast and integration) with a full ban *per se*** **(b) Abandoning any dedicated provision (repeal) and reliance on general provisions risk-assessment approach**	**Idem Option 2**	
Instrument	**Directive**	**Directive**	**Directive or Regulation**	**Regulation**	**Regulation**
Digital solutions in respect of implementation and reduction of administrative burdens	None	Development of digital solutions, such as an IT system (web-crawler) to identify dangerous products sold online and already notified via Safety Gate/RAPEX. It would allow MSAs to carry out online market surveillance tasks more efficiently	Beyond the digital IT systems of Option 1, other digital solutions can reduce the burden linked to the additional obligations on recalls (use of internet and social media to increase recall communication). Aligning to the Regulation (EU) 2019/1020 will also allow to explore digital interlinks between existing market surveillance systems at EU and national level and will therefore make the market surveillance more efficient.	Idem Option 2 + possible digital solutions in the field of product traceability	Idem Option 3

Time horizon	Immediate	Rather short for setting guidance documents. The revision of FIPD) requires adoption of a new legislative act (minimum 1 year)	The obligations under this option would become effective by the revision and entry into force of the revised GPSD.	The obligations under this option would need to be completed by the revision and entry into force of the revised GPSD.	The obligations under this option would need to be completed by the revision and entry into force of the revised GPSD and the new market surveillance Regulation.

Option 1. Enhanced enforcement: Improved implementation and enforcement of the existing legal framework, without revision of the GPSD

This option does not require a legal revision of the GPSD, and would include:

a) *Development of guidance on the safety of new technologies and exploring the use of European standards to address new risks.* The general safety requirement of the GPSD already encompasses protection against all kinds of risks arising from the product to the safety and health of persons. The guidance would clarify how this includes not only mechanical, chemical, electrical risks etc. but also cybersecurity and personal security threats that affect the safety of persons[93], and other risks related to new technologies that potentially affect physical or mental health[94]. The standardisation procedure could be used to elaborate European standards addressing safety requirements for consumer products concerning certain new risks such as cybersecurity risks of new technologies.

b) *More support and promotion of the Product Safety Pledge.* To tackle the safety issues related to online sales (including from third countries), the Pledge would be updated and promoted through awareness campaigns, and other online marketplaces would be encouraged to sign the Pledge. No legal requirements will be introduced for online market places and no person responsible for products in the EU will be available for non-harmonised products sold online.

c) *Development of guidance on product recalls.* The guidance would address current deficiencies concerning the effectiveness and efficiency of recall procedures by economic operators and market surveillance authorities, relying on the current legislation. The guidance would concern e.g. the provision of more transparent recall information to consumers, the use of customer data for direct notifications and cooperation between different actors in the recall process.

d) *Increased funding for joint market surveillance activities among Member States*, so that more coordinated actions of authorities across EU Member States could be conducted, including the joint testing of consumer products. No legal changes in the market surveillance rules, including on penalties, where a light approach, with general provisions on penalties, as it is currently the case in the GPSD, would continue. In this case, the deterrent effect of sanctions depends on the provisions adopted by Member States.

e) *Revision of the Food-imitating Products Directive to clarify its scope*. The provisions on the Food-imitating products would be kept in the FIPD with **two possible sub-options**: (a) food-imitating products could be banned throughout the Union *per se per se* and (b) application of a product safety risk-assessment on a case by case basis to this category of products.

Option 2. Targeted revision of the GPSD (Directive or Regulation)

Option 2 would require a legal revision of the GPSD, which would remain a Directive or become a Regulation. In case the new instrument is also a Directive, changes to the GPSD would need to be transposed by Member States into national legislation. The changes to the legal framework would include:

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93 E.g. a smart watch for children, which does not causes a direct harm to the child wearing it, but lacks a minimum level of security, so that it can be easily used as a tool to have access to the child and therefore endanger its safety.

94 Mental health risks for consumers deriving e.g. from their interaction with humanoid AI systems.

a) *Making explicit how the scope of the legal framework and its definitions apply to risks posed by new technologies but without applying it to standalone software.* The definition of safety in the GPSD would be revised to clarify that the covered risks arising from the product to the safety and physical/mental health of persons include not only mechanical, chemical, electrical risks etc. but also cybersecurity and personal security threats that affect the safety of persons, and other risks related to new technologies that potentially affect health (similar to the guidance that would be provided under Option 1). The definition of product in the GPSD would not be changed, so that safety risks stemming from software are only covered if the software is integrated in a product at the time of its placing on the market (as is currently the case). There will be not specific provisions on or references to software updates.

b) *Adding requirements for online marketplaces by making most provisions of the voluntary Product Safety Pledge legally binding*. The Pledges' commitments e.g. to consult information on recalled/dangerous products available on RAPEX and also from other sources; to take appropriate action in respect to recalled/dangerous products, when they can be identified; to provide single contact points for EU Member State authorities and to cooperate with them; to have an internal mechanism for notice and take-down procedure for dangerous products and other requirements would become legally binding for all online marketplaces targeting EU consumers[95].

c) *Adding requirements for enhancing the effectiveness of product recalls*. Create legal basis for economic operators to use any available customer contact details at their disposal (e.g. obtained through loyalty schemes or online sales) to directly notify the owners of recalled products (without the need of consumer consent). Mandatory key elements would be defined that are to be included in every recall notice (product description with a photograph, description of hazard, instructions on what to do, description of remedy, contact details for queries). Prohibition to use terms decreasing the perception of risk in recall notices (e.g. 'voluntary/precautionary recall' or "overheating" instead of fire). In case not all affected consumers can be contacted directly, businesses would need to disseminate recall announcements on their website, social media, newsletters, retail outlets and other appropriate channels to ensure the widest possible reach.

d) *Ensuring alignment with harmonised market surveillance rules while keeping different legal instruments and simplifying standardisation procedures*. The market surveillance rules provided in the GPSD would be aligned with the provisions in Regulation (EU) 2019/1020. Requirements for businesses would reflect the current obligations under the GPSD, and include complementary requirements in Regulation (EU) 2019/1020 (notably regarding the requirement of an EU responsible economic operator to address the specific issue of direct online

[95] All commitments under the Pledge could become legally binding under this option, except most probably commitment 7 (training to sellers on compliance with EU product safety legislation, etc.) and 12 (exploring new technologies and innovation to improve the detection of unsafe products).

imports from third countries by consumers) and other harmonisation legislation[96]. Traceability requirements would include the requirement to keep supply chain records (to allow for one-up one-down traceability, i.e. the identification of suppliers and clients, except final consumers). As a result, general requirements for businesses and responsibilities and powers of market surveillance authorities would be largely uniform for harmonised and non-harmonised consumer products, including on penalties. Also, standardisation procedures at the Commission level under the GPSD would be simplified.[97]

e) *Integrating the provisions of the Food-imitating Products Directive into the GPSD.* The provisions of the FIPD would be integrated in the GPSD with the same two substantive sub-options as in the Option 1.

Option 3. Full revision of the GPSD (Regulation)

Option 3 would repeal the Directive and ensure even application of its implementation through the choice of a Regulation (i.e. it will be directly applicable in Member States). This option would include **all elements of Option 2 and, in addition**:

a) *Software related rules would be clarified*. The GPSD would explain how software can impact the safety of product and clarify responsibilities to ensure consumer safety in such cases. Under this option the definition of product under the GPSD could be adapted to cover the software updates. Specific provisions and conditions could be elaborated for cases of software updates that affect the safety of the product after a product is placed on the market, e.g. when the software operates a substantial modification of the product impacting the risk it poses to health and safety of consumers. It should be noted that under this option, the revised GPSD would not regulate cybersecurity aspects in general, as that entails different issues such as privacy or data protection; however, it would cover cases when a lack of cybersecurity features can lead to a physical incident and hurt the consumer, therefore not going beyond the area of consumer protection.

b) *Making legally binding most provisions of the voluntary Product Safety Pledge for online marketplaces (as in Option 2) and include new provisions for actors across the online supply chain.* These new provisions for actors across the online supply chain would require them to provide all safety information online that is also required to be provided with a product in 'brick-and-mortar' stores. Online marketplaces would have a duty of care and they will be required to make sure that third party sellers on their platform provide this information together with the product offer (without being required to check the accuracy of the safety information provided). This duty of care obligations would target online market places and will be complementary to the obligations of sellers on the online marketplaces (where the obligations of manufacturer, importer or distributor would apply depending on the specific case), which would be particularly useful in cases where the sellers are located outside the EU.

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[96] See also Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, which provides reference provisions, definitions and general obligations for economic operators for harmonised products.

[97] Changes could concern the involvement of Member States committees at various stages of the process. The elaboration of the European Standards by the European Standardisation Organisations would not be affected.

c) *Establish further mandatory requirements to enhance recall effectiveness.* In addition to all the elements of Option 2, the following would be introduced:

- Economic operators who offer product registration systems and loyalty programmes for other purposes (e.g. marketing or technical support) should offer consumers the possibility to register their contact details specifically to receive possible safety notifications (personal information collected for the purpose of product safety should be limited to the necessary minimum and must not be used for marketing purposes);
- Possibility to set out further requirements for registration of specific categories of products through delegated act;
- Binding template for recall notices to be set out through implementing act;
- Consumers' right to an effective, cost-free and timely remedy(repair, replacement or refund);
- Less burdensome recall procedure for consumers (returning a product should not incur any financial costs, non-portable items to be collected by the operator); Binding requirements for businesses to register voluntary recalls in an EU public database and to monitor recall effectiveness; MSAs would have the possibility to request monitoring data from economic operators and decide if the case can be closed.

d) *Give stronger enforcement powers to Member State authorities (for example on penalties) and establish arbitration mechanism in case Member States have diverging product safety risk assessments.* Building on Option 2, general requirements for businesses and responsibilities of market surveillance authorities would be largely uniform for harmonised and non-harmonised consumer products. However, under Option 3 stronger enforcement rules would be incorporated:

- Penalties: The provisions on penalties would be more clearly defined in a way to ensure a sufficient deterrent effect, while increasing the sanctioning powers of Member States.
- Arbitration mechanism: In case Member States have diverging assessments of the risk posed by a notified product, a mechanism could be triggered where either a group of Member States or the Commission are called to arbitrate.
- Traceability: This option would also create a possibility to set further requirements for traceability systems through delegated acts, for example regarding chemicals in childcare articles.
- Finally, some further improvements to the market surveillance could be envisaged based on the feedback from the stakeholders and study results.

e) *Integrating the provisions of the Food-imitating Products Directive into the GPSD* with the same two substantive sub-options as in the Option 2.

Option 4. New Regulation merging market surveillance provisions of GPSD and Regulation (EU) 2019/1020

This option would provide for a new legal instrument including all elements described under Option 3 and also merging the market surveillance provisions of the GPSD and

Regulation (EU) 2019/1020 on the market surveillance and compliance of products into one new Regulation on market surveillance, so that one single set of rules would apply to harmonised and non-harmonised products.

5.3. Options discarded at an early stage

Even if options 0 and 1 have received little support by stakeholders they have not been disregarded and the impacts of all options are assessed.

Initial policy options presented in the Roadmap/Inception Impact Assessment took into account the results of the GPSD implementation study, which – based on a broad consultation process – had elaborated key shortcomings of the current legal framework and stakeholder suggestions for improvements. In the course of the GPSD study, the completeness of the current set of policy options was validated and no further policy options for consideration were identified. Also the stakeholders did not raise any other new real alternatives during the consultation process.

A potential further policy option, discarded at an early stage, is the **complete repeal of the current GPSD**. The Evaluation of the GPSD (see Annex 5) concludes that, although there is a need for specific improvements and simplification, the GPSD is generally relevant, effective, efficient and coherent, and has EU added value.

This report builds also on the conclusions of the Impact assessment report prepared for the previous proposal to revise the GPSD tabled in 2013. In particular, some of the disregarded or eliminated options after analysis of impacts in 2013 were disregarded also in the current report, e.g. centralisation of market surveillance at EU level, direct applicability of ad-hoc safety requirements, abolition of the general product safety requirement.

Also, the introduction of the **"Made in" clause,** mandatory country of origin labelling for products (as it was proposed in the 2013 Package), has been disregarded at an early stage following the technical study the Commission conducted in September 2014,[98] assessing the costs and benefits of the proposed mandatory country of origin labelling for a number of product categories. The study concluded that there is little evidence of possible positive impacts of this clause on product traceability and safety for any of the product groups. Further reinforced traceability requirements will however be analysed in Option 2 and 3 beyond the "Made in" clause.

Some **alternatives** were considered to certain substantive measures presented in the intervention logic and have been disregarded:

Concerning **new technologies**, it was considered whether the sectorial legislation could cover those new challenges, such as for example the product safety risks linked to cybersecurity. While particular actions at sectorial level might still be needed, it appeared that gaps would remain unless a full safety net is ensured, as it is provided under GPSD in its function of *lex generalis*.

Regarding setting the **requirements for online marketplaces** in the product safety area, an alternative option would have been to define the precise obligations in the proposal for

[98] VVA Europe 2015 https://ec.europa.eu/info/sites/info/files/indication_origin_study_2015_en.pdf

the DSA. The adopted proposal for the DSA has retained nevertheless a more horizontal approach proposing the general obligations for all types of illegal content, leaving the definition of specific product safety obligations of online marketplaces to the product safety legislation.

When it comes to the **traceability requirements**, an alternative option could have been to impose higher traceability requirements for all products. This option has been considered and disregarded because of lack of proportionality.

An important objective of this initiative is also to create a sufficient deterrent effect to incentivise the economic operators to comply with the product safety requirements, which is particularly important in a context where all the products cannot be controlled in view of their huge volumes. The options 3 and 4 propose to increase the deterrent effect of the GPSD by reinforcing the provisions on penalties by setting some harmonised criteria and a minimum threshold for the maximum amount of penalties. A stronger approach on penalties could have been to set up a precise list of infringements and corresponding minimum and maximum amounts for penalties. This option has been disregarded since interfering with Member States' competences.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

The relevant stakeholder affected by the initiative are the economic operators (manufacturers, importers, distributors and online market places), market surveillance authorities (MSAs) and EU consumers. The main costs entailed by complying with the Directive can be classified by stakeholder group as follows:

- **Substantive compliance costs** for economic operators: costs arising for manufacturers to ensure compliance with the product safety requirement (setting up product safety processes, testing, recalls, etc.) and other economic operators' obligations under GPSD (e.g. for distributors), and possible purchasing of standards.
- **Administrative costs** for economic operators to comply with obligations to provide safety information to national authorities on request.
- **Enforcement costs** for MSAs: costs arising from market surveillance activities (implementation, enforcement and monitoring), withdrawal of unsafe products from the market and coordination - internally between MSAs within one country and externally within the Consumer Safety Network and via the Safety Gate/RAPEX. Enforcement and coordination costs for the Commission.
- **Direct regulatory costs** for EU consumers via possible increase of prices or lower choice of non-harmonised products.
- **Direct regulatory benefits**: improved health and safety of EU consumers and the improved environment (decrease of products with both safety and environmental risks, e.g. due to presence of dangerous chemicals) leads to improved well-being. Market efficiency improvements in the form of better quality of non-harmonised products and better information about product safety (e.g. about recalled products) increase trust of consumers in the market and increased purchasing. Alignment of market surveillance rules for harmonised and non-harmonised products create a more level playing field and have therefore positive effect on competition.
- **Indirect benefits**: the decreased costs of injuries has positive impact on national health and consumers' budgets; positive effects on fundamental rights by improving consumer protection, including the protection of vulnerable consumers (children, the

elderly) and on innovation via increased legal certainty regarding the application of consumer product safety rules to new technologies.

- **Cost savings** linked to the simplification of procedures (e.g. standardisation), reduction of regulatory costs for businesses and administrative burdens for MSAs by alignment of market surveillance rules for harmonised and non-harmonised products, integration of safety rules for food-imitating products with the rules for non-harmonised products and choice of a directly applicable legal instrument (Regulation).

6.1. Impacts of Option 1

Effectiveness in achieving the specific objectives

Table 7: Assessment of Option 1 related to the specific objectives[99]

Objectives	Areas	Assessment	Impacts
New technologies	*Certainty regarding coverage of new risks*	Option will to some extent contribute to certainty regarding coverage of new risks, without being legally binding. Implementation differences in Member States may remain.	**neutral / +**
	Certainty regarding coverage of software	Option will not providing clarity of GPSD's application to software.	
Online sales	*Safety of products sold on online platforms*	It is unlikely that safety risks for EU consumers due to products sold on online platforms will be significantly reduced.	**neutral**
	Information of consumers on essential safety aspects	No change to the current situation.	
Recall effectiveness	*Reaching out to consumers affected by recalls*	Option will to some extent contribute to certainty regarding recall procedures, without, however further regulating and therefore addressing the underlying reasons for limited recall effectiveness.	**neutral**
	Information provided in recall notices		
	Monitoring of recall effectiveness		
	Remedies for consumers affected by recalls	No change to the current situation.	
Market surveillance	*Alignment of market surveillance framework for harmonised and non-harmonised consumer products*	Limited increase of EU funding[100] may enhance enforcement, but no change to the current fragmentation of legal framework for market surveillance.	**neutral**
	Deterrence effect	No change to the current situation.	
	Diverging risk assessments by MSAs		
	Simplification of standardisation procedures		
Food-imitating products	*Addressing risks of food-imitating products*	Clarify the regime for the food-imitating products : (a) full ban or (b) risk-assessment approach	**+**

[99] Note: Magnitude of impact as compared with the baseline scenario:
neutral = no significant difference to baseline situation;
+ = positive impact compared to baseline;
++ = significant positive impact compared to baseline.
An indication of neutral/+ or +/++ indicates an intermediate assessment, depending on implementation details and/or circumstances. Costs are indicated as either neutral (no additional costs compared to baseline), or with an indication of the expected increase in EUR terms, again compared to the baseline situation.

[100] Under the current proposal for next Multiannual Financial Framework and the Single Market Programme the yearly amounts foreseen for coordinated market surveillance actions are only slightly higher (EUR 2,8 million) than the spending on these activities in the previous years (EUR 2,4 millions)

The GPSD Study showed that the overall average assessment of the effectiveness of Option 1 in addressing the five challenges mirroring the five specific policy objectives across all respondents and stakeholder groups was **2.9 on a scale of 1 to 5**.

Administrative simplification

Guidance provided under Option 1 could to some extent reduce regulatory complexity and uncertainty regarding the coverage by the GPSD of risks posed by new technologies, as well as regarding applicable procedures for recalls. Also, complementary measures in the standardisation field to address safety requirements for consumer products concerning certain new risks posed by new technologies could have a similar effect. However, as these guidelines and standards would not be legally binding, this reduction can be expected to be minor. In addition, legal uncertainty regarding the application of the GPSD to software will remain. Therefore Option 1 will not significantly reduce the regulatory complexity and burdens for businesses. The simplification potential is therefore very limited, stemming mainly from the clarifications provided under the non-legally binding guidance documents and the revised FIPD.

Responsibilities and powers of market surveillance authorities will remain different for harmonised and non-harmonised consumer products, and related administrative burdens for some authorities will continue. In the survey conducted in the GPSD Study, 16% of authorities reported they currently experience additional costs due to these differences. Also, administrative burdens on Member States in the field of standardisation would not be reduced.

Option 1 does not include any additional administrative requirements for specific types of operators. Only very low burdens are expected for businesses from getting familiar with new guidance documents.

Economic impacts

The GPSD Study showed that all stakeholders estimate the **benefits** of Option 1 on a low level (see Annex 12): companies/business associations estimated benefits 'moderate' (3 in a scale of 5) and MSAs (2.6 in a scale of 5), and other stakeholders highlight even lower ('minor' benefits, 2 in a scale of 5). Businesses assessed the benefits to be 'minor' when it comes to increased business revenue. The assessment of other stakeholders is particularly low with respect to the reduction of legal complexity and improved supply chain management due to improved traceability of products (values of 1.8 and 1.9 respectively in a scale of 5).

Concerning the costs incurred under Option 1, the GPSD Study indicates that implementing this option would not increase companies' **recurrent regulatory compliance costs** (staff costs) or other additional recurrent costs, neither for manufacturers or distributors. Several business respondents indicated that nothing substantial would change with the implementation of Option 1 compared to the status quo, even if better guidance documents could potentially improve clarity and legal certainty and, as a result, create some cost savings.

Option 1 should create minor additional **one-off costs** for businesses related to getting familiar with new guidance provided at EU level. However, the quantitative estimates provided by company respondents in the GPSD Study confirm that no significant additional one-off cost are expected at the EU aggregate level. In conclusion, the GPSD

Study indicates that the implementation of Option 1 should not change one-off and recurrent costs of EU businesses.

No significant **firm-level impacts** are to be expected due to the implementation of Option 1 for specific types of operators, be it SMEs or specific operators such as online traders.

An exception are **businesses that are manufacturing or distributing food-imitating products**. Currently, as explained in the Evaluation, the FIPD is applied differently across EU countries, as some MSAs interpret the FIPD as a per se prohibition of food-imitating products while others do a case-by-case risk assessment of the safety of product. To analyse the impact of the provisions on the **food-imitating products**, **two different sub-options have been considered**: (a) a **full ban** of food-imitating products; or (b) provisions that would include the **food-imitating aspect** (and possibly child-appealing in general) **as an element for the assessment of the risk of products** and require a case-by-case risk assessment, as for other consumer products. We can expect that a targeted revision to better clarify the specific requirements of the FIPD would give manufacturers and distributors more legal certainty in both sub-options. As both manufacturers and distributors already have to comply with the current FIPD, we do not expect additional costs from a revision that merely aims at providing greater clarity and legal certainty respectively. A greater level-playing field regarding the implementation and enforcement of the FIPD in the EU could lead to minor cost savings on the side of manufacturers and distributors of food-imitating products. The GPSD Study concluded that the **negative economic impact** of a full ban of food-imitating products would likely be **minor** in a broader economic perspective, since the number of these products is limited[101]. At the same time the alternative **option (b) is more coherent with the current risk assessment approach in the GPSD** which has already been applied to food-imitating products by a number of MSAs: restriction of the free circulation of a given food-imitating product would be based on the assessment of the particular product's risks and action would be taken according to this assessment. Applying a risk assessment would enable a proportionate corrective measure to be taken.

No **macroeconomic effects** with significant impacts of the implementation of Option 1 on the internal market or trade are expected, since measures under Option 1 are voluntary in nature and are largely cost neutral. Implementation differences in Member States are likely to remain at least partially since the additional guidance provided under Option 1 would not be legally binding. The results of the consultation conducted for the GPSD Study show that stakeholders evaluate the benefits on the internal market and trade minor to moderate[102]. Significant impacts on competition and innovation are also unlikely, as the benefits of guidance in this respect are limited and all measures are quasi cost-neutral for businesses (except in the area of food-imitating products, where a slight benefit is possible due to increased legal clarity). Some benefits are expected due to slightly increased funding of joint market surveillance activities among Member States.

[101] The Evaluation shows that the food-imitating products represent only a very small proportion of the notifications in the Safety Gate/RAPEX

[102] Businesses and business associations assess the potential benefits from better functioning of the EU internal market and more level-playing field among businesses as 'moderate'. The deterrent effect on rogue traders is considered 'minor' to 'moderate', while the benefit of a better access to non-EU/EEA markets is assessed to be 'minor'. On average, MSAs expect lower benefits than businesses. When it comes to other stakeholders, their assessment of Option 1 is much lower at an average of only 1.7 (i.e. below 'minor').

In terms of impact on **consumers**, the GPSD Study shows that the benefits for consumers are judged by stakeholders generally minor to moderate in terms of reduced occurrence of unsafe products, reduced number of accidents and injuries caused by unsafe products and increased consumer trust. Also since Option 1 would, overall, not result in increasing product safety-related costs for economic operators, it is not expected to create any impact on the prices for consumer products in the EU. Due to the voluntary character of measures under Option 1, there should not be any impact on consumer choice.

Concerning the impact on consumers of the sub-options for the food-imitating products, both sub-options would lead to the same level of consumer protection against unsafe products. In particular, lifting the ban in those Member States applying it nowadays, would not lower the consumer protection if the risk-assessment is applied. Indeed, by analogy with the risk assessment methodology under the GPSD, the evaluation of the risk of the product would take into account its food-imitating aspect so the risk for the consumer would be properly assessed and if the product is found to be unsafe, its placing on the market would be prohibited.

The guidance provided under Option 1 and the additional funding of coordinated market surveillance activities could slightly improve the enforcement of the GPSD, with related benefits for consumers. However, since online market surveillance will not be substantially improved, consumers would continue to incur detriment, even if the voluntary safety Pledge would be further promoted. With an increasing role of online platforms in the EU retail sector in the future, amplified by the COVID 19 crisis, costs for society due to unsafe products entering the market through online channels from third countries could increase, although this will also depend whether other measures are taken at EU level, including in the framework of the new DSA. Option 1 is therefore not expected to increase the level of consumer protection, including vulnerable consumer groups such as children and the elderly.

Impacts on Member States

Option 1 is not expected to provide significant benefits for MSAs, except a reduction in uncertainty about GPSD interpretation thanks to the provision of guidance and the possible **additional funding for joint market surveillance activities**. However, it needs to be considered that the increase of this funding will be **limited**, as the budget foreseen for these activities in the Multiannual Financial Framework and the Single Market Programme will only be around **EUR 21 million**, which amounts to a **very small increase of yearly average budget** for these **coordinated activities** (from EUR 2.4 million in 2009-2020 to EUR 2.8 million per year in 2021-2027).

Based on the MSAs' survey, the GPSD Study found that recurrent costs for MSAs should remain the same under Option 1, compared to the baseline situation, and one-off costs would be very low (costs resulting from the development of new guidance documents, and, potentially, the set-up of technical capacities for carrying out market surveillance activities related to new risks).

The proposed measures would not be expected to have other effects on Member States since no modifications of market surveillance mechanisms are proposed.

In case the risk-assessment sub-option were chosen for the treatment of food-imitating products, potential effects could be observed on Member States which have been applying full ban of these products until now. These Member States would need to make

a risk-assessment of these products, but this change should not represent specifically higher costs for these countries since the number of food-imitating products is very low and they already apply the risk-assessment approach for all other products[103].

Social impacts, impacts on fundamental rights, environmental impacts

Due to their limited scope and voluntary character, the measures implemented under Option 1 would not have significant social or environmental impacts, or impacts on fundamental rights. However, the GPSD Study concludes that **if retained, a ban on food-imitating products** from the EU market would have **a negative impact on the freedom to conduct a business as defined under Article 52 of the Charter of Fundamental Rights of the European Union ('Charter')**, while the GPSD Study, based on the feedback from Member States, **could not identify evidence to prove** the intended benefits (better protection of children) to confirm **its proportionality**.

Indeed, food-imitating products are not intrinsically dangerous. They can be if they are so similar to foodstuff that they can be confused with food, and if such confusion could pose a risk (notably the risk to choke or to be chemically poisoned) if consumers would ingest such products. Banning all food-imitating products would mean banning also those food-imitating products that are not dangerous (for instance, those that imitate but cannot be confused with foodstuff, or those that do not present any risk, notably because they are not a small part or no small part could be detached from it). Article 52 of the Charter sets out that limitations on the exercise of the rights and freedoms recognised by the Charter may be made only if they respect the principle of proportionality, are necessary and genuinely meet objectives of general interest recognised by the Union or the need to protect the rights and freedoms of others. A general ban of food-imitating products would result in banning some non-dangerous products, which would be an unjustified and non-proportional restriction of the freedom to conduct a business.

6.2. Impacts of Option 2

Effectiveness in achieving the specific objectives

Table 8: Summary assessment of Option 2, compared to baseline situation

Objectives	Areas	Assessment	Impact
New technologies	*Certainty regarding coverage of new risks*	Legally binding clarifications will avoid uncertainty. Depending on the choice of instrument, implementation differences in Member States may remain	+
	Certainty regarding coverage of software	No change to the current situation	
Online sales	*Safety of products sold on online platforms*	Safety risks for EU consumers due to products sold on online platforms partly reduced, with the effectiveness also depending on other factors	**neutral / +**
	Information to consumers on essential safety aspects	No change to the current situation	
Recall effectiveness	*Reaching out to consumers affected*	Change can be expected to facilitate the use of available customer data,	+

[103] We also note that the risk-assessment of the food-imitating products appears to be relatively simple in practice: e.g. the food-imitating aspect renders highly probable that the product would be put in mouth by children so if small parts of the products can detach easily, the product will likely present a serious risk and prohibited from being placed on the market.

	by recalls	and avoid data protection concerns	
	Information provided in recall notices	Improvement in the information provided to consumers is expected to be achieved	
	Monitoring of recall effectiveness	No change to the current situation	
	Remedies for consumers affected by recalls	No change to the current situation	
Market surveillance	*Alignment of market surveillance framework for harmonised/ non-harmonised consumer products*	Largely uniform general requirements for businesses and responsibilities and powers of market surveillance authorities for harmonised and non-harmonised consumer products expected to be achieved	++
	Deterrence effect	Largely unchanged situation in terms of deterrence of placing unsafe products on the market	
	Diverging risk assessments by MSAs	No change to the current situation	
	Simplification of standardisation procedures	Simplification of standardisation procedures is expected to be achieved	
Food-imitating products	*Addressing risks of food-imitating products*	Clarify the regime for the food-imitating products: (a) full ban or (b) risk-assessment approach	+

In the GPSD Study's survey, all stakeholder groups considered that Option 2 addressed all challenges at least moderately well. Overall, the average assessment across all respondents and stakeholder groups was **3.4 out of 5**.

Administrative simplification

Option 2 is expected to **reduce regulatory complexity and uncertainty**, and thereby to reduce administrative burdens for businesses. Key clarifications regarding the coverage of new risks posed by new technologies will be provided in the new legal instrument. As these will be legally binding, the **regulatory complexity reduction can be expected to be more significant than under Option 1**. Also, **general requirements** for businesses and responsibilities and powers of market surveillance authorities would be **largely uniform for harmonised and non-harmonised consumer products**, which is likely to **contribute to reduce regulatory complexity** and thereby to **reduce administrative burdens for businesses**.

However, **depending on the choice of instrument**, **implementation and interpretation differences between Member States may remain** (**if a directive were chosen**). The legal form chosen under this option 2 matters for a certain number of issues and in particular simplification aspects. Contrary to a directive, a regulation is directly applicable across the Union; there is therefore no need for Member States to transpose EU legislation into national law, which can lead to some implementation differences as analysed in the problem definition. With a regulation, national differences regarding the date and/or manner of transposition would be eliminated, which would facilitate consistent enforcement and level-playing field in the internal market. A regulation ensures better that legal requirements are implemented at the same time throughout the Union; it also better achieves streamlining of terminology, important for defining the scope of the legislation, thereby reducing administrative burdens and legal ambiguities. The choice of Regulation also allows to better deliver on the objective to ensure coherence with the market surveillance legislative framework for harmonised products, where the applicable legal instrument is also a Regulation (Regulation (EU) 2019/1020).

In addition, as **lack of clarity** regarding the **application to software will remain**, uncertainty in this respect will likely not be reduced. At the same time, Option 2 would provide **limited additional requirements for specific operators,** such as requirements for **online marketplaces** resulting from making **mandatory many provisions of the Pledge**, and requirements regarding mandatory key elements that are to be included in recall notices.

Finally, ensuring alignment with harmonised market surveillance rules will reduce administrative burdens on MSAs. Similarly, simplified standardisation procedures at the Commission's level should lead to savings for MSAs and the Commission.

Consequently, simplifications would be achieved under this option by aligning market surveillance procedures for harmonised and non-harmonised products, by simplifying the standardisation procedure and by merging the rules on food imitating-products with the ones for non-harmonised products into one single legal instrument and repealing the FIPD. Also the increase of legal certainty regarding the application of consumer product safety rules to new technologies will likely reduce the regulatory costs for businesses producing new technology products. If the new act will be a Regulation the regulatory burden will decrease even more.

Economic impacts

According to the GPSD Study survey, **businesses expect** that implementing Option 2 would **increase companies' recurrent regulatory compliance costs to some extent**, as well as the **additional one-off cost** linked to the implementation of measures (see Table 9). **Total costs for businesses** in the EU27 in the first year of implementation are estimated at **EUR 36.9 million**, equivalent to 0.004% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products. They would fall in **subsequent years** down to EUR **29.6 million**.

Table 9: Changes in EU companies' costs within and after the first year of implementation of Option 2, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
First year of implementation (total of one-off and recurrent costs)				
Total manufacturing sectors	4.8	6.1	9.9	**20.7**
Total wholesale sectors	2.5	1.7	2.6	**6.9**
Total retail sectors	5.0	0.9	3.5	**9.4**
Total additional costs	***12.2***	***8.8***	***15.9***	***36.9***
Subsequent years (recurrent costs only)				
Total manufacturing sectors	4.3	5.5	8.9	**18.6**
Total wholesale sectors	1.7	1.2	1.8	**4.7**
Total retail sectors	3.4	0.6	2.4	**6.4**
Total additional costs	***9.3***	***7.3***	***13.0***	***29.6***

Source: The survey conducted in the context of the GPSD Study

Estimated **benefits for businesses** linked to cost **savings**, that are currently **caused by differences in the national implementation** of the GPSD and would be partly solved if the new instrument is a Regulation under the Option 2, would amount to **EUR 59 million annually**[104], of which EUR 34 million would be saved by EU SMEs and 26 million EUR saved by EU large businesses respectively, compared to the baseline.

The GPSD Study's survey showed that **MSAs expect considerably more benefits for businesses** from the **implementation of Option 2** (average assessment of 3.3 out of 5, above moderate; see Annex 12) **than businesses/business associations themselves (2.6) and other stakeholders (2.7)**[105], both below moderate. All respondent groups in the survey assigned similar values to the benefits resulting from better information on unsafe products/measures taken by authorities provided through Safety Gate/RAPEX.

Concerning impact on **SMEs**, they generally estimate that a revision of the product safety requirements of the GPSD according to Option 2 would bring a variety of **at least 'minor' to 'moderate' benefits**[106]. At the same time Option 2 would impose **additional adjustment** (e.g. **familiarisation cost**) as well as **compliance costs on SMEs**[107], in particular for manufacturers. Table 9 shows that SMEs would likely face relative higher compliance costs than large companies from the implementation of the proposed policy measures.

Even though the relative cost increases are generally higher for SMEs, t**he net impact on SMEs overall costs depends on the benefits** that can result from a revised GPSD aligned to the market surveillance rules and traceability requirements in Regulation (EU) 2019/1020. We expect the **SMEs would save EUR 34 million of the costs that currently arise from inconsistencies in the implementation and enforcement of the GPSD across the EU**. Taking into consideration these benefits and the fact that the changes in SMEs' costs from Option 2 are very small, we expect that the **overall net effect from Option 2 on SMEs' costs is rather low** and therefore unlikely to affect SMEs' operations.

As regards the **impact on online marketplaces**, the **additional costs** from Option 2 making most of the Product Safety Pledge obligations binding, would be **minor** for **those companies** that **already signed the Pledge**. By contrast, **non-signatory** marketplaces would likely face **additional compliance costs**[108]. In particular, some stakeholders were

[104] The baseline costs linked to the different implementation of the GPSD are estimated to amount to 119 million EUR annually (see section 7). As Options 3, 4 and possible 2 foresee to recast the GPSD as a Regulation, implementation differences would be avoided (due to the direct applicability of the new regulation in Member States), even if some differences in the national interpretation of rules may remain. Accordingly, we assume a 50% reduction of businesses' additional costs in this respect in case of choice of Regulation as legal instrument.

[105] Indeed other stakeholders are mainly consumer organisations, which showed a clear preference for Option 3 and 4.

[106] Significant benefits due to improved quality/lifecycle of products and a deterrent effect on rogue traders, relatively strong benefits are increased consumer trust, better supply chain management due to improved traceability of products and better access to the market in non-EU/EEA. These areas are seen as benefits that SMEs assess to be 'moderate' to 'significant'. This is also the case for lower operational risks for businesses and easier compliance with product safety requirements. By contrast, SMEs considered several benefits to be less than 'moderate', including a more level playing field among businesses and greater legal certainty.

[107] This is particularly the case for SMEs that (voluntarily) decide to install and operate customer registration systems. Similarly, mandatory elements for product recalls (product description with a photograph, description of risk, instructions on what to do, link to a recall website and free phone number or online service for queries) would increase the cost of SMEs that have put unsafe consumer products to the market.

[108] Two online platforms provided quantitative estimates for the expected impact on recurrent costs, stating that their companies' overall consumer product safety-related costs would increase by 10%.

concerned that these compliance costs might specifically affect small companies and create a deterrent effect on new market entrants, with potential negative effects on competition between marketplaces. Such costs should however be low, as many obligations under the Pledge that would be implemented relate to a 'notice and action' procedure specifically tailored for product safety (i.e. a reactive approach, where marketplaces only monitor the information provided by the MSAs about unsafe products but do not need to monitor the safety of products they list by themselves).

Concerning the **impact on producers of food-imitating products**, the impacts are the same as in Option 1. Concerning the **macroeconomic effects**, the interviewed stakeholders find that the implementation of Option 2 would have a minor to moderately positive impact on the functioning of the EU's internal market and international trade[109]: measures to clarify the coverage of new risks by new technologies in a revised legal instrument, as foreseen under Option 2, can address a part of the uncertainties linked to the implementation of some of the key concepts in the GPSD and new technology products, whereby uncertainties would remain with respect to the actual effectiveness of such measures, but also with respect to the coverage of software. It is possible that Member States could resort to national measures in this respect, which would create an obstacle to the free movement of goods or services and lead to an uneven level playing field for businesses in the future. Still, benefits can be expected from the clarification of safety risks stemming from new technologies, recall procedures and more coordinated actions by MSAs. Reduced legal complexity and uncertainty could reduce companies' administrative burdens to some extent, which could have a moderate positive impact on the functioning of the EU's internal market and international trade.

Similar to Option 1, the impacts from Option 2 on EU **companies' competitiveness** are expected to be relatively small as companies' additional costs incurred by Option 2 in the first year of implementation would represent only 0,004% of their annual turnover, we do not expect significant impacts on competition for EU businesses, neither for competition within the Single Market nor with regard to non-EU competitors.

As concerns innovation, due to the limited impact on companies' compliance costs **no significant impacts on EU companies' overall innovative capacities are expected**, i.e. higher budgets resulting from savings in compliance costs that translate to expanded research and business development activities. On the other hand, new regulatory requirements for online platforms might result in less innovation in some online platform business models over time, depending on the extent to which new requirements lead to additional costs, which appear, however, to be limited under Option 2.

In term of **impact on consumers**, the alignment with the provisions of Regulation (EU) 2019/1020 on market surveillance and clarifications provided in the new legal instrument could improve the enforcement of the GPSD, with related benefits for consumers. Also concerning online sales, making relevant provisions of the Pledge binding should lead to better monitoring of unsafe products by marketplaces, as there would be a regular exchange with market surveillance authorities. Option 2 would therefore be expected to increase the level of protection of EU consumers to some extent, by reducing the

[109] MSAs are on average the most positive stakeholder group about the benefits that would result from the implementation of Option 2 with an average of 3.8 (i.e. seeing close to 'significant' benefits). By contrast, the averages for both companies/business associations and other stakeholders are slightly lower (3.2 and 3.4 respectively, i.e. between 'moderate' and 'significant' benefits).

incidence of unsafe products in online sales channel. The GPSD Study estimated that consumers would therefore benefit in terms of **reduced consumer detriment based on the value of unsafe products**[110]. This detriment reduction is expected to amount to approximately **EUR 333 million in the first year of implementation,** increasing to approximately **EUR 1.03 billion over the next decade.** As regards improving the recall effectiveness and therefore reducing number of unsafe products remaining in hands of consumers would also bring benefits: the GPSD Study estimates under a scenario of somewhat improved recall effectiveness as expected under Option 2, the **consumer detriment in the EU to be reduced by EUR 205 million** in Option 2 compared to the baseline. This impact on consumers could be also relevant for specific vulnerable consumer groups such as children, and the elderly, as they are often more affected by unsafe products.

The survey of the GPSD Study shows that the **benefits for consumers** are judged by companies/business associations and MSAs as 'moderate' (average values of 3.1 for companies/business associations and 3.4 for MSAs in a scale of 5). Benefits include a reduced occurrence of unsafe products and a reduced number of injuries caused by them, as well as a resulting increase in consumer trust. Other stakeholders are less positive (below 'moderate', average value of 2.6 out of 5). As the implementation of Option 2 would only result in minor increases of consumer product safety-related costs for EU companies, the impacts from Option 2 on prices of consumer products in the EU are expected to be negligible. None of the measures considered under Option 2 would be expected to have a significant impact on consumer choice in the EU.

Concerning the impact on consumers of the sub-options for the food-imitating products, we consider that both sub-options lead to the same level of consumer protection against unsafe products, as analysed under Option 1.

Impacts on Member States

The GPSD Study reports that MSAs stated that Option 2 is expected to be more suitable than Option 1 to improve the current legal framework managing the risk of unsafe products being placed in the EU market, but the exact benefits would depend on its actual implementation. Generally, a more uniform framework for harmonised and non-harmonised consumer products, a simplification of standardisation procedures and a clarification of rules regarding product recalls foreseen under Option 2 would, over time, lead to a reduction of administrative burdens for MSAs. The GPSD Study estimates that, if a Regulation is chosen as legal instrument, benefits for MSAs arising from the alignment of the provisions for market surveillance of harmonised and non-harmonised products would lead to improvements in efficiency of market surveillance, and related **cost savings,** which are estimated at **EUR 0.7 million per year** across the EU[111].

Under Option 2, MSAs could be impacted by a broadening of market surveillance responsibilities (e.g. from modified definitions as regards risks posed by new

[110] Consumer detriment linked to the value of unsafe products, calculated on the basis of the purchase price of unsafe products.

[111] See baseline description. The proposed measures under Options 2 (if Regulation), 3 and 4 would fully align provisions for the market surveillance of harmonised and non-harmonised consumer products so that the cost burden estimated in the baseline as EUR 0.7 million will be reduced accordingly.

technologies). New responsibilities are generally reflected by a greater need for internal and external resources respectively.

The GPSD Study estimates the total **additional recurrent costs for MSAs in EU27 of approx. EUR 6.7 million annually**[112]. Concerning one-off costs, the few cost estimates that were provided by MSA respondents indicate that the **one-off adaptation and implementation costs are considered to be moderate**.

Option 2 would align the enforcement powers of MSAs regarding non-harmonised products with their powers for harmonised products. Thereby, specific gaps such as legal difficulties to conduct mystery shopping for authorities in some Member States would be addressed. However, the deterrence effect on rogue traders would not be increased, as enforcement powers would not be further strengthened through penalties and sanctions. Likewise, no arbitration mechanism would be created for cases of divergences in the product safety risk assessment between MSAs, and there would be a continued reliance on informal approaches in case risk assessments of MSAs diverge to harmonise the treatment of products on the Single Market.

Social impacts

The implementation of Option 2 is expected to potentially have **some positive social impacts with regard to public health and safety and health systems**. The clarification of covered risks, mandatory obligations for online platforms (in line with the Pledge) and the alignment with the provisions of Regulation (EU) 2019/1020 will, to some extent, improve market surveillance and enforcement. To the extent that the number of unsafe products on the market is somewhat reduced by these measures in the mid- to long term, this could potentially lead to a **lower number of injury cases** caused by consumer products in need of medical attention or hospitalisation, hence decreasing public health expenditure for the treatment of product related injuries. However, due to the limited amount of measures taken under Option 2 that could effectively reduce consumer injury-related detriment in the EU, any impact on health systems would be expected to be considerably **more uncertain and smaller in size** than under Option 3.The **current cost of health care utilisation for product-related injuries in the EU** are estimated by the GPSD Study to 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. A revised GPSD may contribute thereby to lowering these health care costs for the society.

Environmental impacts

The GPSD Study showed that, while authorities see 'moderate' benefits regarding improved lifecycle/quality of products and a higher level of the protection of the environment due to the reduction of unsafe products that also have environmental impacts, companies/business associations and other stakeholders only see between 'minor' and 'moderate' benefits. The implementation of **Option 2 is likely to have positive environmental impacts**, to the extent that it clarifies the application of the general safety requirement to products containing environmentally harmful substances that also pose a risk to human health and safety. Already today around 25% of the

[112] It should be noted that the actual percentage changes would differ for individual MSAs due to different national institutional market surveillance systems and organisational characteristics, e.g. the degree of centralisation, MSAs' product coverage and the actual assignment of new competences and enforcement requirements.

products notified in Safety Gate/RAPEX presented a chemical substance risk with adverse health effects to consumers. The relevant chemicals were often also harmful to the environment (e.g. lead and mercury).

Impacts on fundamental rights

Option 2 is expected to improve consumer safety to some extent and also to reduce product-related environmental risks (see above). The implementation of a revised GPSD according to Option 2 shall hence have a **positive impact and ensure a somewhat higher level of consumer protection and a higher level of environmental protection** in line with the Charter. However, there would be no right to effective, cost-free remedies for consumers that own a recalled product, which would limit the positive impact of this option.

At the same time Option 2 imposes additional requirements for businesses, but these do **not affect the fundamental freedom to conduct a business** as the former are necessary to pursue the general European Union interest of increasing consumer protection and are proportional to the aim pursued, given that the resulting compliance costs are estimated to be very limited compared to the businesses' turnover. The negative effect of a potential ban of food-imitating products would be the same as developed under Option 1.

6.3. Impacts of Option 3

Effectiveness in achieving the specific objectives

Table 10: Summary assessment of Option 3, compared to baseline situation

Objectives	Areas	Assessment	Impact
New technologies	*Certainty regarding coverage of new risks*	Legally binding clarifications will avoid uncertainty. The choice of a Regulation will avoid implementation differences in Member States	++
	Certainty regarding coverage of software	Coverage of software by GPSD clarified	
Online sales	*Safety of products sold on online platforms*	Safety risks for EU consumers due to products sold on online platforms would be partly reduced (and more so than under Option 2)	+ / ++
	Information of consumers on essential safety aspects	Achievement of objectives can be expected	
Recall effectiveness	*Reaching out to consumers affected by recalls*	The option can be expected to increase the availability and facilitate the use of customer data for recall purposes	++
	Information provided in recall notices	Improvement in the information provided to consumers achieved	
	Monitoring of recall effectiveness	Improvement in the monitoring of recalls is expected to be achieved, also depending on implementation	
	Remedies for consumers affected by recalls	Higher consumer participation in recalls expected	
Market surveillance	*Alignment of market surveillance framework for harmonised and non-harmonised consumer products*	Largely uniform general requirements for businesses and responsibilities and powers of MSAs for harmonised and non-harmonised consumer products expected to be achieved	++
	Deterrence effect	Deterrence effect likely to be achieved, depending on the maximum levels of penalties and sanctions foreseen	
	Diverging risk assessments by MSAs	Risk assessment are likely to become more harmonised, achieving the desired effect	
	Simplification of standardisation	Simplification of standardisation procedures is expected to be achieved	

	procedures		
Food-imitating products	*Addressing risks of food-imitating products*	Clarify the regime for the food-imitating products: (a) full ban or (b) risk-assessment approach	+

The stakeholder survey in the GPSD Study confirmed that all stakeholder groups considered that Option 3 addressed all challenges at least moderately well with the overall average assessment across all respondents and stakeholder groups at **3.8 on the scale from 1 to 5**.

Administrative simplification

Option 3 would provide several legally binding clarifications, **reducing regulatory uncertainty** in this respect. General requirements for businesses and responsibilities and powers of market surveillance authorities would be largely uniform for harmonised and non-harmonised consumer products, and implementation differences in Member States would be reduced, which is likely to contribute to reduced regulatory complexity and thereby to reduced administrative burdens for businesses.

On the other hand, Option 3 would include **some additional administrative requirements for specific types of operators** (e.g. the requirement to provide essential safety information online for online traders). The most comprehensive requirements would apply in the context of recalls, which will likely lead to increased administrative burdens. The GPSD Study concluded that as currently the effectiveness of recalls is considered to be limited, these additional measures and the related administrative burdens appear to be proportionate.

Finally, the **simplification of the standardisation process** has the **potential to reduce administrative burdens** on Member States and at EU level by streamlining the related EU process. There is also potential for **decreasing the regulatory burden for companies** thanks to the arbitration mechanism on the risk assessment.

Also, the choice of Regulation instead of Directive under this option will further reduce the regulatory burden through a consistent application of product safety rules across the EU.

Economic impacts

The survey conducted in the GPSD Study estimates[113] that the **additional recurrent costs** would increase under Option 3 as well as the **additional one-off cost** (see Table 11). **Total costs for businesses** in the EU27 in the first year of implementation are estimated at **EUR 196.6 million**, equivalent to 0.02% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products. They would fall in **subsequent years** to **EUR 177.8 million**. The rise in costs for businesses in Option 3 is due to the increased substantive provisions under this Option, requiring investments on the side of businesses, in particular regarding the online sales and recalls.

[113] The accuracy of the given estimates depends on the implementation details

Table 11: Changes in EU companies' costs within and after the first year of implementation of Option 3, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
First year of implementation (total of one-off and recurrent costs)				
Total manufacturing sectors	26.9	34.4	55.7	**17.0**
Total wholesale sectors	12.3	8.5	12.7	**33.6**
Total retail sectors	24.3	4.6	17.1	**46.0**
Total additional costs	*63.5*	*47.6*	*85.6*	***196.6***
Subsequent years (recurrent costs only)				
Total manufacturing sectors	25.7	32.9	53.2	**111.7**
Total wholesale sectors	10.2	7.1	10.6	**27.9**
Total retail sectors	20.2	3.8	14.2	**38.2**
Total additional costs	*56.1*	*43.8*	*78.0*	***177.8***

Source: The survey conducted in the context of the GPSD Study

Concerning the stakeholders views, the GPSD Study showed that companies expect the implementation of Option 3 to cause changes in their recurrent costs, e.g. costs related to additional staff and additional resources for due diligence measures including the establishment of IT systems and external services, in addition to one-off costs, such as familiarisation costs, adaptation costs to regulatory changes (e.g. for external advice).

Businesses expect that implementing Option 3 would increase companies' recurrent regulatory compliance costs, generally more for manufacturers than wholesalers and retailers, as they might have to adjust different stages of the value-adding process to new regulatory requirements.

Estimated benefits for businesses linked to **cost savings**, that are currently **caused by differences in the national implementation** of the GPSD are the same under Option 3 as in Option 2 due to the choice of Regulation, amounting to **EUR 59 million annually** (EUR 34 million saved by EU SMEs and 26 million EUR by EU large businesses). These costs savings can be deducted from the costs, i.e. net costs in the first year would be EUR 138 million in the first year.

The implementation of Option 3 would be expected to address current gaps in the product safety regime for non-harmonised products and thereby safeguard the continued free movement of goods in the Single Market. This would likely contribute to positive spill-over effects on consumer trust, demand, production and employment, compared to the baseline scenario, which is beneficial for all undertakings.

Companies and business associations saw **less benefits** (between 'minor' and 'moderate') **than MSAs and other stakeholders**, who assessed benefits to be mostly considerably more than 'moderate' and close to 'significant' (see Annex 12).

As concerns the benefits for **SMEs**, the GPSD Study shows that ***small companies*** generally estimate that Option 3 would bring a variety of at least 'minor' to 'moderate' benefits, especially due to its **deterrent effect** on rogue traders and **better detection of unsafe product**s. However, Option 3 is considered by small companies as less beneficial

when it comes to reducing legal complexity or making compliance with product safety requirements easier for SMEs. In the case of ***medium-sized companies***, Option 3 is seen as a **suitable contribution to an increased level-playing field** among businesses and to have a significant benefit linked to reducing the occurrence of unsafe products and for contributing to a better functioning of the EU internal market. Finally, moderate benefits are expected regarding the potential to increase business revenue or consumer trust.

Even though the relative **cost increases are generally higher for the SMEs**, the impact on SMEs overall costs is still considered moderate when measured against the benefits that would result from a greater level of regulatory harmonisation and reduced regulatory complexity through the choice of a Regulation, **savings being estimated at EUR 34 million for EU SMEs**. The changes in SMEs costs are estimated to be limited and Option 3 would not be expected to affect operations considerably[114].

Online marketplaces interviewed generally agree that the measures under Option 3 would bring several benefits[115]. In the GPSD Study, some businesses also stated that obligations for online marketplaces need to go beyond the Pledge's provisions and be aligned with those obligations that need to be met by offline importers/distributors, including applying ex-ante and ex-post measures and meeting traceability requirements.

Marketplaces also indicated that Option 3 would increase in particular their recurrent costs. The additional costs would generally be relatively limited for signatories of the Pledge. By contrast, non-signatory platforms would likely face additional compliance costs. These compliance costs might specifically affect small platforms and create a deterrent effect on new market entrants, with potential negative effects on competition between platforms, depending on the size of the additional costs. Due diligence obligations in terms of product safety might require more efforts, but would likely imply less efforts than those of brick and mortar distributors for fulfilling their obligations under the current regime, thanks to the easier product and customer traceability on the online interface of a given platform.

Online marketplaces and other online sellers would also be affected by a requirement to ensure that all safety information is provided online in the same vein as it is required "offline". We expect these costs to be very limited for both online platforms and online sellers, as this information is already available and does not go beyond what is indicated on the packaging.

Concerning the **impact on producers of food-imitating products**, the impacts are the same under Option 3 as in Option 1 and 2.

Concerning the **macroeconomic impacts**, the results of the consultation conducted for this study indicate that all stakeholder groups see **important benefits** of Option 3 in

[114] This consideration is also true for specific information obligations, such as the obligation for actors across the online supply chain to provide all safety information online that is also required to be provided with a product in 'brick and mortar' stores, and the related obligation for online platforms to make sure that third-party sellers, such as SMEs, provide this information. We expect these costs to be relatively minor for companies selling consumer products on these platforms, including SMEs.

[115] According to them option 3 would improve consumer trust, provide better information on unsafe products and ensure more effective measures taken by MSAs through Safety Gate/RAPEX, and provide greater legal certainty and less complexity. Online platforms respondents also tended to agree that the measures in Option 3 would have a deterrent effect on rogue traders and reduce the occurrence of products presenting health and safety risks in the Single Market.

terms of a better functioning EU internal market and a better level-playing field among businesses, partly through the deterrent effect on rogue traders. All these potential benefits were assessed as being 'moderate' to 'significant' in the GPSD Study's survey.

The alignment of the market surveillance rules for all products and a clearer legal framework under Option 3 should overall significantly reduce the businesses' compliance costs and administrative burdens, which would level the playing field for companies from different countries within the EU and may help many European businesses to be more competitive internationally. At the same time, a more harmonised regulatory level-playing field within the EU will also induce non-EU companies to market their products in the EU, with positive impacts on intra-EU competition. The additional gains in EU companies' competitiveness are expected to be very moderate as companies' current compliance costs with consumer product safety legislation are already relatively low[116], accounting for relatively small shares of total revenues. Moreover, additional regulatory requirements would level potential cost reductions.

Depending on the actual implementation, Option 3 should also create a higher deterrent effect on rogue traders and therefore ensure a better level-playing field for companies by ensuring that all bear the compliance costs with products safety: this was an important point raised in the different consultation activities.

Due to the **relatively low additional costs for businesses, representing 0.02% of their annual turnover in the first year of implementation,** that would result from Option 3, we expect neither significant distortions in competition and international trade for EU businesses, nor significant impacts on EU companies' overall innovative capacities[117]. The GPSD Study nevertheless expects positive impacts on competition-driven innovation due to a greater degree of harmonisation and greater legal certainty (e.g. development of new innovative information and traceability systems).

Concerning the **impact on consumers**, the implementation of Option 3 would result in **greater benefits for consumers** due to broader coverage and greater effectiveness of the GPSD in protecting consumers from unsafe products, particularly with respect to the mitigation of risks from new technologies and the coverage of products sold via online channels. Option 3 could therefore be expected to increase consumer safety in the online environment and have positive effects on consumer trust, which might translate in higher demand for consumer goods that are sold via online channels. The GPSD Study estimated that consumers would therefore benefit in terms of **reduced consumer detriment based on the value of unsafe products**[118]. This is expected to amount to approximately **EUR 1.0 billion in the first year of implementation,** increasing to approximately **EUR 5.5 billion over the next decade.** Improving the recall effectiveness and therefore reducing the number of unsafe products remaining in hands of consumers would also bring benefits: the GPSD Study estimates under a scenario of significantly improved recall effectiveness (under the assumption that return rates of recalled products are doubled due to legislative measures and more deterrent sanctions and penalties as expected under

[116] The GPSD Study found that companies already do a lot for safety as usual business.
[117] However, new regulatory requirements for online platforms might result in less competitive dynamism and innovation in online platform business models over time, depending on the extent to which new requirements lead to additional costs (and their size compared to other cost factors), similarly to Option 2
[118] Consumer detriment linked to the value of unsafe products, calculated on the basis of the purchase price of unsafe products as explained above.

Option 3), the **consumer detriment due to ineffective recalls to be reduced by EUR 410 million** in Option 3.

The survey in the GPSD Study showed that stakeholders consider that Option 3 provides 'moderate' to 'significant' benefits for consumers. These include a **reduced occurrence of unsafe products** and a reduced number on injuries caused by them, as well as a resulting increase in consumer trust.

Some of the additional costs incurred to businesses by Option 3 would be passed on, both up- and downstream the product value chain, and thereby impact consumer prices. However, as most businesses report relatively low additional one-off and recurrent costs, the short and medium- to long-term impacts on consumer prices in the EU are expected to be negligible. Also, the GPSD Study does not expect a significant negative impact on consumer choice in the EU under Option 3[119].

On the other hand, a limited effect pertaining to the affordability of products is also possible. While the increase in consumer prices is overall considered negligible under Option 3, purchase prices for some non-harmonised products might be affected (e.g. products that are most cheaply ordered through online platforms from non-EU/EEA traders), and low-income consumers with high price-elasticity may reduce their purchases.

Concerning the impact on consumers of the sub-options for the food-imitating products, we consider that both sub-options lead to the same level of consumer protection against unsafe products, as analysed under Option 1.

Impacts on Member States

Based on the results from the Study, efficiency gains by MSAs would mostly arise from the alignment of the provisions for market surveillance of harmonised and non-harmonised products. This would lead to improvements in efficiency of market surveillance, and related **cost savings,** estimated at **EUR 0.7 million per year** across the EU under Option 3, similarly to Option 2. Also, streamlined standardisation procedures and an arbitration mechanism that provides clarification regarding risk assessments in case of disputes between MSAs could lead to additional cost reductions for MSAs over time.

Concerning the costs, the Study estimates that Option 3 would lead to **total additional recurrent costs of MSAs** in EU27 of approx. **EUR 6.7 million annually** and only relatively moderate one-off adaptation and implementation costs.

Generally, the efficiency of market surveillance processes with implications across the EU would be increased under Option 3, mainly via an increased deterrent effect through provisions on penalties and arbitration mechanism.

Social impacts

The implementation of Option 3 is expected to potentially have positive social impacts with regards to **public health** and **safety and health systems, higher than in Option 2**.

[119] This will depend more on other measures taken at EU level (e.g. changes to the VAT regime, the provisions of the new DSA), which may impact market access for products sold directly to consumers by non-EU/EEA traders through online marketplaces.

The introduction of additional requirements for traceability and product recalls are expected to improve the effectiveness of recalls of unsafe products from consumers. For instance, the cost savings from directly informing consumers affected by a recall rather than using indirect communication channels have been estimated at €73 million in 2019, i.e. a fifth of the overall estimated cost of recall ineffectiveness[120]. In addition, increased enforcement powers for Member States to impose penalties and sanctions are anticipated to significantly improve market surveillance and enforcement. Consequently, the current cost of health care utilisation for product-related injuries in the EU of approximately EUR 6.7 billion per year could be further reduced under Option 3.

Environmental impacts

On the benefits related to environment of Option 3, the Study reports that while authorities see 'moderate' to 'significant' benefits regarding improved lifecycle/quality of products and a higher level of environmental protection due to the reduction of unsafe products that also have environmental impacts, companies/business associations and other stakeholders only see benefits that are (close to) 'moderate'. The same analysis concerning the hazardous chemicals applies here as under Option 2, but the **positive impact of Option 3 is amplified by the expected better product safety enforcement**.

Impacts on fundamental rights

Option 3 is expected to improve consumer safety whilst also reducing environmental risks (see below). It would thus have a **positive impact and ensure a higher level of consumers' life as well as consumer protection and environmental protection** in line with the Charter. This positive impact should be amplified by better product safety enforcement.

The additional requirements imposed on economic operators **do not affect the fundamental freedom to conduct a business**, as they are necessary to pursue the general EU interest of increasing consumer protection and are proportional to the aim pursued, given that the resulting compliance costs are estimated to be comparatively low compared to the businesses' turnover. The negative effect of a potential ban of food-imitating products would be the same as developed under Option 1.

6.4. Impacts of Option 4

The main significant difference between options 3 and 4 concerns the **merger of legal instruments for the market surveillance rules for harmonised and non-harmonised products** into one single Regulation. Therefore the assessment of impacts will concentrate only on this additional element (the rest of the analysis under Option 3 is also valid for Option 4, unless stated otherwise in this section).

Effectiveness in achieving the policy objectives

Creating a single set of rules that would apply to harmonised and non-harmonised consumer products will simplify the EU legal framework greatly. It can be expected that the objective to create uniform requirements for businesses and responsibilities and

[120] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

powers of market surveillance authorities for harmonised and non-harmonised consumer products will be fully achieved. All stakeholder groups considered that Option 4 addressed all challenges at least moderately well. The average assessment across all stakeholder groups was **3.8 out of 5** (similar to Option 3).

Administrative simplification

In addition to Option 3, a single set of rules for market surveillance of harmonised and non-harmonised consumer products in the EU could, overall, result in even less legal complexity. This could translate into **simplifications for businesses and MSAs in countries where current national law implements the GPSD and harmonised product legislation through different legal instruments**. However, where all product safety legislation is already transposed into a single national product safety law (which is the case in some countries), simplifications through a new EU legal instrument are likely to be very limited.

Economic impacts

The GPSD Study showed that businesses expected costs from Option to be significantly higher compared to Option 3 (see Table 12). **Total costs for businesses** in EU27 in the first year of implementation are estimated at **EUR 331.1 million**, equivalent to 0.03% of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products. They would fall in **subsequent years** to **EUR 296.3 million**.

Table 12: Changes in EU companies' costs within and after the first year of implementation of Option 4, in million EUR

	From 0 to 49 employees	50 – 249 employees	250 or more employees	Total
First year of implementation (total of one-off and recurrent costs)				
Total manufacturing sectors	45.0	57.7	93.4	**196.0**
Total wholesale sectors	21.0	14.5	21.6	**57.0**
Total retail sectors	41.2	7.8	29.0	**78.0**
Total additional costs	***107.2***	***79.9***	***144.0***	***331.1***
Subsequent years (recurrent costs only)				
Total manufacturing sectors	42.7	54.8	88.7	**186.2**
Total wholesale sectors	17.1	11.8	17.6	**46.5**
Total retail sectors	33.6	6.4	23.7	**63.6**
Total additional costs	***93.4***	***72.9***	***130.0***	***296.3***

Source: The survey conducted in the context of the GPSD Study

Compared to Option 3, Option 4 comes therefore to substantial additional costs for businesses even if there is no substantive difference regarding the regulatory obligations for businesses and integration of legal instruments should overall reduce regulatory complexity.

A possible explanation for this is that businesses were generally uncertain about the precise implications of Option 4 and tended to provide cautious estimates with regard to additional costs from new regulatory obligations that might arise if one single set of rules would apply. The data on costs for businesses under different options provided by the support study are based on the **cost estimations provided directly by the businesses** during the survey. When analysing the reasons why businesses were reporting higher costs for Option 4, it appeared that for businesses the legal certainty, clarity of their

obligations, even application across the EU and predictable legal environment are very important. This was also confirmed by the **meetings with businesses associations**. If the rules were set in one legal instrument, that would provide simplicity but proportionally more for Member Sates authorities (in particular in those Member States where market surveillance authorities handle both harmonised and non-harmonised products together) than for businesses. On the contrary, businesses perceived some regulatory risk in Option 4 linked to the possible reopening of Regulation (EU) 2019/1020 for which negotiations have been recently concluded. Businesses had already to invest into the compliance with this new market surveillance Regulation and perceived that merging the rules could lead to reopening of market surveillance provisions already agreed and would create uncertainty about their future legal environment. It should be noted, however, that these **costs reported by businesses might be inflated** since they are not based on any specific calculation grounds but simple assumptions. If the new market surveillance framework would integrate the provisions relevant for economic operators in Regulation (EU) 2019/1020, such a new legal instrument would not entail additional costs for businesses. Since Regulation (EU) 2019/1020 is setting up rules for market surveillance for harmonised products, any integration of market surveillance rules under one unique legal instrument would therefore mainly impact Member States rather than businesses, in particular by creating benefits for those Member States where the same authorities handle both categories of products, harmonised and non-harmonised.

This difference in viewpoints between businesses and national authorities has been also confirmed by the general assessment of the benefits of Option 4 in the external survey: Businesses have been more sceptical, and saw only slightly less than 'moderate' benefits on average (2.9 on a scale of 5), while market surveillance authorities assessed the Option 4 as bringing close to 'significant' benefits (value of 3.9).

Other economic impacts (both micro- and macroeconomic impacts) as well as **impact on consumer and households** are **expected to be identical to the impacts under Option 3**.

The survey of the GPSD Study shows that **MSAs expect on average considerably more benefits** that would result from an implementation of Option 4 than businesses/business associations and other stakeholders[121]. It is notable that the expected benefits of Option 4 are considered to be slightly higher by all stakeholders than the benefits of Option 3.

Impacts on Member States

MSAs responding to the Study's survey stated that having the same rules for all harmonised and non-harmonised products would induce benefits beyond those already identified under Option 3.

The Study found that Option 4 would bring an increase in **recurrent costs of MSAs of 5% of total annual staff-related costs**: this would amount to total additional costs of MSAs in the EU27 of approx. **EUR 3.3 million annually**[122]. The few numbers that were

[121] Overall, MSAs assessed a value of 3.9, or very close to 'significant' benefits. MSAs especially expect 'significant' benefits from greater legal certainty and reduced legal complexity (values of 4.3 and 4.1 respectively). Also other stakeholders see this option bringing 'moderate' to 'significant' benefits (average 3.5). Businesses are more sceptical, and see slightly less than 'moderate' benefits on average (2.9).

[122] Actual percentage changes would differ for individual MSAs due to different national institutional market surveillance systems and organisational characteristics, e.g. the degree of centralisation, MSAs' product coverage and, after all, the actual assignment of new competences and enforcement requirements.

provided by MSA respondents indicate that the one-off adaption and implementation costs are considered to be relatively minor (e.g. to prepare some national guidance, new communication strategy and to strengthen cooperation at the national level).

Social impacts, environmental impacts and impacts on fundamental rights

As the measures implemented under Option 4 are **identical** to the measures implemented under **Option 3**, the two options are expected to have identical impacts in a social or environmental perspective, as well as on fundamental rights.

7. HOW DO THE OPTIONS COMPARE?

In this section, we compare the results of the impact assessment of the four options, based on the elements developed in the section 6 and the results of the GPSD Study.

Expected achievement of objectives

Table 13: Comparative assessment of impact on objectives

Area	Option 1	Option 2	Option 3	Option 4
Ensure general safety rules, including for product risks linked to **new technologies**	neutral / +	+	++	++
Address safety challenges in the **online sales channels**	neutral	neutral / +	+ / ++	+ / ++
Make product **recalls** more effective	neutral	+	++	++
Enhance **market surveillance** and ensure better alignment of rules	neutral	++	++	++
Address safety issues related to **food imitating products**	+	+	+	+
Total effectiveness score by stakeholders (scale 1-5)	**2,9**	**3,4**	**3,8**	**3,8**

Source: The survey conducted in the context of the GPSD Study

Option 1 would be expected to achieve only one of the five policy objectives, with some additional benefits due to reduction of uncertainty (provision of EC guidance). Option 2 appears more effective in reaching objectives, with some identified gaps being closed and uncertainty reduced by legal measures; however some other gaps remain (e.g. regarding software, product recalls and online sales channels). Options 3 and 4 would most likely achieve all the defined objectives of the initiative.

Administrative simplification

Table 14: Comparative assessment of impact on administrative simplification

Area	Option 1	Option 2	Option 3	Option 4
Reduction of regulatory complexity and uncertainty	neutral / +	neutral / +	+	+ / ++

Option 1 is expected to bring slight reduction of regulatory complexity and uncertainty (via guidance). There are no new administrative requirements, however: administrative burdens due to current fragmentation of legal regime continue (experienced by 16% of MSAs and 42% of companies responding to the survey in the GPSD Study as explained in the baseline section). Option 2 would bring some additional reduction of regulatory

complexity and uncertainty, especially if a Regulation was chosen and involve only very limited additional administrative requirements for specific operators.

Under **Options 3 and 4, the reduction of regulatory complexity and uncertainty is the most significant** (all regulatory gaps closed), with related reduction in administrative burdens for businesses. Some additional administrative requirements concern specific types of operators, the most comprehensive ones concern recalls, which would be limited to companies that have brought unsafe products on the market. Option 4 will further reduce regulatory complexity and bring simplicity, as one single set of rules would apply to harmonised and non-harmonised products.

Economic impacts

Table 15: Comparative assessment of micro- and macroeconomic impacts

Area	Option 1	Option 2	Option 3	Option 4
Benefits for businesses	neutral / +	neutral / + (Benefits of EUR 59 million/year, if Regulation)	+ Benefits of EUR 59 million/year	+ Benefits of EUR 59 million/year
Cost of businesses (EU27)	neutral	Increase by < EUR 37 million/year	Increase by < EUR 197 million/year	Increase by < EUR 332 million/year
Macroeconomic impacts (Internal market, trade, competition, innovation)	neutral	neutral / +	+	+

Estimated benefits for businesses linked to **costs savings**, that are currently **caused by differences in the national implementation** of the GPSD and would be partly solved if the new instrument is a Regulation **(Options 2, 3 and 4),** would amount to **EUR 59 million annually**[123], of which EUR 34 million would be saved by EU SMEs and 26 million EUR saved by EU large businesses respectively, compared to the baseline.

Other additional economic benefits for businesses are expected to be minor under Options 1 and 2, mostly related to reduction of uncertainty due to guidance (Option 1) or the coverage of certain gaps in a recast GPSD (Option 2). **Benefits are expected to increase with Options 3 and 4**, as all legislative gaps identified in the problem analysis are closed and related uncertainty is avoided. The measures taken regarding online sales contribute to safeguarding a level-playing field for businesses and the deterrence of rogue traders, which are expected to have concrete benefits at firm level, especially in those areas where consumer trust and safety are affected by unsafe products entering the EU through direct online business to consumer transactions.

[123] The baseline costs linked to the different implementation of the GPSD are estimated to amount to 119 million EUR annually (see section 7). As Options 3, 4 and possible 2 foresee to recast the GPSD as a Regulation, implementation differences would be avoided (due to the direct applicability of the new regulation in Member States), even if some differences in the national interpretation of rules may remain. Accordingly, we assume a 50% reduction of businesses' additional costs in this respect in case of choice of Regulation as legal instrument.

Table 16: Changes in EU companies' costs within and after the first year of implementation of Options 1 to 4, EU27, in million EUR

	Option 1	Option 2	Option 3	Option 4
First year of implementation (total of one-off and recurrent costs)				
Manufacturing sectors	0	20.7	17.0	196.0
Wholesale sectors	0	6.9	33.6	57.0
Retail sectors	0	9.4	46.0	78.0
Total additional costs (EU27)	***0***	***36.9***	***196.6***	***331.1***
Subsequent years (recurrent costs only)				
Manufacturing sectors	0	18.6	111.7	186.2
Wholesale sectors	0	4.7	27.9	46.5
Retail sectors	0	6.4	38.2	63.6
Total additional costs (EU27)	***0***	***29.6***	***177.8***	***296.3***
Equivalent to the share of turnover of EU companies for manufacturing, wholesale and retail of non-harmonised consumer products (first year of implementation):				
Share in turnover	***0%***	***0.004%***	***0.02%***	***0.03%***

There are no changes in compliance costs for EU companies under Option 1, and only expected to a minor extent under Option 2. Compliance costs of businesses are expected to increase more significantly under Options 3 and 4, however still representing a small fraction of companies' turnover, maximum 0.03% for Option 4.

Under **options 2 to 4** (see Tables 9, 11, 12), the effects of additional compliance costs will have a **larger relative cost impact on SMEs** than on large companies. Even though the relative cost increases are higher for SMEs, the impact on SMEs overall costs is **still considered moderate when measured against the benefits** that would result from a greater level of regulatory harmonisation. The changes in SMEs costs are small and implementation of any of the options would not be expected to significantly affect SMEs.

Minor impacts on online platforms are expected under Option 2 for those that are not yet signatories of the Pledge. Under Options 3 and 4 impacts on online platforms are higher, due to due diligence obligations in terms of product safety. However this would likely imply less efforts than those the classical distributors have today under GPSD and therefore proportionate to the general objective.

With respect to macroeconomic impacts, the impacts are expected to be mostly limited, with most (positive) impacts to be expected under Options 3 and 4. Both options would be expected to lead to a more aligned and clearer EU legislative framework as well as reduced legal complexity, which could overall significantly reduce the part of companies' compliance costs.

Impacts on consumers and households

The consumers will benefit from the reduction of the unsafe products on the EU market. The expected impact of the different options on the reduction of the consumer detriment linked to the value of unsafe products is presented in Table 17[124].

[124] Estimation of the impact on the injury related detriment could not be done due to the lack of data.

Table 17: Expected reduction in consumer detriment due to unsafe products– EU27, in EUR million per year

Year	Option 1	Option 2	Option 3	Option 4
2025 (expected 1st implementation year)	0	333	1 038	As Option 3
2026	0	704	2 153	
2029	0	821	3 924	
2034	0	1 031	5 491	

Options 3 and 4 are likely to be more effective than options 1 and 2 to address the challenges for product safety posed by online sales channels. The measures taken under Options 3 and 4 also contribute to aligning the level of product safety between the online and offline sales channels and increasing it, and thereby to reducing the incidence of unsafe products on the market overall. Measures taken under **Options 3 and 4 are also expected to reduce consumer detriment estimated on the basis of the value of unsafe products by approximately EUR 1.0 billion in the first year of implementation, increasing to approximately EUR 5.5 billion over the next decade**, much higher than in Option 2 and 1. This represents the decrease of financial costs for consumers since they would avoid buying unsafe products. The reason for this increase over time is that overall consumer detriment is expected to grow in the mid-term in the baseline scenario, due to increasing consumption and a continuing shift to e-commerce.

Also, enhancing recall effectiveness would reduce the consumer detriment since less unsafe products would remain in hands of consumers and they might get compensated for the recalled products. Guidance measures under Option 1 in the area of product recalls are not expected to lead to a significantly higher recall effectiveness, and therefore are not expected to reduce related detriment. In contrast, **Options 3 and 4 could be expected to substantially reduce consumer detriment related to the value of unsafe products which were not effectively recalled by more than EUR 400 million per year** (Option 2 by half of this amount).[125]

Table 18: Expected reduction in consumer detriment due to ineffective recalls – EU27, in EUR million per year

Year	Option 1	Option 2	Option 3	Option 4
Reduction of consumer detriment	0	205	410	410

The other impacts on consumers and households have been estimated as follows:

Table 19: Comparative assessment of other impacts on consumers and households

Area	Option 1	Option 2	Option 3	Option 4
Consumer prices	neutral	neutral	neutral	neutral
Consumer choice	neutral	neutral	neutral	neutral
Consumer safety and vulnerable consumers	neutral	+	++	++

No impacts on consumer prices and choice are expected, as estimated increases in compliance costs are small compared to baseline costs, and companies' overall product

[125] This estimate is based on a number of scenario assumptions, to provide a reasonable and cautious estimate of consumer benefits due to improved recall effectiveness. A key assumption is that the detriment incurred by consumers in case of a recall of an unsafe product is equivalent to at least its purchase price (a recalled, unsafe product could also cause additional detriment linked to damage to persons, other goods or the environment).

safety-related costs, including regulatory compliance costs, account for only very limited shares of the companies' turnover.

Regarding consumer safety and the protection of vulnerable consumer groups, the four options differ: Options 3 and 4 are expected to provide a higher level of protection in terms of consumer safety and the protection of vulnerable consumer groups, as existing regulatory gaps are closed and the related policy objectives are better achieved.

Impacts on Member States

Table 20: Comparative assessment of impact on Member States

Area	Option 1	Option 2	Option 3	Option 4
Benefits for MSAs	neutral / +	+ Benefits of EUR 0.7 million/year	++ Benefits of EUR 0.7 million/year	++ Benefits of EUR 0.7 million/year
Costs for MSAs (EU27)	neutral	mostly neutral (<EUR 7 million/year)	mostly neutral (<EUR 7 million/year)	mostly neutral (<EUR 4 million/year)
Other effects on Member States	neutral	neutral / +	+	+

Benefits for MSAs would mostly arise from the alignment of the provisions for market surveillance of harmonised and non-harmonised products. This leads to improvements in efficiency of market surveillance, and related **cost savings,** which are estimated at **EUR 0.7 million per year** across the EU (for Option 2 if Regulation is chosen and Options 3 and 4)[126]. Also, streamlined standardisation procedures and an arbitration mechanism that provides clarification regarding risk assessments in case of disputes between MSAs could lead to additional cost reductions for MSAs over time.

Cost for MSAs are not expected to increase significantly under any of the options. With Option 1, no additional costs are to be expected. Under the other options, estimates of additional costs are between **EUR 3.3 million/year** (**Option 4**) and **EUR 6.6. million/year** (in **Options 2 and 3** respectively), the difference being related to the expected degree of legislative alignment (the most far-reaching alignment of the legislative framework is under Option 4, which leads to most efficiency gains).

Social impacts, impacts on fundamental rights and environmental impacts

Table 21: Comparative assessment of other impacts

Area	Option 1	Option 2	Option 3	Option 4
Social impacts	neutral	neutral / +	neutral / +	neutral / +
Environmental impacts	neutral	neutral / +	+	+
Impacts on fundamental rights	neutral	neutral / +	+	+

Option 1 is not expected to have significant **social impacts** and Option 2 only to have some positive ones, to the extent that number of unsafe products and product-related

[126] See baseline description. The proposed measures under Options 2 (if Regulation), 3 and 4 would fully align provisions for the market surveillance of harmonised and non-harmonised consumer products so that the cost burden estimated in the baseline as EUR 0.7 million will be reduced accordingly. Legislative fragmentation between harmonised and non-harmonised products currently creates costs for MSAs, estimated to amount to EUR 0.7 million annually (total for the EU27). If the new legislation is a Regulation aligning rules for harmonised and non-harmonised products, it would create benefits in form of costs savings to MSA which are estimated to fully reach the amount of EUR 0.7 million per year since the legal fragmentation would disappear.

environmental risks are reduced. **Most positive social impacts are expected under Options 3 and 4**, due to enhanced market surveillance which should reduce the number of unsafe products on the market in the mid- to long term, and consequently to a lower number of injury cases, hence lowering public health costs.

Also reduction of product-related environmental risks decreases in particular in Options 3 and 4, to the extent that the application of safety requirement in this respect is clarified and effectiveness of recalls of products posing environmental risks is improved.

Options 1 and 2 are not likely to have significant impacts on fundamental rights (Option 2 possibly minor), while Options 3 or 4 are expected to have a positive impact and ensure a higher level of the consumer protection and environmental protection. Even if Options 3 and 4 impose additional requirements for businesses, these do not affect the fundamental freedom to conduct a business and appear to be proportional to the general objective pursued. However, a ban of food-imitating products from the EU market would have a negative impact on the freedom to conduct a business, and its proportionality regarding Art 52 of the Charter would need to be proven.

Impacts of sub-options for food-imitating products

A **full ban** of food-imitating products **(sub-option (a)) and case by case risk-assessment** of food-imitating products **(sub-option (b))** appear to both deliver the same level of consumer protection since in both cases unsafe products would be subject to corrective measures. In **both options there is a benefit** linked to better clarification and harmonisation of the rules which would lead to higher legal certainty and level-playing field for economic operators in both sub-options. The **broad economic negative impacts** of **a full ban of food-imitating products** would likely be **minor** since the number of these products is limited. But a full ban on food-imitating products from the EU market without risk-assessment would have **a negative impact on the freedom to conduct a business**, while there is **no evidence** to prove that it protects better consumers, in particular children, **to confirm its proportionality**. At the same time, **Option (b) is fully coherent with the current risk-based assessment approach in the GPSD** and **more proportionate** to the possible economic impact of corrective measures on economic operators.

Impacts of the choice of the legal instrument

The analysis shows that **a regulation is preferable to a directive in terms of choice of the legal form**. A regulation is directly applicable in all Member States; there is therefore no need for Member States to transpose EU legislation into national law and no need to provide them with time to do so. Possible national differences regarding the date and/or manner of transposition would be eliminated with a regulation, which would facilitate consistent enforcement and level-playing field in the internal market. A regulation ensures better that legal requirements are implemented at the same time throughout the Union; it also better achieves streamlining of terminology, important for defining the scope of the legislation, thereby reducing administrative burdens and legal ambiguities; this is particularly true in light of the fact that one of the purposes of the revised GPSD is to make it as coherent as possible with Regulation (EU) 2019/1020, which is indeed a Regulation.

From a subsidiarity and proportionality perspective, the choice of the legal delivery instrument in the form of regulation or a directive does not differ in term of impact. In

both cases, the subsidiarity principle is respected since the EU action is necessary to harmonise the general product safety requirement in the EU and ensure therefore safety of products, consumer protection and level-playing field in the Single Market. Both instruments are proportional since the requirements introduced are proportionate to achieve the level of product safety needed to ensure consumer protection and the level playing-field for businesses.

The choice of a **Regulation** instead of a Directive under the Options 3 and 4 (and possible Option 2) will further **reduce the regulatory burden** thanks to a more consistent application of product safety rules across the EU.

Table 22 below presents the overview of all the impacts analysed in this IA report. Concerning the methodology for the comparison of impacts, the report generally operates with the "+/-" rating system for impacts that were qualitatively assessed. However, one composite indicator representing the "expected achievement of objectives" was computed based on 5 qualitative indicators measuring the degree the 5 specific objectives of the GPSD would be achieved. The scale "1-5" was chosen for it to allow for a more accurate overall score (2.9, 3.8 etc.) of the aggregate of the 5 impacts assessed with the "+/-" rating (which has only 5 scales: --, -, neutral, +, ++).

Table 22: GPSD Overview of the impacts of policy options

	Option 1 Enhanced enforcement		Option 2 Targeted legal revision	Option 3 Full legal revision	Option 4 Integration of rules
Expected achievement of objectives (scale 1-5)	2,9		3,4	3,8	3,8
Administrative simplification	neutral / +		neutral / +	+	+ / ++
Economic impacts **Benefits for businesses** **Benefits if Regulation**	neutral / + NA		neutral / + EUR 59 million/year	+ EUR 59 million/year	+ EUR 59 million/year
Cost for businesses (EU27) Increase by ***Share in turnover***	neutral ***0%***		< EUR 37 million/year ***0.004%***	< EUR 197 million/year ***0.02%***	< EUR 332 million/year ***0.03%***
Macroeconomic impacts (Internal market, trade, competition, innovation)	neutral		neutral / +	+	+
Impacts on consumers **Expected reduction in consumer detriment due to unsafe products – EU27, in EUR million per year**	1st year	0	333	1 038	1038
	10th year	0	1 031	5 491	5491
Expected reduction in consumer detriment due to ineffective recalls – EU27, in EUR million per year	0		205	410	410
Consumer prices	neutral		neutral	neutral	neutral
Consumer choice	neutral		neutral	neutral	neutral
Consumer safety and vulnerable consumers	neutral		+	++	++
Impacts on Member States **Benefits for MSAs** **Benefits if Regulation**	neutral / + NA		+ EUR 0.7 million/year	++ EUR 0.7 million/year	++ EUR 0.7 million/year
Costs for MSAs (EU27)	neutral		mostly neutral <EUR 7 million/year	mostly neutral <EUR 7 million/year	mostly neutral <EUR 4 million/year
Other effects on Member States	neutral		neutral / +	+	+
Social impacts	neutral		neutral / +	neutral / +	neutral / +
Environmental impacts	neutral		neutral / +	+	+
Impacts on fundamental rights	neutral		neutral / +	+	+

Coherence with other EU policy objectives

Options 3 and 4 deliver the most on the Digital priorities of the EU. These options have the highest impact on the online sales and, in line with the EU's objectives to Shape EU's digital future, these options contribute to make sure that online platforms treat their users fairly and take action to limit the spread of unsafe products online. Also these options provide higher safety and legal certainty for connected products and cybersecurity risks, in line with the EU's actions in the AI and cybersecurity fields. Options 3 and 4 also deliver the most in term of positive environmental impacts and are therefore in line with the EU Green deal priority of the Commission.

Stakeholder views on the options

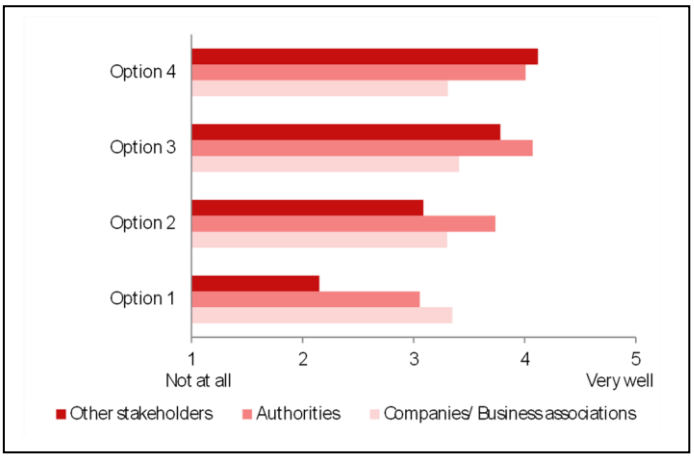

Figure 5: In your view, to what extent would Option [...] effectively address the following challenges for product safety? – Average across all challenges

Source: The survey conducted in the context of the GPSD Study[127]

Authorities and other stakeholders assessed Options 3 and 4 as being most effective, and considered them to well address the five objectives of this initiative. In contrast, average assessments by companies/business associations do not show a considerable variation between the options. They consider all four options to address the challenges slightly better than 'moderately well'.

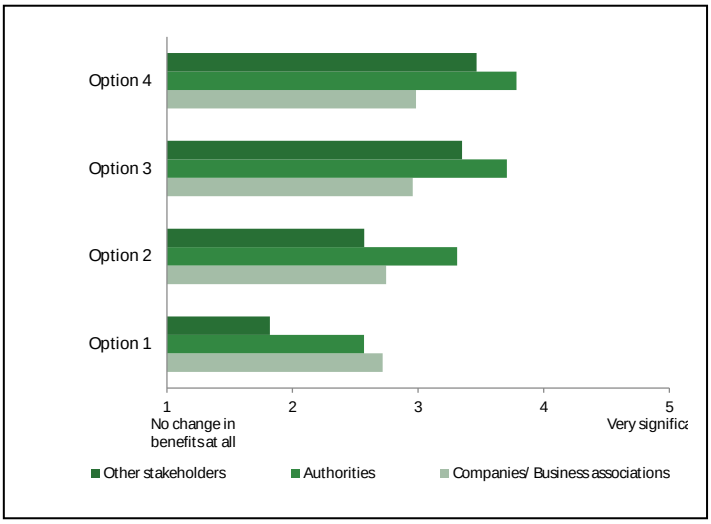

Figure 6: Where do you see the greatest additional benefits that would result from the implementation of Option […]? – Average across all benefit categories

Source: The survey conducted in the context of the GPSD Study

[127] In total, 153 survey responses were received, of which 27 responses to the survey of consumer organisations and other general stakeholder; 48 responses to the survey of authorities, 37 responses to the survey of business associations and 41 responses to the survey of companies.

Businesses find the benefits of Options 3 and 4 to be 'moderate' on average, but still clearly more beneficial than Options 1 and 2. All stakeholders provided the following ranking of benefits for Options 3 and 4, with average above 'moderate' in all three stakeholder groups: (1) Better functioning EU internal market, (2) Reduced occurrence of products with health and safety risks, (3) Greater legal certainty, (4) More level-playing field among businesses, (5) Reduced number of accidents/injuries caused by unsafe products, (6) Better information on unsafe products, (7) Deterrent effect on rogue traders.

In the OPC, the **stakeholders showed a clear support** to certain of the proposed provisions under Option 2, 3 and 4, e.g. **to increase the role of online marketplaces** as regards the safety of products offered on their website, along the principles stated in the Pledge[128] and to **create an obligation to have a responsible economic operator in the EU** (supported by 70% of stakeholders)[129]. Also, a large majority of respondents expressed that **products which resemble foodstuff should be incorporated into the general product safety legal instrument** (69%)[130]. Stakeholders expressed also their support for certain additional provisions foreseen under the Option 3 and 4, e.g. on **new technologies**: When asked whether the definition of a product in the GPSD should specifically encompass software incorporated into the product, the majority of respondents agreed, even in case the software is downloaded after the product has been sold (56%). A clear majority of respondents favoured safety obligations for manufacturers of products incorporating AI applications at the design stage and also during the lifecycle of the product (75%)[131]. Also, a large majority of respondents agreed that the **system of product traceability should be reinforced** in the GPSD (82%)[132].

Ranking of options

All the options defined in the report propose specific actions to address all five problems identified. However, the analysis of impacts shows that some options deliver better on the defined objectives than others.

Option 1 has considered how to best respond to the specific objectives **without revising the GPSD**. Several non-legislative measures have been considered, in particular issuing guidance documents on the applicability of the GPSD to new technologies and on recalls and exploring extension of the voluntary measures under the Product Safety Pledge for online sales. However, the different consultations showed that such non-legally binding measures would not tackle the identified shortcomings. Also additional funding possibilities for market surveillance have been considered. But the agreement on the EU budget for next years showed that the EU funding of the joint market surveillance activities by the EU budget will remain stable; moreover, in view of the budget

[128] See Annex 11 on results of the OPC. When asked about the role that online marketplaces should play regarding the safety of products offered on their websites, the most commonly supported notions were that they should remove dangerous products listed on their website when notified (77%), that online marketplaces should prevent the appearance of dangerous products, including their reappearance once they have been removed (66%) and that they should inform sellers of their obligation to comply with EU rules on products (64%). More than half of the respondents agreed that online marketplaces should inform consumers when a dangerous product has been removed from the marketplace (55%).

[129] See Annex 11 on results of the OPC. A large majority of respondents considered that products covered by the GPSD should only be placed on the EU market if there is an economic operator established in the EU responsible for product safety purposes (70%).

[130] See Annex 11 on results of the OPC.

[131] Idem

[132] Idem

constraints in Member States, aggravated by the current Covid-19 crises, we do not expect any increase of resources dedicated to market surveillance activities by Member States themselves.

Under Option 2 and 3 several **legislative actions** have been considered to tackle the specific objectives: Option 3 being more ambitious, addresses also better the identified shortcomings as data shows. Option 4 has considered a full integration of market surveillance instruments, as it was proposed in 2013, to analyse whether this option would still be valid after the recent adoption of Regulation (EU) 2019/1020.

Regarding the **food-imitating products**, different options have been looked at, namely: 1) to maintain a separate Directive on food-imitating products; 2) to merge the provisions of the current FIPD into the new GPSD; 3) to abandon targeted provisions on food-imitating products and instead use the general provisions to ensure safety of such products. For the first two options, the possibility of developing guidance has been considered in order to overcome the different interpretation by Member States; however, the consultation of Member States showed that the divergences in interpretation of the Food-Imitating Products Directive were so important that a legal revision of the rules was necessary to ensure its even application.

Furthermore, the assessment showed that a general ban of food-imitating products would result in banning some non-dangerous products, which would be an unjustified and non-proportional restriction of the freedom to conduct a business. It is therefore essential that food-imitating products follow the same risk-based approach that prevails for the other consumer products. Also keeping a separate regime for food-imitating products has been considered as not necessary in view of the low number of related notifications in the Safety Gate/RAPEX. To assess the safety of these products, their food-imitating aspect can be taken into account in the risk assessment under the GPSD, which appears then to be an appropriate legal instrument to cover the safety of these products. Therefore the third option consisting in abandoning targeted provisions on food-imitating products and instead using the general provisions and the risk-based approach contained in the GPSD to ensure safety of such products appears as the most appropriate.

Table 23: Ranking of the options

	Assessment	Ranking
Option 1	While Option 1 is causing no costs for businesses and MSAs, it is unlikely to be adequate to address the problems identified. While uncertainty will be reduced due to Commission guidance, and coverage of online platforms is expected to increase through the promotion of the Product Safety Pledge, safety risks due to products sold on online platforms are expected to continue, as will the other gaps identified.	**4**
Option 2	Option 2 is causing extremely limited costs (<0.004% of turnover for business, mostly neutral for MSAs), and is likely to be partially adequate to address the identified problems. Gaps will remain regarding the coverage of software, and implementation differences in Member States will likely remain. Option 2 would only partly reduce the consumer detriment, in comparison to Options 3 and 4.	**3**
Option 3	Option 3 is linked to somewhat higher costs (<0.02% of turnover for business, mostly neutral for MSAs) and is mostly adequate to address the problems identified. Gaps will be closed, and implementation differences avoided. However, while safety risks for EU consumers due to products sold on online platforms could be partly reduced (and more than under Option 2, as online platforms would have a duty of care), their mitigation will also depend on continued surveillance of platforms and other factors (adoption of DSA). Option 3 would considerably reduce the consumer detriment (due to the loss of value of unsafe products) by 1 billion EUR in the first year of implementation and by EUR 5.5 billion over the next decade.	**1**
Option 4	Option 4 leads to higher costs for business (<0.03% of turnover) than Option 3 and is	**2**

mostly neutral for MSAs. It is also considered to be mostly adequate to address problems, as measures under Options 3 & 4 are almost identical. Reduction of the consumer detriment would be the same as under Option 3.

As indicated in the Table 23, **Option 3** seems to deliver the best results in terms of meeting the defined objectives while keeping the economic impact limited, and is therefore the **preferred option**. Option 4 could deliver broadly the same results in term of objectives but with higher costs for businesses and administrative burdens (mainly linked to uncertainties in revising the Regulation (EU) 2019/1020 on market surveillance which has not entered fully into force yet).

In this IA, the ranking of the options has been done on the basis of the general comparison of the impacts and not specifically on a Multi-criteria analysis (MCA)[133]. Indeed, the comparison table of the impacts of policy options clearly shows that Options 3 and 4 perform better overall. The evidence was gathered from multiple data sources and the results were triangulated to ensure the robustness of the methodology. Based on the analysis, policy Options 3 and 4 would perform equally well except under three dimensions: administrative simplification, the costs for businesses and the costs for Member States. Under Option 3, the costs for business would be lower by ~EUR 135 million/year, while under Option 4 the costs for Member States would be lower by ~EUR 3 million/year and could further reduce regulatory complexity and bring simplicity. Option 3 delivers the best results while keeping the economic impact limited, and is therefore the preferred option. For this reason, a Multi-criteria analysis ('MCA') was considered to bring more complexity compared to the added value it would have in determining the preferred option.

Nonetheless, the MCA was tested on the criteria (impacts) in the comparison table and the results are highly sensitive to the weights attributed: either Option 3 or Option 4 are obtaining the highest overall score, depending on the factors which are given slightly more importance. The main reason is that the two options have very similar scores (as explained above). Moreover, in the MCA, the monetary (absolute) values are standardised: the 40% difference in costs for business (from EUR 332 million/year to EUR 197 million/year) is considered the same as the 40% difference in costs for Member states (from EUR 7 million/year to EUR 4 million/year). This economic impact is significant and the MCA would not pick it up accordingly.

The actual effect of the different options will depend on the concrete implementation and enforcement of the initiative at national level and in particular on the **level of resources attributed to the MSAs and the EU budgets allocated to market surveillance**. The level of allocated resources would however not change the ranking of the options, in particular because some of the actions foreseen can deliver on the objectives without higher budgets, e.g. deterrent effect of penalties foreseen under Option 3 and 4.

The level of allocated resources would nevertheless impact the overall effectiveness of the enforcement of the options. Concerns related to the lack of adequate resources in the competent authorities of some Member States has been expressed by stakeholders during the consultation process. None of the options envisages to set any obligation on the

[133] The multi-criteria analysis is one of the tools presented in the Better Regulation "Toolbox" (Tool #63) to compare the different policy options. It is a non-monetary approach and its main advantage is that it allows to simultaneously consider a significant number of objectives, criteria and relations. MCA gives the opportunity to deal with policy issues characterised by various conflicting assessments, thus allowing for an integrated assessment.

amount to be invested on product safety tasks by Member States since it is set at national level for market surveillance, which remains within remit of national powers. The legislative options envisage rather mechanisms allowing economies of scale and better functioning of market surveillance, such as reinforced cooperation among MSAs including in enforcing measures adopted, more power for MSAs and more effective measures at their disposal, the possibility to reclaim from the relevant economic operator the totality of the costs of their activities in case of dangerous products, the introduction of Union testing facilities which can ease the testing activities for MSAs (some of these measures are foreseen already in Regulation (EU) 2019/1020 for harmonised products).

An effective enforcement of the different options will be ensured by monitoring of reported data on enforcement capacities of Member States (e.g. in the context of the Consumer Scoreboard or via possible reporting obligations) and raising awareness about market surveillance needs in term of resources and tools. Also under Options 3 and 4 the arbitration mechanism will allow more harmonised enforcement of product safety.

The efficiency of the different options can be also enhanced by **improving the operation of Safety gate/RAPEX** (e.g. by tackling the delays identified in the Evaluation between the detection of a dangerous product in a Member State and its notification to the Safety Gate/RAPEX) and **facilitating international cooperation**, in particular in the context of the exchanges of information on dangerous products between the Safety Gate/RAPEX and third countries. The Evaluation found that the procedure for setting up such arrangements to exchange non-public information from the Safety Gate/RAPEX could be clarified to cover the different levels of exchanges between the EU system and third countries (in particular via legal revision under options 2, 3 and 4). Such exchanges can enhance the efficiency of Member State's market surveillance actions. Also, enhancing product safety worldwide will have a positive impact on protection of EU consumers by limiting the entry of dangerous products to the EU market.

All the options, and in particular the legislative options 2 to 4, including the preferred Option 3, conform to the **principles of subsidiarity**, since the new legal provisions relate to areas where EU action brings added value to ensure level-playing field on the EU market and higher product safety, while fully respecting the national competences (these options harmonise the obligations on economic operators and respect powers for MSAs). All options also **conform to the principle of proportionality** given that the size of the identified problem is considerable (high presence of unsafe consumer products on the EU market and related high consumer detriment) and the costs associated with the different options are limited. Also the choice of Regulation as Union action is coherent with satisfactory achievement of the objective to ensure level-playing field and effective and even enforcement at national level.

8. PREFERRED OPTION

8.1. Preferred option – Option 3

In view of the data and the analysis presented in the previous sections, **the preferred policy option is Option 3**. This policy option addresses all identified problems and objectives in the most effective, efficient and proportionate way, proposing a legal revision of the GPSD to make it not only fit for purpose now, but also in the future by improving its 'safety net' function.

Concerning the objective related to **food-imitating products**, **the sub-option (b), risk-assessment approach, is preferred** since it is more coherent and proportionate than sub-option (a), a full ban *per se* of these products.

The **operational objectives** under Option 3 are as follows: it would add legal clarity concerning the coverage of risks of new technologies (cyber-security and other risks of new technologies affecting consumer health) and the role of software for product safety. It would make most provisions inspired by the Product Safety Pledge legally binding for online marketplaces and add additional requirements to improve transparency and duty of care by online marketplaces. It would enhance recall effectiveness by introducing mandatory requirements on product recalls and customer traceability. It would also better align the GPSD with market surveillance rules for harmonised products, enhance traceability and integrate and clarify the rules for the food-imitating products. It would provide for increased enforcement powers for Member States, an arbitration mechanism to solve divergent risk assessments and the possibility to adopt delegated acts to improve traceability systems. It proposes a burden reduction measure by simplifying standardisation procedures.

In particular, the preferred option will revise the Directive to include inter alia the following provisions to tackle **product safety challenges posed by online sales**:

- **New obligations for manufacturers and distributors** to include in their online offers the same information like for the physical offers, namely information on the name and contact details of the manufacturer and of the responsible economic operator in the EU if applicable, safety information and instructions. The online market places should also ensure that this information is displayed with the online listings. This information allows better traceability of products needed for market surveillance and better safety information in the online sales.
- **Establishment of the figure of a responsible economic operator in the EU**, in line with Regulation (EU) 2019/1020 on market surveillance, to tackle the issue of direct imports from outside the EU. This Regulation applies this obligation only for certain categories of harmonised products and could be extended to all consumer products to make sure that consumers and national authorities can always address an operator based in the EU for any consumer product potential safety issue.
- **New enforcement powers for market surveillance authorities** to carry out online investigations, in line with Regulation 2019/1020 on market surveillance. For example, the possibility for authorities to carry out inspections using a covered identify or the power to shut down webpages;
- **New product safety obligations for online marketplaces**, in line with the general principles set in the DSA. While manufacturers will remain the main responsible economic operators for the safety of a product, online marketplaces could play an important role and exercise a duty of care in relation with their responsibilities, e.g. making efforts to identify dangerous product offers already removed from their websites but that keep reappearing. That duty of care would be different than for distributors as they do not have a physical contact with the product, so their role will focus on doing their most to ensure that their websites do not offer dangerous products, and if they do, they cooperate with authorities for corrective actions.

With regards to **software updates,** the preferred option aims to shift the responsibility for the safety of a product from the initial producer to the actor in charge of the update in case of 'substantial modification'. If certain criteria are met, in the case of modifications such as software updates that alter the safety of the product, the responsibility for safety would shift to the actor in charge of such modification. For example, if an application

aimed to improve the efficiency of a battery is downloaded into a device and consequently the hazards of the device increase, the software developer would become the responsible actor. That would ensure that actors in charge of substantial modifications take into account the impact of their changes on a specific product. In any case, this would not apply for most software updates, such as the download of games that do not interfere with the safety of a device.

Under Option 3, **the revised GPSD would be complementary to the other ongoing policy initiatives** mentioned in part 1. The advantage of clearly integrating aspects of substantive alternative policy areas into product safety legislation is therefore to ensure a real safety net for consumers, making possible that that all non-food consumer products on the EU market are safe. The revised GPSD under the preferred option will address the convergences between product safety and the other policy areas, but it will not go beyond those to avoid any overlaps.

Beyond the legal revision of the GPSD, the **self-regulatory instruments** such as the Product Safety Pledge could be strengthened to complement the legal framework. The Pledge could be further used to continue the operational cooperation between online marketplaces and MSAs and to include the commitments that would not become binding, as well as potential new commitments. This way the Pledge would continue to play a complementary role to the legal framework.

Other voluntary cooperation actions with online marketplaces could be explored, such as the actions taken in the beginning of the COVID-19 crisis where the online marketplaces, upon a call for cooperation from the Commission, acted against online scams and new dangerous products related to the pandemic.

8.2. REFIT (simplification and improved efficiency)

GPSD being part of REFIT, the report has analysed how the current legal framework could be simplified, improve the efficiency and decrease administrative burden. The following actions under Option 3 should lead to such higher efficiencies:

Table 24: REFIT Cost savings under the preferred option

REFIT Cost Savings – Preferred Option – Option 3		
Description	***Amount***	***Comments***
Alignment to market surveillance procedures for harmonised products would simplify the market surveillance rules	**Cost savings for MSAs:** around **EUR 0.7 million per year** across the EU. Cost saving for businesses are included in the line below on cost savings linked to more uniform implementation of market surveillance rules.	Benefits are mainly for MSAs and businesses active in both harmonised and non-harmonised product areas.
Conversion to a Regulation would ensure a common application of product safety rules and avoid inefficiencies and regulatory costs/burdens related to the inconsistent implementation of the GPSD across the EU	Lower regulatory burden and costs Cost savings for businesses : around **EUR 59 million annually** (around EUR 34 million saved by EU SMEs and	Benefits for all stakeholders (reduced burdens and costs for businesses and MSAs and better enforcement and product safety for

	26 million EUR saved by EU large businesses)	consumers)
Simplifying the standardisation procedure under the GPSD would decrease the administrative burden	Simplify and reduce regulatory costs	Beneficial to all stakeholders since standards could be referenced faster
Clarification of scope and definitions regarding the application of consumer product safety rules to new technologies would lead to higher legal certainty regarding the application of consumer product safety rules to new technologies, which will likely reduce the costs relating to businesses' (especially SMEs') efforts to design innovative, safe and cyber-secured products.	Reduced regulatory costs	Benefits for businesses producing new technology products and consumers of these products because of legal clarity and better safety.
Repealing Directive 87/357/EEC and integrating rules on food-imitating products into the revised GPSD would simplify the product safety legal framework and increase coherence in implementation by Member States	Lower regulatory burden and costs	Benefits for producers of food-imitating products, for MSAs and consumers
Arbitration mechanism on diverging risk assessments would lower the regulatory burden for MSAs by helping to resolve disputes on risk assessments	Reduced regulatory burden	Benefits for MSAs and consumers
Potential future introduction of improved digital solutions for product traceability through delegated acts The Study identified e-labelling solutions for traceability information as potential complementary measure to increase efficiency of product safety market surveillance.	Reduced administrative burdens	Beneficial for MSAs, businesses and consumers
Digital interlinks between existing market surveillance systems at EU and national level (including customs) similarly to Regulation (EU) 2019/1020 will make the market surveillance more simple and efficient through connecting Safety Gate/RAPEX with the EU Customs database	Lower regulatory burdens	For MSAs, customs authorities

Beyond these simplifications and higher efficiencies, this initiative endeavours to keep regulatory burdens to the minimum necessary both for businesses and Member States to what is strictly needed to ensure consumer protection against unsafe products.

To avoid any legal uncertainties and related burdens, the revised GPSD would avoid any overlaps between lex generalis and lex specialis, by defining its scope. Also the ongoing work related to product safety under other initiatives has been and will be duly taken into account to avoid overlaps and overregulation.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

The Commission will monitor the implementation of the revised GPSD, if adopted along the preferred option, with regards to the achievement of policy objectives identified in this Impact Assessment in order to be able to assess its effectiveness in the future evaluation. A commitment to evaluate the impacts of the new legislative act, if proposed, will be included in the draft proposal. The Commission will start monitoring the implementation of the revised GPSD after the entry into force of the initiative. The indicators proposed to monitor the achievement of policy objectives identified in this Impact Assessment are presented below.

The monitoring will be done mainly by the Commission, based on regular EU-wide consumer surveys and data provided by businesses and MSAs. The monitoring and evaluation will be done on the basis of existing data sources where possible to avoid additional burdens on the different stakeholders. The new legislative act, if proposed, will set out reporting obligations for Member States. This reporting will be done on the basis of enforcement indicators which will be further defined by a study. The Commission has already identified some gaps concerning enforcement indicators, and will launch a study to establish a new set of enforcement indicators[134].

Tables 25 and 26 below provide an exhaustive list of monitoring indicators. A methodological study for the design of enforcement indicators is ongoing to identify which enforcement indicators are the most suitable to measure the achievement of the different objectives and on which Member States could report in practice so that the Commission can receive reliable and comparable data for the next evaluation of this initiative. Through this study the Commission could complement the list of the most suitable indicators for the monitoring system.

The Commission has already mapped existing sources of injury information and looked into the possibility of establishing a EU-level injury database to help the implementation of the product safety legislation[135]. It is currently assessing the costs and benefits or setting up such a EU wide injury database (via coordinated actions with Member States).

Table 25: Monitoring indicators for the main policy objectives

Policy objectives	Monitoring indicator	Data source	Data collected already?	Actors responsible for data collection
Product safety	Number of unsafe products on the market	Safety Gate/RAPEX gives a proxy	Yes	Commission
	Consumer detriment	Future study (data for past available from the GPSD Study)	Not in a recurrent way	Commission via study
	Consumer trust in product safety and experience of product-related injury	Consumer Conditions Scoreboard	Yes	Commission via regular surveys
Proper functioning of Single Market	Number of unsafe products on the market	Safety Gate/RAPEX gives a proxy	Yes	Commission
Safety net function, also new technologies	Number of unsafe new technology products	Safety Gate/RAPEX gives a proxy	Yes	Commission
	Consumer concerns about safety of IoT products	Eurostat ICT survey, Consumer Markets Scoreboard		Commission via regular consumer surveys
Product safety in the online sales	Number of unsafe products found online	Safety Gate/RAPEX gives a proxy	Yes	Commission
Product recalls more effective and efficient	Number of recalls and recalled products	Safety Gate/RAPEX	Yes	Commission

[134] For the future reporting obligations under the revised GPSD, the Commission will consider the reflections and work engaged in the harmonised area on the monitoring and reporting in order to aim for consistency and to avoid any duplication or unnecessary burden on national administrations in the collection of relevant data and information.
[135]https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/docs/Final_JRC_Report_Injury_and_acccident.pdf

	Market practices regarding product recalls and product registration schemes/loyalty programmes	(Coordinated) market surveillance activities	Not in a recurrent way	Member States, Commission
	Self-declared data on recall participation and product registration and on exposure to recall information	Consumer Conditions Scoreboard	Yes	Commission via regular surveys
	Hard data on recall participation	Monitoring data to be collected by economic operators	No	Economic operators (Member States will be able to request this information)
Enhanced market surveillance and ensure better alignment with harmonised products	Enforcement indicators as defined by the study commissioned by the EC mentioned above	National sources, to be defined by the commissioned Study	No or only partially	Member States based on indicators defined by the study
Safety of food imitating products	Number of unsafe food-imitating products	Safety Gate/RAPEX gives a proxy	Yes	Commission
	Number of disputes on risk assessment of these products between Member States	Safety Gate/RAPEX	Yes	Commission

Table 26: Monitoring indicators for the operational objectives – Option 3

Operational objectives	Monitoring indicator	Sources of data and/or data collection methods	Data collected already?	Actors responsible for data collection
Clarify coverage of risk and products linked to new technologies	Number of questions raised on the applicability of new technology products	RAPEX contact points Wiki	Yes	Commission
Clarify the application to software	Number of notifications related to safety issues raised by software	Safety Gate/RAPEX	Yes	Commission
Making most provisions of the Pledge legally binding for all online marketplaces	KPIs and qualitative data (idem Pledge)	Monitoring reports of the Pledge	Yes, to be reinforced	Online platforms - Pledge signatories
Providing all safety information online that is also required to be provided offline	Number of cases where diverging level of information offline/online found	Regular checks in the context of (coordinated) market surveillance activities	No	Member States, Commission
Introducing a duty of care for online marketplaces	Number of cases where duty of care not respected	Regular checks in the context of (coordinated) market surveillance activities	No	Member States, Commission
Introducing mandatory requirements for recalls	Number of cases where new recall provisions not fulfilled	Regular checks in the context of (coordinated) market surveillance activities	No	Member States, Commission
Introducing mandatory requirements for customer traceability	Number of cases where new recall provisions not fulfilled	Regular checks in the context of (coordinated) market surveillance activities	No	Member States, Commission

Align with market surveillance and traceability rules for harmonised products	-	Legal analysis	-	Commission
Requiring an economic operator in the EU	Number of cases where this economic operator is missing	Regular checks in the context of (coordinated) market surveillance activities	No, can be included in the Pledge monitoring	Member States, Commission, online marketplaces
Simplifying the standardization procedures	Average duration of the standardisation procedure	Observed durations	Yes	Commission
Strengthening the enforcement powers of MSAs	Number of enforcement measures adopted at national level	Implementation reports of Member States	Yes (for past)	Commission based on Member States input
	Level of penalties foreseen at national level	Legal analysis	Yes (for past)	Commission based on Member States input
Introducing the arbitration mechanism	Number of disputes on risk assessment solved	Safety Gate/RAPEX	Yes	Commission
Incorporation of provisions on the food-imitating products in the new legal act	Number of disputes on risk assessment of these products between Member States	Safety Gate/RAPEX	Yes	Commission

Annex 1: Procedural information

10. LEAD DG, DECIDE PLANNING/CWP REFERENCES

This Staff Working Document was prepared by the Directorate-General for Justice and Consumers (DG JUST).

The Decide reference of this initiative is PLAN/2019/6283 Review of the general product safety directive -Proposal for a regulation on general product safety.

This includes the Impact Assessment report as well as the GPSD Evaluation Report, in annex to this Impact Assessment.

11. ORGANISATION AND TIMING

- An Inter Service Steering Group (ISSG) has been established to support the work of DG JUST on the evaluation and impact assessment of this initiative set up.
- DGs participating in this ISSG: SG, LS, CNECT, COMP, ENV, GROW, JRC OLAF, SANTE, TAXUD
- This GPSD ISSG held 5 meetings times (one informal meeting on 14/02/2020 and four formal meetings on 12/06/2020, 08/10/2020, 18/11/2020 and 07/12/2020). DG JUST consulted the ISSG on the different steps of this initiative: Roadmap/Inception Impact Assessment, Consultation strategy, Open Public Consultation questionnaire, the study underlying the evaluation and impact assessment (ISSG provided comments on all study steps and reports) and finally on the draft Impact Assessment report.
- Publication in EUROPA of the Roadmap on the evaluation/Inception Impact Assessment, 30 June 2020
- Launch of the Open Public Consultation on the combined Roadmap/Inception Impact Assessment, 30 June 2020 - 6 October 2020 (14 weeks).

12. CONSULTATION OF THE RSB

The RS has been consulted on the Impact assessment report and issues a 'positive opinion with reservations' on it.

The two tables below present the elements of the RSB opinion and how the report has been updated to take them into account:

Main issues raised by the RSB in its opinion and related updates
(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.
Related updates: • The report clarifies the overall structure of the EU Product safety framework in more detail by explaining the interlink between the GPSD and the other sectorial and harmonised legislation at

EU level and the role of GPSD as safety complementing the other legislation to ensure the safety of EU consumers for any product now and in the future. The report includes more graphical presentation of the general products safety framework. • The interlink with the recent and ongoing initiatives, in particular those on digital platforms, cybersecurity, circular economy and artificial intelligence, has been better explained.
(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.
Related updates: • The report better explains the structure of the options and how they address the objectives but in a different level of depth. • The discarded options has been further developed in the revised IA report. In particular, the report explains why some options already analysed and disregarded in the IA in 2013 can still be disregarded now (e.g. to have different safety requirements for harmonised and non-harmonised products, extending the scope to services, abolition of the general product safety requirement). Also the report explains that some options have been considered and disregarded because of lack of proportionality, e.g. higher traceability requirements for all products. • The report explains that other stakeholders did not have raised any other new real alternatives in the consultation process until now.
(3) The report does not explain in a convincing manner why the estimated costs for business under the integration option (option 4) are much higher than those of the full legal revision option, although in terms of substance the options seem very similar.
Related updates: • Under Option 4 the businesses reported higher costs to our contractor. The report admits that these costs might be inflated and a clear disclaimer has been included at this respect in the revised report.

Specific improvements requested by the RSB	How the RSB comments have been addressed in the revised IA report
(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 fallback 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.	Cf main issue 1 Explained the interaction of the GPSD with other EU legislation and initiatives relating to product safety
(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.	Cf main issue 1 Included a diagram presenting the product safety legal framework Better explained the scope of the GPSD and the proposal Better explained the concept of risk in particular in the context of new technologies (cybersecurity risks) and how these risks could be assessed (e.g. when substantial modification of the product)
(3) The report should reinforce the problem analysis	Gaps and deficiencies better explained in the problem definition.

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.	Achievements and limitations of the Product safety Pledge better spelled out as well as lesson learnt.
(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.	Cf main issue 2 The option packages presented in more detail, beyond the summary table. The alternative options, which have been discarded have been included in the IA report. But no new policy options. The further use of self-regulatory instruments such as the Product Safety Pledge after the adoption of the initiative has been explained. Examples of other voluntary cooperation actions with platforms, e.g. during COVID crisis, have been introduced.
(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.	Cf main issue 3 The report reviewed the underlying cost data under Option 4 and provides the necessary disclaimers.
(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.	A detailed presentation of the measures under the different options (cf point (4)) includes now these clarifications. The report presents specific explanation of measures to tackle safety issues related to consumers' online purchase from third countries as well as software updates. The sanction regimes have been explained under the different options and alternatives analysed. The report now elaborates on ways how to ensure better enforcement: e.g. introduction of the arbitration mechanism, collecting data on enforcement capacities of Member States in the context of the Consumer Scoreboard to raise awareness.
(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. Some more technical comments have been sent directly to the author DG.	The report contains now a reinforced explanation on the simplifications, avoiding overlaps and overregulation and how the initiative would keep the minimum necessary regulatory burden while ensuring the objectives. Other technical comments (e.g. providing summary table of the costs of different options) have be taken into account.

13. EVIDENCE, SOURCES AND QUALITY

Studies commissioned or supported by the European Commission

- Study to support the preparation of an evaluation of the General Product Safety Directive as well as of an impact assessment on its potential revision, Civic consulting, March 2021
- Study for the preparation of an Implementation Report of the General Product Safety Directive, Civic consulting, July 2020
- Study on the assessment of the opportunities for increasing the availability of EU data on consumer product-related injuries, European Commission's Joint Research Centre's, May 2020
- Behavioural Study on strategies to improve the effectiveness of product recalls, LE Europe, June 2021
- Survey on consumer behaviour and product recalls effectiveness, April 2019
- Implementation of the new Regulation on market surveillance: indication of origin, VVA Europe, May 2015

External Expertise

- Consumer Safety Network (CSN)
- Sub-Group on Artificial Intelligence, connected products and other new challenges in product safety to the Consumer Safety Network

Selective bibliography

- Bernstein A. (2013), 'Voluntary Recalls', University of Chicago Legal Forum, 1: 394 ff., available at: http://chicagounbound.uchicago.edu/uclf/vol2013/iss1/10 and Jacoby J. (1984), 'Perspectives on Information Overload', Journal of Consumer Research
- OECD (2020)- 'E-commerce in the time of COVID-19', available at http://www.oecd.org/coronavirus/policy-responses/e-commerce-in-the-time-of-covid-19-3a2b78e8/#biblio-d1e705
- OECD (2018), 'Enhancing Product Recall Effectiveness Globally', available at https://www.oecd-ilibrary.org/science-and-technology/enhancing-product-recall-effectiveness-globally_ef71935c-en

Other Sources

- Eurostat
- European Injury Database (IDB)
- Safety Gate/RAPEX
- WHO CHOICE

Annex 2: Stakeholder consultation

1. Consultation strategy

The impact assessment (IA) for the revision of the General Product Safety Directive 2001/95/EC (GPSD) was supported by the following consultation activities:

- public consultation on the Inception IA and roadmap;
- an open public consultation (OPC);
- stakeholder workshops;
- ad-hoc contributions and targeted consultations with Member States (MS) and other stakeholders.

The objective of these consultations was to collect qualitative and quantitative evidence on all key elements of the IA, from relevant stakeholder groups and the general public.

The stakeholder groups identified as relevant are:

- Consumers and consumer organisations,
- Businesses and business organisations,
- Member States market surveillance authorities,
- Other product safety experts.

The consultations were publicised via social media posts, emails to existing networks (including in the Safety Gate- RAPEX weekly update newsletter on dangerous products), regular meetings of the expert groups and networks, as well as in speeches delivered by high-level Commission officials.

2. Overview of consultations

a) Consultation on the combined evaluation roadmap and inception impact assessment

The consultation on the combined evaluation roadmap and Inception IA took place between 23 June and 1st September 2020. 44 answers were received: 20 from business associations, 9 from company/business organisation, 5 from consumer organisations, 2 from non-governmental organisations (NGOs), 3 from citizens, 2 from public authorities, 1 from a trade union, 2 other, and additional 3 feedback were not relevant (because the questionnaire was empty or contained almost no information).

Most of the stakeholders supported the GPSD revision, almost half of them being in favour of the full revision (options 3+4).

Option 0 (status quo)	1 stakeholder
Option 1 (better implementation and enforcement)	7 stakeholders
Option 2 (targeted revision)	10 stakeholders (some willing only changes regarding the online dimensions)
Option 3 (full revision)	12 stakeholders
Option 4 (integration of legal instruments)	9 stakeholders (mainly consumer organisations)

The feedback on the IIA (summarised in the next section) has included the objectives as well as the set of options to be analysed in the IA.

b) Open public consultation on a new Consumer agenda

The open public consultation (OPC) ran between 30 June 2020 and 6 October 2020, in order to gather views of the public on the 'New Consumer Agenda' as well as on three legislative proposals in the area of EU consumer policy, including the review of the GPSD. The public questionnaire available in the 24 official EU-languages was targeting a wide range of stakeholders, both the general public and relevant organisations and institutions.

The section on the GPSD in the public consultation included questions related to both the evaluation of the GPSD and the IA for its revision. The number of respondents that answered at least one question in this section is 257. The majority of respondents were business associations and EU citizens (each 26%), followed by company/business organisations (15%). Other respondents included public authorities (11%), consumer organisations (8%), non-governmental organisations (7%), academic/research institutions (3%), non-EU citizens (1%) and other respondents (3%).

The full report on the results of this OPC has been published on the Have Your Say page.[136]

Annex 13 contains the summary of the replies of the OPC GPSD part.

c) EU Workshop on strategies to maximise the effectiveness of product recalls

The EC organised on 23 October 2019 a workshop on the effectiveness of recalls in order to take stock of existing market practices and regulatory approaches, and identify possible new avenues to maximise recall effectiveness. 68 participants took part in the workshop, including regulators from around the world, representatives of international organisations, consumer organisations, industry and academics. The workshop was divided into three thematic sessions, focusing on i) strategies to facilitate direct consumer contact, ii) strategies to increase consumer response to recalls and iii) roles and responsibilities in the recall process.

d) 2020 International Product Safety Week (IPSW)

The EC organised the International Product Safety Week on 9-12 November 2020[137]. This event is the largest gathering of product safety experts from all around the world and it takes place every two years. More than 500 participants from 73 countries registered for the 2020 online edition, including regulators, businesses, or consumer organisations. Two sessions were organised on topics of interest for the revision of the GPSD, namely

[136] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12466-General-Product-Safety-Directive-review/public-consultation

[137] https://ec.europa.eu/info/events/international-product-safety-week-2020-2020-nov-09_en

on traceability and recalls. Input on these two topics was collected both from a wide diversity of panellists and also from the audience via interactive online surveys.

e) European Consumer Summit 2020

The EC organised the European Consumer Summit on "Consumers in the Green and Digital Transition: Challenges and solutions for a new consumer policy", which took place on 30-31 January 2020[138]. This event gathered over 500 stakeholders including policymakers, national enforcement authorities, academia, consumer and business organisations, and youth representatives, from all Member States. Sessions were notably organised on "safety and consumer protection in online trade" and "Artificial Intelligence –a consumer-centric approach". Input was also gathered from the audience via interactive surveys.

f) Workshops on online marketplaces and product safety

The EC held a number of workshop sessions related to online marketplaces and product safety on 8, 10, 13 and 17 July 2020. The objective of the workshops was to gather up-to-date information on the state of play concerning the main challenges in addressing the sale of illegal goods online. It focused in particular on measures and good practices from marketplaces and the cooperation with authorities and relevant third parties. Input gathered through these sessions aimed at feeding into the revision of the e-commerce Directive and of the GPSD. The workshops gathered more than 60 participants each, covering a very wide range of stakeholders, such as online marketplaces, retailers, industry associations, consumer organisations and MS authorities. Annex 14 contains the minutes from these workshops.

g) Ad hoc contributions and consultations

Input from a variety of stakeholders (Member States authorities, consumer organisations, businesses, business organisations…) has been collected, notably via extensive consultations, in the framework of the dedicated study for the evaluation and impact assessment of the Directive as well as the study supporting the preparation of the implementation report of the Directive.
Input has also been received from the following stakeholders via ad hoc contributions and/or ad hoc consultations: consumer organisations, businesses, business organisations, national chamber of commerce, trademark association. Further bilateral discussions were also held with Member State authorities.

Stakeholders' input was also collected through the expert group 'Consumer Safety Network' and the Sub-Group on Artificial Intelligence (AI), connected products and other new challenges in product safety.

A workshop of the Consumer Safety Network expert group was organised on 19 November 2020 to discuss the study results supporting the implementation report of the

[138] https://ec.europa.eu/info/events/european-consumer-summit-2020-2020-jan-30_en

Directive, the evaluation and the impact assessment, as well as specific topics of interest (penalties, operator-based market surveillance and cooperation with customs authorities).

The consultations for the evaluation and impact assessment of the revision of the General Product Safety Directive, which forms part of the wider consultation strategy on the New Consumers Agenda, have also benefitted from the consultations on other ongoing initiatives of the European Commission, namely linked to the White Paper on Artificial Intelligence and the proposal for a Digital Services Act.

3. Summary of the results of the consultations

In the following summary, "consumer representatives" means national and EU-level consumer organisations, "business representatives" includes national and EU-level business organisations,

"MS authorities" includes national market surveillance authorities and government authorities in charge of product safety.

1) Preserving the safety net role of the GPSD

The overall feedback among all stakeholder groups is that the GPSD is a useful legislation and its safety net principle should be preserved. Consumer representatives also emphasised the precautionary principle being a key pillar of the product safety legislation.

However, a large majority of respondents expressed that current EU safety rules for non-food consumer products covered by the GPSD could be improved in specific areas to be more adequate to protect consumers (71% in OPC).

2) Tackling the challenges posed by new technologies

Stakeholders acknowledge that new technologies raise many challenges. Different stakeholders favoured different approaches to tackle these. In the OPC, almost half the respondents considered the safety of products involving new technologies not to be adequately regulated (47%). The majority of respondents agree that the definition of a product in the GPSD should specifically encompass software incorporated into the product, even in case the software is downloaded after the product has been sold (56%). About a quarter of respondents considered that only software already installed into the product when sold should be included.

Almost all respondents support the introduction of a requirement for products that could be modified via software updates/download or machine learning to remain safe throughout their lifetime (very important for 72%, rather important for 24%). A clear majority of respondents also favoured safety obligations for manufacturers of products incorporating AI applications at the design stage and also during the lifecycle of the

product (75%), whereas only 9% of respondents expressed that the obligations should be limited to the design stage.

In the consultations, consumer representatives and several MS authorities expressed their support in extending the definition of 'safety' to include (cyber)security aspects that have an impact on safety. In the consultation on the Roadmap/Inception IA, technology-oriented businesses showed more reluctance regarding the inclusion in the GPSD of new technologies and new risks related to them as they point out the possible overlap with other pieces of legislation. Their preference is that the GPSD remains a technology-neutral tool, and that risks linked to new technologies are covered in other more specific pieces of legislation.

3) Addressing safety issues associated with products sold online

The issue of products coming directly or via online platforms from outside the EU was a recurrent issue mentioned in the consultations. Businesses and business representatives stress the level-playing field angle and they point out that currently, many EU retailers suffer from unfair competition in relation to operators based in third countries. Consumer representatives call to close loopholes regarding international e-commerce. Consumer representatives and other stakeholders also mentioned the issue of dangerous products reappearing on online marketplaces. MS authorities stress the difficulty to control products coming from third countries and to take enforcement actions against economic operators outside the EU.

In the OPC, the majority of respondents expressed that they were aware of problems associated with online marketplaces having no direct legal obligations for the safety of products hosted on their platform by sellers (53%). When asked about the role that online marketplaces should play regarding the safety of products offered on their websites, the most commonly supported notions were that they should remove dangerous products listed on their website when notified (77%), that online marketplaces should prevent the appearance of dangerous products, including their reappearance once they have been removed (66%) and that they should inform sellers of their obligation to comply with EU rules on products (64%). A lower number of respondents thought that online marketplaces should do a cursory check on all products offered on their website to identify products that likely do not comply with safety rules (42%).

Views diverge between stakeholders when it comes to the obligations of online marketplaces:

- Consumer representatives are in favour of strengthening their responsibilities across the supply chain.

- Businesses' views are heterogeneous, in particular:

    - Retailers argue that online marketplaces play a key role in the supply chain, and therefore they should have a corresponding responsibility.

- Online marketplaces responding to the OPC expressed that they would also accept some of the Product Safety Pledge's provisions being binding, but not more.

According to the participants of the session on the safety of product sold online at the EU Consumer Summit 2020, voluntary commitments are not sufficient (89% of respondents),enhanced responsibility for online marketplaces are needed, as well as better enforcement (for instance regarding website blocking by authorities).

4) Improving market surveillance rules and enforcement

Stakeholders from all categories are in favour of aligning market surveillance rules between harmonised and non-harmonised products. Some stakeholders insisted on the fact that the GPSD relies too much on ex post market surveillance, and more action on ex ante prevention should be done at different levels. Member States' authorities lack of resources for market surveillance was also repeatedly mentioned in consultations. Other challenges mentioned in the OPC included the insufficient number of control checks carried out, including by customs (29%), insufficient cooperation between market surveillance authorities in the EU (27%), and divergences between authorities in the assessment of product risks (19%).

Regarding the introduction of a "responsible person" in the revised GPSD, a large majority of respondents in the OPC considered that products covered by the GPSD should only be placed on the EU market if there is an economic operator established in the EU responsible for product safety purposes (70% in favour). Consumer representatives support the introduction of such "responsible persons" in the EU, in line with Regulation 1020/2019, but stress that their responsibilities should be strengthened.

Consumer representatives also call for increased international cooperation on market surveillance, product safety, customs and enforcement.

5) Revision of the standardisation process

Stakeholders are mostly in favour of simplifying the standardisation process to develop new standards. Consumer organisations suggested the Commission Decision on safety requirements to become legally binding.

6) Including food-imitating products in the scope of the revised GPSD

Most stakeholders are in favour of incorporating the food-imitating legislation into the GPSD. In the OPC, a large majority of respondents expressed that products which resemble foodstuff should be incorporated into the general product safety legal instrument (69%). In the consultation on the inception IA, including this element in the product safety risk assessment was the favoured approach. No support was expressed to the full ban of food-imitating products. Consumer representatives also suggest including risk assessment criteria regarding the child-appealing aspect of products in the revised GPSD.

7) Improving the framework for product recalls

Stakeholders' opinions differ regarding the need to tackle recalls in the revised GPSD. In the consultation on the inception IA, some stakeholders stressed that this issue is mostly linked to consumers' behaviours or to rogue traders. In the OPC, approximately a fifth of respondents regarded as problematic that there were no specific requirements for product recalls (22%). However, a consumer representative pointed out that this issue might not appear very important precisely because consumers are not sufficiently aware about recalls. Consumer representatives and many MS authorities are in favour of addressing them in the legislation or through guidance.

The crucial importance of using direct communication to consumers for recalls has been repeatedly stressed in the consultations, whenever it is possible, for instance because the product was registered, bought online, or bought with the use of loyalty card. Direct notification was also judged as being by far the most effective channel to spread recall information (according to 92% of respondents in the survey held during the IPSW session on product recalls).

There was also a general agreement among respondents that companies should be obliged to use customer data at their disposal to contact affected consumers directly in case of recalls (60% 'strongly agreed' and 32% 'tended to agree', IPSW survey). In this regard, businesses and authorities call for more clarity on data protection aspects and compliance with the General Data Protection Regulation. Several stakeholders mentioned that consumers should be able to choose to receive safety notifications only (when registering a product or subscribing to a loyalty scheme).

Consumer representatives and authorities also stressed that online marketplaces should play a facilitating role in recalls, taking advantage of the channels and systems they have already put in place to communicate with both consumers and sellers. In the OPC, more than half of the respondents agreed that online marketplaces should inform consumers when a dangerous product has been removed from the marketplace (55%). The potential benefits linked to connected products were also stressed: when a connected product itself is subject to a recall, this technology can be used to warn consumers or, if they fail to act, switch off the product or reduce its performance.

Participants in the workshop on recall effectiveness and IPSW session on recalls agreed that a recall notice should be easy to read, straight to the point and clearly describe the risk and action to take. Several stakeholders stressed that some key elements and ground rules, applicable to all recall notices, should be standardised and made compulsory.

8) Improving traceability along the supply chain

A large majority of stakeholders agree that the system of product traceability should be reinforced in the GPSD (82% in favour in the OPC). The elements that most respondents in the IPSW online survey wanted to see as mandatory is the type, batch or serial number or other element allowing the identification of the product (85%). This was followed by the manufacturer's name (81%), the importer's name (63%) and the trademark (59%).

Most respondents also favoured the possibility to have traceability information available in an electronic format only, for instance via a QR code (55%). However, the consumer representative noted that vulnerable consumers who do not necessarily have the capacity to read a QR code should not be left aside.

Stakeholders also appear to be in favour of the introduction of a "one up one down" traceability requirement in the revision of the GPSD, whereby economic operators have to keep information about the upstream and downstream economic operator in the supply chain (93% in favour in the slido survey conducted at the recall session of the IPSW). Consumer representative explained that a differentiation between durable and non-durable goods would be relevant when it comes to the number of years during which such information should be kept. Moreover, the role of online marketplaces in improving product traceability was also stressed, notably that they should check that traceability information is available before listing a product.

Stakeholders would also welcome the possibility to set up additional traceability requirements for the components of the product (74% in favour, IPSW survey). Consumer representative stressed that because of the growing importance of the circular economy, traceability is increasingly important not only for the product itself but also for its components.

9) Better tackling of chemical risks

Consumer representatives consider that the revised GPSD should play the role of a real safety net for chemicals in all products, by setting detailed chemical safety criteria for non-harmonised consumer products through implementing measures.

10) Addressing counterfeit products

Brand owner organisations stressed that the GPSD should be amended to tackle counterfeit unsafe products.

4. Use of the results of the consultations

The results from the consultation activities have been incorporated throughout the IA from the problem definition to possible options and their impacts. The consultations have confirmed the relevance of the five objectives identified in the inception impact assessment, as well as the elements and the options proposed to answer these objectives. The results have also been taken into account in the Evaluation (Annex 5) for the assessment of the GPSD against the five evaluation criteria, to reflect the different views of the stakeholders.

Moreover, some elements raised in the consultations will be included as accompanying implementation measures of this initiative, notably regarding international cooperation: consumer representatives have called for good examples of cooperation between regulators, such as the EU-Canada arrangement on product safety alerts, to be

replicated with other countries. This will be included in the larger implementation strategy.

Regarding the inclusion of the fight against unsafe counterfeit products in the scope of the revision of the GPSD, this issue was duly taken into consideration, but was not included in the scope of the IA. Indeed, counterfeit products are already addressed by EU legislation, and unsafe products are covered including by the GPSD, regardless of their authenticity. Even though counterfeit products can pose safety risks, the safety of a given product has to be analysed based on a risk assessment.

Annex 3: Who is affected and how?

1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

In case the preferred option 3 is retained, the initiative will have **practical implications on both the economic operators handling products covered by the GPSD** (it can be producer, distributor, importer, online marketplaces or fulfilment house) and **market surveillance authorities in the Member States**.

Under Option 3, **businesses** will have additional requirements: manufacturers and importers will have additional traceability requirements and online traders (online retailers, distributors or marketplaces) will have the requirement to provide the same information online, which is available offline (traceability and other mandatory safety information). This would imply for businesses setting up internal mechanisms to ensure they comply with these traceability and transparency provisions. Comprehensive additional requirements would apply in the context of recalls for all businesses, but these additional requirements would have practical implications only to those companies that have actually brought unsafe products onto the market. Online marketplaces will also have to make sure they set up internal mechanisms to comply with most of the Product Safety Pledge's provisions and the duty of care responsibility, which would also apply to them. In addition, companies selling in the Single Market from outside the EU will have to set up arrangements to ensure that the products sold in the EU have a responsible economic operator. Finally, enhanced penalties would have an impact on the non-complaint businesses.

A broadening of market surveillance responsibilities, new competences and a greater need for internal and external resources respectively to perform the market surveillance (e.g. the new tools for market surveillance online broaden the possibilities of MSAs and may require additional resources and skills), will impact **market surveillance authorities in Member States.** However, the provisions on MSAs' powers are largely aligned to the existing market surveillance provisions applicable to harmonised products under Regulation (EU) 2019/1020. Therefore, these provisions are not new to MSs and in particular for those MSs where MSAs handle already both categories of products, harmonised and non-harmonised. The practical implications are therefore rather better synergies and use of existing structures and resources than new additional needs. The extended coverage of risks from new technologies (e.g. cyber-security risks that have an impact on safety) would be expected to increase the need for professional staff and external expertise on the side of MSAs to check the safety of new technology products.

The practical implications will start operating as soon as the revised GPSD has entered into force.

2. SUMMARY OF COSTS AND BENEFITS

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)
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	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

	'moderate' and close to 'significant'.	
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 non-harmonised products. **Cost savings for MSAs** estimated at **EUR 0.7 million per year** across the EU.	Main impact on MSAs due to aligning market surveillance provisions between harmonised and non-harmonised products, more aligned enforcement 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 for product safety	Direct costs	-	-	Familiarisation costs, adaptation costs to regulatory changes Total costs of businesses in the EU27 in the 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	Additional regulatory compliance costs, related to staff and additional resources (more for 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)	Only relatively moderate one-off adaptation and implementation costs.	total additional recurrent costs of MSAs in EU27 of approx. **EUR 6.7 million annually**

				retail of non-harmonised consumer products.			
	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 online in the same vein as it is required "offline"	Direct costs	-	-	-	Costs to be very limited for both online platforms and 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	-	Higher administrative burden for recalls and	-		

		remedy)		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	-	-	-		-	-

(1) Estimates to be provided with respect to the baseline; (2) costs are provided for each identifiable action/obligation of the preferred option otherwise for all retained options when no preferred option is specified; (3) If relevant and available, please present information on costs according to the standard typology of costs (compliance costs, regulatory charges, hassle costs, administrative costs, enforcement costs, indirect costs; see section 6 of the attached guidance).

Annex 4: Analytical methods

This Annex provides an overview of the following analytical methods and techniques as well as the related data sources used for the impact assessment:

- Estimation of the detriment due to product-related injuries and fatalities in the EU;
- Estimation of costs of compliance with the GPSD for EU businesses;
- Estimation of costs of compliance with the GPSD for Member states;
- Estimation of the costs of implementing specific policy options for the potential revision of the GPSD;
- Estimation of benefits of measures concerning online sales channels;
- Estimation of benefits of measures in the field of recalls; and
- Methods for other supporting estimations.

They are elaborated in the following sub-section.

1. Estimation of the detriment due to product-related injuries and fatalities in the EU

The cost of non-fatal product related injuries in the EU

For the calculation of the cost of non-fatal product related injuries in the EU[139], we use the European Injury Database (IDB) as a source of data on product-related injuries. The data are voluntarily contributed by the Member States participating in the IDB, which were 15 out of 28 Member States in 2016[140]. Two levels of datasets exist in the IDB: the full dataset indicated as IDB-FDS and the minimum dataset referred to as IDB-MDS. The IDB-FDS provides more detailed information with regards to the circumstances of the injury and the products involved, in comparison to the IDB-MDS, which includes limited information pertaining to the injury, but provides data that can be used to extrapolate data to the EU level. For the analysis, both datasets have been used.

The analysis focused on accidental, non-intentional injuries and excluded transport injury events and work-related injuries. As IDB data has also been used as an indicator for the European Commission's Consumer Market Scoreboard, we have selected the same product groups used by the Consumer Market Scoreboard to define consumer products as represented in the IDB[141].

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139 The analysis refers to the European Union of 27 Member States. The monetary values in the analysis are expressed in EUR 2017; in cases where 2017 values have not been available, monetary values were inflated to 2017 values using Eurostat's Labor Cost IndexEurostat, Labour cost index by NACE Rev. 2 activity - nominal value, annual data [lc_lci_r2_a]. NACE_R2: Industry, construction and services (except activities of households as employers and extra-territorial organisations and bodies). Extracted 16/06/2020.

140 Ibid., p. 26.

141 See European Commission (2014), 'Consumer Markets Scoreboard. Making markets work for consumers', 10th edition, p. 60-61.

To estimate the number of injuries related to different product groups we have used the number of injuries recorded in the IDB-FDS between 2013-2017. On basis of the data provided in the IDB we estimated the total number of injuries in the EU27 on average per year between 2013-2017, using Eurostat population data to extrapolate the FDS data. The method for extrapolation is elaborated in detail in Annex IIc.

Health care utilization

Health care utilization costs include the costs of hospitalization/hospital admission, the costs of treatment in a hospital emergency department, as well as the costs of being treated in a non-hospital setting e.g. at a doctor's office or as an outpatient. To calculate the cost of health care corresponding to the product-related injuries, it is necessary to retrieve data regarding the consequences of the injuries in terms of the required medical attention as well as the unit costs for each type of health care. The data contained in the IDB-FDS enabled us to identify between three different groups of product-related injuries in terms of the type of treatment required: Patients with product-related injuries that are sent home after treatment; Patients with product-related injuries that are either treated and referred to a general practitioner for further treatment or treated and referred for further treatment as an outpatient; Patients with product-related injuries that are treated and admitted to hospital or transferred to another hospital.

To arrive at the costs of health care utilization we used the approach as described in the following box:

Health care utilisation costs for a given injury type can be estimated by multiplying the average cost of treatment by the number of cases, as indicated below:

$$HeathCareUtil_{EU} = \sum [NrInjuries_{EU,Cat} \times AvgTreatmentCost_{EU,Cat}]$$

Where:

$HealthCareUtil_{EU}$ is the total cost of health care utilisation at the EU level;

$NrInjuries_{EU,Cat}$ is the number of product-related injuries by treatment category;

$AvgTreatmentCost_{EU,Cat}$ is the average cost of treatment for the given injury in a given MS, by treatment category.

For assessing average treatment costs, we used unit cost values for health service delivery from the WHO-CHOICE project, which are provided for different world regions in 2010 international dollars[142]. After converting the two types of costs into EUR 2010 using the OECD purchasing power parity (PPP) exchange rate[143], we inflated them to EUR 2017 using Eurostat's Labor Cost Index. Based on these conversions we calculated the average cost per inpatient bed hospital day and the average cost per outpatient visit. We used the calculated values to estimate respectively the cost of the three groups of treatment (as indicated above).

142 WHO Economic Analysis and Evaluation Team (2010), 'WHO-CHOICE estimates of cost for inpatient and outpatient health service delivery', pp. 1-60, available at: https://www.who.int/choice/cost-effectiveness/inputs/country_inpatient_outpatient_2010.pdf.

143 OECD (2020), Purchasing power parities (PPP) (indicator), available at: doi: 10.1787/1290ee5a-en (accessed on 06 July 2020).

Productivity losses

The cost of productivity losses is considered for this assessment to correspond to the value of missed time from work. The cost of productivity losses was calculated first by estimating the number of work days lost as a consequence of the injury related to a product and then multiplying this number by the EU average gross daily earnings. Product related injuries for which the type of treatment is not indicated or recorded are not taken into account for the assessment of productivity losses. The detailed approach for determining productivity losses is provided in the following box:

The cost of **productivity losses** for a given treatment category are calculated as the cost of missed work. In order to account for the fact that a disproportionate number of injuries occur among children, we take into consideration the proportion of victims that are of working age. The calculation can be expressed as:

$$ProdLoss_{EU} = \sum [NrInjuries_{EU,Cat} \times WAPop_{EU} \times LMP_{EU} \times Wage_{EU} \times DaysLost_{Cat}]$$

Where:

$ProdLoss_{EU}$ is the total cost of productivity losses in the EU;

$NrInjuries_{EU,\ Cat}$ is the number of product-related injuries in a given treatment category;

$WAPop_{EU}$ is the proportion of the injured persons that are of working age;

LMP_{EU} is the labour market participation rate in the EU for working age population;

$Wage_{EU}$ is the average daily wage in the EU; and

$DaysLost_{Cat}$ is the average number of days of work lost for a given treatment category.

Loss of quality of life

To estimate the impact of the injury in terms of reduced life quality we use the Quality Adjusted Life Year (QALY), a measure that integrates evaluation of the quality and quantity of life[144]. For calculating the cost due to reduced quality of life, we have used the following approach[145].

Loss of quality of life will be considered for serious injuries, which are considered to be those for which hospitalisation was required, according to the following equation.

$$LossQualityLife_{EU} = \sum [NrInjuries_{EU,Hosp,Inj} \times LossQALY_{Inj} \times ValueQALY_{EU}]$$

Where:

$LossQualityLife_{EU}$ is the monetised total loss of quality of life of patients hospitalised due to product-related injuries in the EU;

$NrInjuries_{EU,Hosp,\ Inj}$ is the number of hospitalised cases for each main type of injury related to products in the EU;

$LossQALY_{Inj}$ is the Quality Adjusted Life Year loss for each main type of injury;

$ValueQALY_{EU}$ is the monetary value assigned to a Quality Adjusted Life Year.

For each of the injuries we have identified on basis of IDB data, we used a corresponding

144 Adler, Matthew D. "QALY's and Policy Evaluation: A New Perspective." *Yale Journal of Health Policy, Law, and Ethic*s 6, (2006), Hammitt, James K. "QALYs Versus WTP." *Risk Analysis* 22, no. 5 (2002): 985-1001.

145 See Karapanou, Vaia. *Towards a Better Assessment of Pain and Suffering Damages for Personal Injuries. A proposal based on Quality Adjusted Life Years.* Cambridge, Antwerp, Portland: Intersentia, 2014.

QALY-weight that expresses the impact of the injury in terms of the quality of life of individuals, using relevant specific estimates. Another approach that has been used to estimate the WTP for a QALY involves taking advantage of the existing literature on the Value of Statistical Life (VSL). This approach, the validity of which was also confirmed by an expert of the European Chemicals Agency (ECHA), is also consistent with the VSL approach that is used below to calculate the cost of premature death. We followed this approach to derive the monetary value for one QALY, using the VSL range of estimates between €3.5 million (lower estimate) and €5 million (higher estimate) included in the Commission's Better Regulation Toolbox[146]. After expressing them in EUR 2017 using the labour cost index we converted them to VSLY estimates by applying a discount factor of 4%[147] and a remaining life expectancy of 35 years, which is commonly considered as the remaining life expectancy of an adult at the time of injury[148]. Finally, considering that the resulting values based on the VSL are upper bound estimates that tend to overestimate the value per QALY by a factor of two on average, we divided the estimated amounts by two[149]. The resulting range of willingness to pay estimates per QALY used in this study are listed in the following table.

Source	WTP for a QALY estimate
Civic Consulting based on VSL estimates provided in EU Commission's Better Regulation Toolbox	€101 706 (low estimate) €123 500 (medium estimate) €145 294 (high estimate) (in EUR 2017)

The cost of product related premature death in the EU

In order to arrive at the number of fatal injuries in Europe, we have used the WHO Mortality Database (WHO-MDB) which contains data for all countries participating in WHO[150]. To enable a selection of fatal injury incidents that are relevant for this analysis we have filtered existing data by selecting injury incidents based on specific ICD-10 codes. Based on the incidence figures extracted from the WHO dataset we calculated the cost of premature death related to the selected fatalities. Our approach is detailed in the box:

Cost of premature death is estimated for all non-intentional fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) outside of work-related locations, on basis of the following equation:

$$LossFatal_{EU} = NrFatal_{EU} \times VSL_{EU}$$

Where:

146 Better Regulation Toolbox complementing the better regulation guideline presented in SWD(2017) 350, p. 245.

147 Better Regulation Toolbox complementing the better regulation guideline presented in SWD(2017) 350, p. 503.

148 To estimate VSLY we use the formula VSLY= r*VSL/(1-(1+r)^-L) where r is the discount rate and L is remaining life expectancy, see also Joseph E. Aldy & W. Kip Viscusi, 2008. "Adjusting the Value of a Statistical Life for Age and Cohort Effects," The Review of Economics and Statistics, MIT Press, vol. 90(3), pages 573-581.

149 Daniel Herrera-Araujo, James K. Hammitt & Christoph M. Rheinberger (2020), "Theoretical bounds on the value of improved health", *Journal of Health Economics 72*, p. 1-15.

150 WHO Mortality Database, accessible at: https://www.who.int/healthinfo/mortality_data/en/.

$LossFatal_{EU}$ is the monetised total loss due to the relevant fatalities in the EU;

$NrFatal_{EU}$ is the number of relevant fatalities in the EU;

VSL_{EU} is the monetary value of a statistical life in the EU.

The monetary value used to quantify the value of a statistical human life is derived from individuals' willingness to pay (WTP) to eliminate a small risk of dying[151]. Numerous studies exist in which the VSL has been empirically estimated using the hedonic wage method, the stated preference method or other methods[152]. We have used the estimates provided by the European Chemicals Agency (ECHA) to calculate the cost of premature death, which are also referred to as reference values in the Better Regulation Toolbox of the European Commission[153]. More specifically we use the average value of the higher and lower estimate for the value of a statistical life provided by ECHA (EUR 4.25 million) as a standard assumption for the cost of a premature death, while retaining the low and high estimates for later sensitivity analysis. Expressed in 2017 values (again inflated by using the labour cost index), we arrived at a VSL estimate of EUR 4.6 million. We have used this estimate to arrive at the annual cost of premature death due to fatalities caused by mechanisms relevant for product safety.

2. Estimation of costs of compliance with the GPSD for EU businesses (baseline business costs)

We first focused on the estimation of the baseline market size, i.e. the total turnover of EU businesses from manufacturing and/or selling non-harmonised consumer products in the EU[154], before analysing company level compliance cost data, and extrapolating it to EU level, based on the estimated baseline market size. The analysis is structured according to six steps:

Step 1: Estimation of EU companies' total annual turnover from the production and/or sales of non-harmonised consumer products in the EU

Based on NACE industry codes and sector descriptions, we identified those manufacturing sectors (NACE Rev. 2, B-E), wholesale services sectors and retail sectors (NACE Rev. 2, G) in which consumer products are produced and/or sold, i.e. we excluded sectors that clearly focus on the production and sales of industrial products. Sectors related to motor vehicles have been excluded, in line with the focus on non-harmonised consumer products. While retail sale can be assumed to be largely related to consumer products (although retailers may also sell to professional users, and may sell services), the wholesale and manufacturing in the listed areas clearly also contain industrial/professional products, an issue considered in Step 3 below. To arrive at the share of non-harmonised products produced and/or sold in these sectors, we applied the

151 It can also be derived by the willingness to accept (WTA) a small probability of death.

152 The stated preference method tries to elicit the value of non-market goods by directly asking people how much they value these goods while the hedonic wage method uses labor market data that reveal the trade-offs workers make between job risks and additional pay. The hedonic wage method belongs to the group of revealed preference methods which infer WTP / WTA values from observed behaviour. See Alessandra Arcuri, 2012, "Risk Regulation" in: Roger J. Van den Bergh & Alessio M. Pacces (ed.), Regulation and Economics, chapter 6, Edward Elgar Publishing.

153 Better Regulation Toolbox complementing the better regulation guideline presented in SWD (2017) 350, p. 245.

154 All estimates in this section refer to the EU27 as of 2020.

estimate provided in the 2017 EU impact assessment for the new Market Surveillance Regulation, which estimated that about 54% of products circulating within the European Single Market are harmonised products and 46% are non-harmonised products[155].

Step 2: Deduction of extra-EU export

To calculate the net turnover for non-harmonised consumer products that are only sold in the EU, we deducted the share of extra-EU exports from the total turnover of EU companies. The calculation is based on an approximation of sector-specific export shares. The extra-EU trade by enterprise characteristics data provided by Eurostat do not exactly match the sector classification of turnover data by enterprise size class[156]. We therefore approximated the extra-EU export shares of manufacturing, wholesale and retail sectors on the basis of those sectors for which we found full concordance in the two datasets[157]. The estimated extra-EU export shares of manufacturing, wholesale and retail sectors were subtracted from the annual turnover of EU companies with non-harmonised products in the selected sectors.

Step 3: Deduction of industrial and professional products

We corrected the EU turnover derived in Step 2 by the percentage shares of turnover that can be attributed to the production and/or sales of consumer products in manufacturing, wholesale and retail sectors. For this purpose, we drew on a different dataset, namely the final consumption expenditure of households by consumption purpose[158]. We again correct for the share of harmonised products, and arrived at an estimate for total household consumption of non-harmonised products. For the following analysis we assumed that this consumption of non-harmonised consumer products is equivalent to the total turnover from non-harmonised consumer products sold by EU retailers. The estimated retail turnover from non-harmonised products indicated before was adjusted accordingly, and the resulting amount was allocated between the three enterprise size classes. Due to data limitations, the same methodology could not be applied for manufacturing and wholesale sectors[159]. For manufacturing and wholesale sectors, we estimated the share of turnover that can be attributed to consumer products on the basis of the share of "consumer-oriented" wholesale services in total wholesale services. It is assumed that the same share reflects the portion of consumer products produced and/or sold by manufacturers. Based on this approach, we could calculate the total annual EU turnover of EU companies from non-harmonised consumer products.

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155 SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795.

156 In the Annex, we provided detailed trade volumes of extra-EU exports by NACE Rev. 2 activity and enterprise size class.

157 These sectors are: "Manufacture of textiles, Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials", "Manufacture of paper and paper products", "Manufacture of computer, electronic and optical products", "Manufacture of electrical equipment", "Manufacture of furniture", "Wholesale trade, except of motor vehicles and motorcycles", and "Retail trade, except of motor vehicles and motorcycles". In the Annex, we provide shares of extra-EU exports in key consumer products sectors broken-down by enterprise size class.

158 Eurostat, Final consumption expenditure of households by consumption purpose (COICOP 3 digit) [nama_10_co3_p3].

159 Eurostat data do not allow to extract "pure" consumer products for manufacturing and wholesale sectors, i.e. final products that are consumed by households.

Step 4: Derivation of empirical estimates for companies' product safety-related costs on the basis of survey responses

In our company cost survey and the complementary interviews conducted with selected companies, businesses were asked to indicate staff time used for managing product safety, testing for product safety, recalls and other consumer product safety related activities. We asked respondents to consider all costs for ensuring product safety of both harmonised and non-harmonised consumer products (excluding pharmaceuticals, medical devices or food), as the identification of costs for non-harmonised products only was not considered to be feasible. In addition to staff requirements, companies were asked to provide estimates for other costs to comply with safety requirements for consumer products (e.g. costs for external legal advice, costs for external safety testing, costs for certification of safety of products etc.)[160]. The cost estimates provided by the respondents also include business-as-usual costs, which would incur even in absence of product safety regulation (see Step 6). These estimates were used to estimate companies' annual regulatory compliance costs in Euro terms. The calculation of Euro-denominated costs for staff was based on the EU's (weighted) average wage for the business economy, which in 2019 was 27.50 Euro per hour[161]. To account for overhead costs, a 25% mark-up was added to staff-related costs. Subsequently, the costs for each company were related to the EU turnover for consumer products, i.e. we expressed companies' annual cost resulting from activities to comply with safety requirements for (harmonised and non-harmonised) consumer products as a share of the related turnover.

Step 5: Extrapolation of EU companies' annual costs related to the GPSD incl. business-as-usual costs that occur also in absence of regulation

For each enterprise size class, we multiplied the empirical median values for companies' relative product safety-related costs, which were derived in Step 4, with the annual turnover of EU companies that can be attributed to the production and/or sales of non-harmonised consumer products in the EU (Step 3). The results of this calculation still include business-as-usual costs.

Step 6: Deduction of business-as-usual costs and extrapolation of EU companies' annual compliance cost related to the GPSD

In our company survey and interviews, we asked businesses to indicate the share of the total product safety-related costs that they would incur anyway (i.e. even in absence of product safety legislation, e.g. because these costs relate to due diligence), hereafter referred to as business-as-usual costs, BAU. These estimates reflected the self-assessment of the companies that are part of the sample, and are therefore subjective in nature. However, as concerns differences between manufacturers, on the one hand, and wholesalers and retailers, on the other, we considered the estimates to be in line with expectations and a credible basis for the final step of the assessment. We applied the empirical median values of these shares to the product safety-related cost estimates derived in Step 5. Excluding business-as-usual costs, we obtained compliance costs of EU companies that can be attributed to non-harmonised consumer products, i.e. the costs for businesses to comply with the GPSD.

160 Business stakeholders were asked to estimates average costs per month in EUR.

161 Labour cost for LCI (compensation of employees plus taxes minus subsidies), provided by Eurostat.

3. Estimation of costs of compliance with the GPSD for Member States (baseline costs for Member States)

The estimation of MSAs' staff-related costs related to market surveillance activities for non-harmonised consumer products in the EU was based on the following three steps:

Step 1: Identification of MSAs annual FTEs for market surveillance activities related to non-harmonised consumer products

For our estimate we used the number of full time equivalent (FTE) staff for market surveillance of consumer products as provided in the country research. Where the available country estimates related to the market surveillance of non-harmonised consumer products, this figure was directly used in the calculation. Where estimates related to the total staff for market surveillance of both harmonised and non-harmonised consumer products, we allocated staff according to the 54%/46% ratio for harmonised/non-harmonised products circulating within the European Single Market to derive an estimate for related market surveillance activities[162]. It should be noted that a share of 46% in staff time for market surveillance of non-harmonised consumer products is 12 percentage points higher than the empirical median share indicated by MSAs for activities devoted to non-harmonised products in the stakeholder survey (34%), potentially causing an estimate at the higher end of MSAs' actual costs that can be attributed to market surveillance activities for non-harmonised consumer products. For seven countries, no information on staff numbers was available at all.

Step 2: Approximation of annual FTEs for market surveillance activities related to non-harmonised consumer products for countries for which data was not available

For the seven countries, for which no staff data was available (Croatia, Germany, Hungary, Italy Slovenia, Slovakia, and Spain) we estimated the number of FTEs on the basis of the data for the remaining 20 Member States. To account for institutional differences with regard to the level of centralisation, we considered two clusters of countries, in line with the characteristics of the respective market surveillance systems as described above: Cluster 1: responsibility for market surveillance is centralised (no sub-national administrations involved); Cluster 2: responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations, in line with the administrative structure of the country.

[162] As mentioned before, the 2017 EU impact assessment for the new Market Surveillance Regulation estimated that about 54% of products circulating within the European Single Market are harmonised products and 46% are non-harmonised products. See SWD(2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795.

To derive estimates for the number of FTEs per million population for Slovenia and Slovakia (more centralised market surveillance), we applied the sample median of 3.5 FTEs per million population. To derive FTE estimates for the number of FTEs per million population for Croatia, Germany, Hungary, Italy and Spain (more decentralised market surveillance), we applied the sample median of 4.6 FTEs per million population.

Step 3: Calculation of annual staff costs for market surveillance activities related to non-harmonised consumer products

In the final step, we calculated the EUR equivalent of the estimated number of staff required for market surveillance of non-harmonised consumer products by multiplying the number of FTEs per million population by:

- The size of population for each country (in million);
- The number of person-hours per year (1 720) [163]; and
- The average wage of 28.00 EUR, which corresponds to the EU27 average wage of "administrative and support service activities" (18.70 EUR) and "professional, scientific and technical activities" (37.30 EUR) for 2017 (latest figure available in Eurostat database).

4. Estimation of the costs of implementing specific policy options for the potential revision of the GPSD

Companies assessed in their responses to our cost survey the change that the implementation of each option would cause in their recurrent costs, e.g. costs related to additional staff and additional resources for due diligence measures such as IT systems and external services, in addition to one-off costs, such as familiarisation costs and costs from adapting to regulatory changes (e.g. for external advice). Both types of costs were analysed.

To estimate the impact of the implementation of each option on EU businesses' recurrent costs, we applied the percentage change in recurrent (annual) costs as assessed by respondents to the estimated annual product safety-related costs of companies producing and/or selling consumer products in the EU (baseline estimates). Applying the sample median as best estimate for the extent to which recurrent costs would increase under each option, we calculated the change in the estimated annual consumer product safety-related costs of EU businesses in Euro terms for manufacturers, wholesalers and retailers.

Our estimation of EU businesses' total one-off costs was based on individual respondents' estimates for the total additional staff needed and the total additional non-staff costs that arise from familiarisation and implementation efforts under each option. Based on the respondents estimates, we calculated staff costs in Euro terms and added other (non-staff) one-off costs. The calculation of Euro-denominated costs for staff was based on the EU's (weighted) average wage for the business economy, which in 2019

[163] Following EU Horizon 2020 guidelines, one person year corresponds to 1 720 person-hours per year. See, e.g. the H2020 Programme: User's Guide for the Personnel Costs Wizard.

was 27.50 Euro per hour[164]. To account for overhead costs, a 25% mark-up was added to staff-related costs.

The total one-off costs for each company were divided by the EU turnover for consumer products, i.e. we expressed companies' total additional one-off costs resulting from activities to comply with safety requirements for consumer products under Option3 as a share of the related turnover. Applying the sample median to the estimated annual turnover for manufacture, wholesale and retail of consumer products in the EU resulted in estimates for additional one-off cost for manufacturers, wholesalers and retailers.

The estimate of recurrent and one-off costs of MSAs was conducted using a similar approach, with estimates on how the implementation of each option would change their recurrent costs derived from the answers to our survey of authorities. Again, we multiplied the empirical median with baseline costs, to estimate recurrent costs, and separately assessed one-off costs.

5. Estimation of benefits of measures concerning online sales channels

No consistent data is available on the incidence of unsafe products on the EU market. In the analysis, we used stakeholder assessments as best available estimate to first analyse the potential detriment accruing currently to consumers due to unsafe products on the EU market, and then consider the impact that increasing e-commerce and the implementation of different policy options could be expected to have on this baseline situation. A key challenge in this respect is the size of the detriment to consumers posed by unsafe products. An unsafe product could lead to injuries and fatalities, which cause substantial detriment in the EU every year. Due to data limitations, it is not possible to quantify the occurrence of product-related injuries and fatalities, or damage to other goods caused by unsafe products according to sales channel. We therefore in this analysis use as proxy for the detriment caused by an unsafe product its value (as expressed by its purchase price). This approach seems to rather underestimate than overestimate detriment, in light of the different situations analysed. In our baseline analysis, we have estimated the total EU27 household consumption of non-harmonised consumer products (excluding food and medical products) at EUR 428 664 million per year. Combining this data with the estimate of the incidence of unsafe consumer products, we derive the value of unsafe products per year (which is in our approach equivalent to the related consumer detriment) at EUR 3.9 billion for the online sales channels, and EUR 15.4 billion for brick-and-mortar shops and other offline sales channels, for a total of EUR 19.3 billion. This figure is by its nature an approximate estimate, as the data on which it is based has considerable limitations, and the result is affected by the underlying assumptions.

6. Estimation of benefits of measures in the field of recalls

A fundamental obligation that derives from the GPSD is the obligation of producers and distributors to notify the authorities and take the necessary actions for consumer protection, once one of the products that they have placed on the market is identified as dangerous[165]. The limited effectiveness of recalls also leads to consumer detriment, the size of which is estimated in this annex.

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[164] Labour cost for LCI (compensation of employees plus taxes minus subsidies), provided by Eurostat.

[165] GPSD Art 5 (3).

For estimating consumer detriment due to ineffective recalls, we follow the approach explained above, namely to use the value of an unsafe product as a proxy for the detriment it causes to consumers that have bought it (a detailed justification of this approach is provided in the same Annex). When using the value of a recalled product to analyse consumer detriment, two situations can be differentiated:

1. *An unsafe product is recalled and returned to a producer.* The resulting consumer detriment can be approximated as being zero[166];
2. *An unsafe product is recalled and not returned to a producer.* In this case the consumer detriment is the value of the product, as discussed.

Under a scenario of improved recall effectiveness, consumer detriment in the EU can be expected to be reduced by more than EUR 400 million per year. As mentioned above, this estimate is based on a number of scenario assumptions, which have been chosen with the aim to provide a conservative estimate of consumer benefits due to improved recall effectiveness. A key assumption is that the detriment incurred by consumers in case of a recall of an unsafe product is equivalent to its purchase price. This is a very restrictive assumption, as it does not consider situations in which a recalled, unsafe product caused damage to persons, other goods or the environment. Also, the return rates underlying the improved effectiveness scenario are still relatively low and might be further increased through appropriate measures by producers and authorities, considering e.g., the increased availability of customer data in online transactions. If return rates were to be improved beyond our assumptions, consumer detriment would accordingly be further reduced, compared to the estimate provided.

7. Methods for other supporting estimations

Other supporting estimations include the analysis of costs of mandatory accident reporting and the extrapolation of the number of parcels imported to the EU. In both cases, baseline data was extrapolated using relevant data sources from international organisations or data from non-EU countries in which comparable measures were taken. For more details on the methodological approach taken in each case, see the relevant section of the report.

8. Validation and quality assurance of results of analyses conducted

Great care was taken to explore all possible data sources at EU level and from international databases to use the best available data, which is a key element of quality assurance. All analyses were validated internally by different members of the team, to safeguard internal consistency and accuracy. Finally, in major analyses external expertise was involved, either through advisory roles (e.g. an expert of EuroSafe supported the data extraction process related to the IDB), or through providing advice on specific methodological issues. These included the WHO, which was consulted on possible approaches to group ICD-10 codes, and ECHA, which provided advice on the most appropriate method to determine VSLY values.

Sensitivity analysis was used to assess robustness of estimates against different assumptions, where relevant. With respect to the estimation of detriment, we elaborated

[166] In reality, even in this situation consumers incur a detriment due to the time spent for the transaction, e.g., for returning the product by mail or in person to a shop. However, this additional detriment is not considered here, provide a conservative, simplified estimate.

sensitivity scenarios concerning the cost of premature death and the loss of quality of life. The first scenario to be tested against the main scenario involved using the lower estimate of the VSL to recalculate the costs incurred as a result of premature death. The second scenario involves the opposite recalculation, namely using the high estimate of the VSL and the corresponding QALY value to recalculate the costs incurred as a result of premature death and of lost quality of life. The third and fourth scenarios take into account the fact that the type of the injury as such e.g. injury to muscle, burn etc. does not convey the severity of the injury which may significantly influence the magnitude of the loss. Therefore, to account for the possibility of a mild and severe occurrence of the same type of injury we estimated the loss of quality of life using both low and high QALY losses per each type of injury. The rest of the assumptions (monetary value of a VSL, a QALY) remained the same as in the main scenario. The fifth and final sensitivity scenario involved taking into account for the calculation of the cost of premature death only the fatalities caused by mechanisms relevant for product safety that occur at home keeping everything else constant.

Annex 5: Evaluation report

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Glossary

Term or acronym	*Meaning or definition*
AI	Artificial Intelligence
BAU	Business as Usual
CETA	EU-Canada Comprehensive and Economic Trade Agreement
CSN	Consumer Safety Network
DGCCRF	Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes, France
DSA	Digital Services Act
EEA	European Economic Area
EFTA	European Free Trade Association
EU	European Union
EQ	Evaluation Question
FIPD	Council Directive 87/357/EEC concerning the safety of food-imitating products
GPSD	Directive 2001/95/EC on the general safety of products
IA	Impact Assessment
IoT	Internet of Things
NLF	New Legislative Framework
OECD	Organisation for Economic Cooperation and Development
OPC	Open Public Consultation
Safety Gate/RAPEX	The rapid alert system for dangerous non-food products
Subgroup	The Subgroup on AI, connected devices and other new challenges in product safety to the Consumer Safety Network
SME	Small and Medium Enterprise
UCPD	Unfair Commercial Practices Directive
VAT	Value Added Tax

1. INTRODUCTION

1.1 PURPOSE AND SCOPE

Over two decades, the Directive 2001/95/EC on the general safety of products ('the Directive') has established a product safety framework to ensure the safety of consumer products.

In February 2013 the Commission adopted the Product Safety and Market Surveillance Package[167], whose aim was, among other things, to revise the Directive. The proposed rules however were not adopted by the Council and the Parliament, due to the lack of political consensus on the so called "made-in" clause. Consequently, the proposals were withdrawn in September 2020.

Since the adoption of the Directive in 2001, new developments in products and markets have occurred, in particular as concerns products incorporating new technologies and e-commerce. In addition, the adoption of new legal instruments, such as the recently updated Regulation on market surveillance and compliance of products[168], has had as a consequence that the Directive's provisions on market surveillance are not fully in line with market surveillance rules for harmonised products.

The Directive has never been evaluated since its entry into force[169]. In light of the above-mentioned developments, the Commission has carried out an **Evaluation** of the Directive to assess its performance. This evaluation has been prepared **back-to-back with the Impact Assessment** for a proposal to revise the Directive. This was justified as at the time of the launch of this initiative the Commission had already quite some evidence to support the evaluation and the impact assessment. An impact assessment was already carried out by the Commission in 2013, as well as for the recently adopted Regulation (EU) 2019/2010 on market surveillance and compliance of products. Moreover, both the Evaluation and the Impact assessment were supported by a number of studies and other data gathered through consultation. A **report on the implementation of the Directive** also accompanies the Impact Assessment and the Evaluation, as established in Article 19(2) of the Directive.

The **geographical scope** of the evaluation covers 31 countries (EU28, Iceland, Liechtenstein and Norway). It focuses on the period from 2004 (i.e. subsequent to the deadline for its transposition and application according to Article 22 of the Directive) to 2020, seeking to understand trends over this period wherever possible. This evaluation

[167] COM(2013) 78 final - The Product Safety and Market Surveillance Package

[168] Regulation (EU) 2019/1020 Regulation on market surveillance and compliance of products

[169] The Product Safety and Market Surveillance Package did not include a proper evaluation of the Directive 2001/95/EC according to Better Regulation rules.

also covers Council Directive 87/357/EEC concerning the safety of food-imitating products (FIPD)[170].

This evaluation assesses the following criteria: **relevance** (whether the tools of the Directive correspond to current needs), **effectiveness** (whether the original objectives have been achieved), **efficiency** (the functioning of the Directive from a simplification and burden reduction perspective), **coherence** (how the Directive works together with other legislation in the field of safety of consumer products), and the **EU added value** of the Directive. The evaluation's findings have **fed into an Impact Assessment** of the policy options, which addresses the problems identified, including those related to food-imitating products.

2. BACKGROUND TO THE INTERVENTION

2.1 DESCRIPTION OF THE INTERVENTION AND ITS OBJECTIVES

The Directive has a **twofold objective**. On the one hand, according to its recital (2), the Directive pursues the aim of improving the functioning of the internal market. As recital (3) confirms, it has introduced a common legislative framework in order to avoid disparities between Member States that could have emerged in the absence of Union law. At the same time, the Directive intends to achieve a high level of consumer protection by introducing a general product safety requirement and other measures (recital (4)). Both aims are interrelated, it is the safety requirement for consumer products envisaged by the Directive, which prevents disparities that would lead to creating barriers to trade and distortion of competition within the internal market.

The Directive establishes a **general safety requirement** for all consumer products, as it obliges the producers to only place safe products on the market.

The Directive applies to **all sales channels, offline and online**.

Safety of services falls outside the scope of the Directive, but in order to secure a high level of consumer protection, its provisions also apply to products that are supplied or made available to consumers in the context of a service used by them. The safety of equipment used by the service provider, in particular that on which the consumers ride or travel, is nevertheless excluded. However, products which are actively operated by the consumer at the premises of a service provider, such as hairdryers available to guests in hotels rooms, are subject to the provisions of the Directive.

One of the key characteristics of the Directive is its role as a **"safety net"**, as it applies insofar as there are no more specific provisions with the same objective in EU product harmonisation legislation. Therefore, it complements sectorial legislation, as it covers all aspects and risks not specifically addressed, thus ensuring a high level of protection of consumers.

[170] Council Directive 87/357/EEC of 25 June 1987 on the approximation of the laws of the Member States concerning products which appearing, to be other than they are, endanger the health or safety of consumers

Standards are very important for the implementation of the Directive. The general safety requirement can be difficult to apply for businesses and national authorities because of the lack of a common benchmark on what constitutes a "safe" product. Therefore, the Commission can make use of European standards to make this general safety requirement more operational. European standards are voluntary and market-driven[171] and their advantage is not only that they replace the corresponding national standards in all Member States, making the life of businesses, including SMEs, easier, but in particular that products are presumed safe if they conform to voluntary national standards transposing European standards, which are referenced in the EU Official Journal. Standards therefore serve a double purpose: facilitating market access and ensuring product safety. The first step in the standardisation process under the Directive is a Commission Decision to set the so-called "safety requirements" to be met by the standards[172]. The second step is the adoption of a Commission Decision[173] issuing the formal standardisation request ("mandate") to the European Standardisation Organisations to develop standards compliant with the EC-adopted safety requirements. The last step takes place after the European standardisation organisation has developed the standard in conformity with the safety requirements. At this stage, in case the Member States in the Committee established in Article 15 of the Directive vote favourably and the Commission consider that the standard complies with the requirements of the GPSD, the Commission adopts a Commission Decision to publish the reference to this standard in the EU's Official Journal. A more detailed explanation of the standardisation procedure is detailed in Annex 10.

The Directive provides for additional **duties for economic operators**, which can be differentiated between measures to be taken before or after the product is placed on the market:

- *Pre-market obligations*: Besides the general safety requirement, the Directive requires producers to inform consumers of any risks associated with the products they supply. The aim is to enable consumers to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks. This obligation must be fulfilled when the product is made available on the market. It not only relates to information on the proper use of the product (as described in user manuals), but also to risks that come, for example, with the age or the long-term use of the product. Producers should also

[171] They are developed by the European Standardisation Organisations (CEN, Cenelec, ETSI), recognised by the Regulation on European Standardisation 1025/2012. ANEC, the European association representing consumers in standardisation, is funded by the EU budget and participates as an observer in the Consumer Safety Network.

[172] It is based on preliminary work undertaken with Member States, industry and consumer associations (i.e. involving the Consumer Safety Network) to check the feasibility, the relevance and to reach consensus about the contents of the safety requirements.

[173] This is done in compliance with the Standardisation Regulation 1025/2012.

make sure that any product present on the market can be traced to swiftly enable removal if necessary to avoid putting consumers at risk.

- *Post-market obligations*: Producers and distributors shall cooperate with the competent authorities on actions taken to avoid the risks posed by products which they supply or have supplied. Producers and distributors are also required to immediately notify the respective authorities in EU Member States in case they know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement. Accordingly, producers shall withdraw unsafe products from the market, publish warnings of unsafe products or recall products from consumers on a voluntary basis or at the request of the competent authorities. Distributors are required to act with due care and within the limits of their respective activities, they need to participate in monitoring the safety of products placed on the market.

To complement this and in order to ensure appropriate enforcement of the EU product safety requirements, the Directive also sets out **responsibilities for Member States** to establish systematic approaches to perform effective market surveillance. Member States establish or nominate national authorities competent to monitor the compliance with the product safety requirements and give the necessary powers to these authorities to take appropriate measures under the Directive. National market surveillance authorities have a responsibility to:

- check whether products available on the market are safe;
- ensure product safety legislation and rules are applied by manufacturers and other actors in the supply chain;
- take appropriate action in case a unsafe product is detected on the market.

The Directive sets up the **Rapid Alert System for non-food Consumer Products (**hereinafter **"Safety Gate/RAPEX")**. This system establishes the circulation of information among the Commission and Member States' authorities on measures taken by Member States' authorities and economic operators in relation to products posing a serious risk to the health and safety of consumers. Information on non-serious risks can also be circulated under Safety Gate/RAPEX. The Commission publishes relevant information concerning all notifications on the EU Safety Gate website[174]. Member States are required to follow up the notifications of products posing a serious risk and inform the Commission of any measures adopted. The system has been expanded by Regulation 765/2008[175] to apply also to measures adopted in relation to professional products and to other public interests beyond safety, such as the protection of the environment and security.

[174]https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rape x/index_en.htm

[175] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93

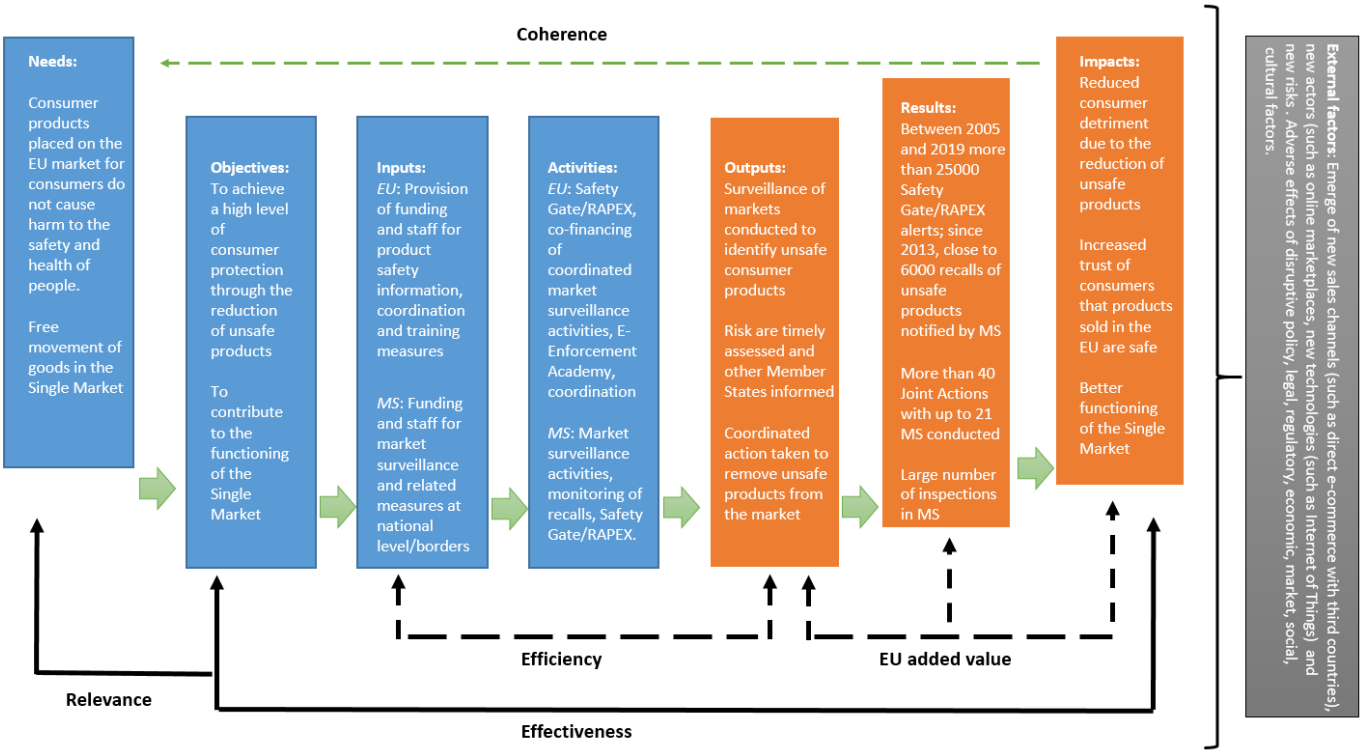
In some exceptional circumstances, **Article 13** of the Directive allows the Commission to adopt temporary measures (valid for 1 year), via a decision, to ensure the safety of certain products. It can be used in situations where at the same time Member States significantly differ on the approach how to deal with the safety risk; where the risk needs to be dealt with a high degree of urgency or where the risk can be eliminated only by adopting appropriate measures at EU level.

This evaluation also covers **Council Directive 87/357/EEC (FIPD)**, that applies to products "which, although not foodstuffs, possess a form, odour, colour, appearance, packaging, volume or size, so that is likely that consumers, especially children, will confuse them with foodstuffs and in consequence place them in their mouths, or suck or ingest them, which might be unsafe and cause, for example, suffocation, poisoning, or the perforation or obstruction of the digestive tract."

2.2 BASELINE AND POINTS OF COMPARISON

An intervention logic was developed for the purposes of this evaluation (see Figure 1). It shows the logical sequence and causal relationships between the Directive's rationale, based on identified needs, its objectives, the activities undertaken, the intended results (outputs), outcomes and impacts. The figure also shows other external factors (beyond the Directive's control) that may influence the impacts and outcomes.

Figure 1: Intervention logic



Source: GPSD Study

This evaluation takes also into account the accompanying Implementation Report 2019 as established in Article 19 of the Directive.

3. IMPLEMENTATION / STATE OF PLAY

The first general product safety directive was adopted in 1992[176]. That directive was amended (resulting in Directive 2001/95/EC on the general safety of products, subject of this evaluation) in order to complete, reinforce or clarify some of its provisions in light of experience as well as relevant developments on consumer product safety, together with the changes made to the Treaty, especially in articles concerning public health and consumer protection, and in the light of the precautionary principle.

All EU Member States notified **transposition measures** of the Directive, and this evaluation showed that there have not been any problems in the transposition of the Directive into national legislation. There are no open infringements regarding the implementation of the Directive.

Member States are responsible for appointing competent authorities responsible for the implementation of the Directive at national level and for ensuring that the Directive is effectively enforced within their territories. In addition, Article 10 of the Directive sets up an informal network of the Member States' authorities aimed at further enhancing administrative cooperation (the "**Consumer Safety Network**"). Given that the Directive forms part of the EEA Agreement, the same rules and mechanisms are also in place in the EFTA countries applying the EEA Agreement, i.e. Norway, Iceland and Liechtenstein.

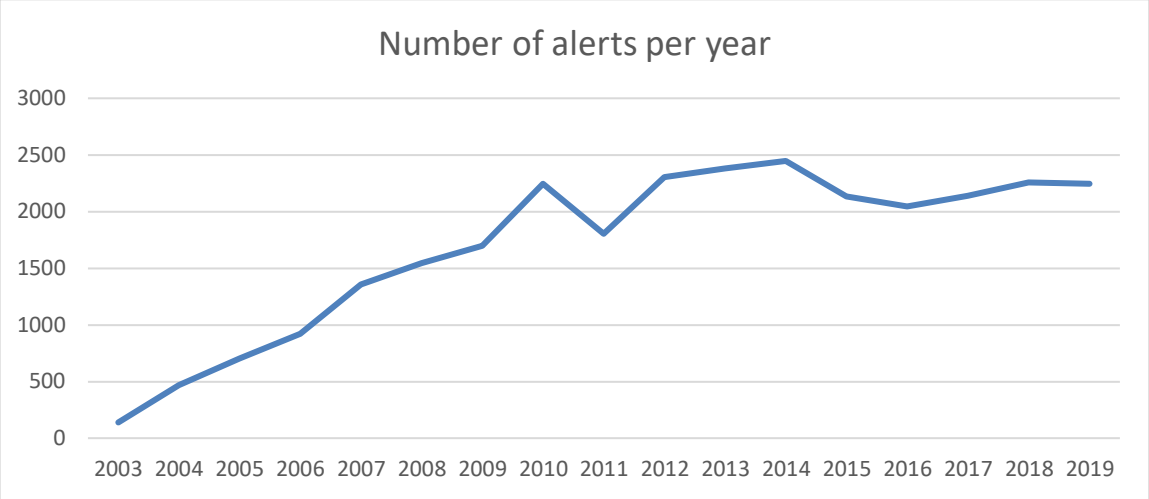
Most market surveillance authorities in the Member States work on the basis of annual inspection programmes which take into account, among others, previous experiences and findings, products that are frequently found unsafe and consumer complaints. If necessary, all Member States carry out controls and tests which are not necessarily foreseen in their programming, for example in emergency situations. To provide assistance to the European network of Member States' product safety authorities, the Commission has co-funded more than 50 **joint actions on market surveillance** among these authorities since 2007.

Regarding the implementation of the **Safety Gate/RAPEX**, the number of measures reported in the system has increased progressively over the years and since 2012 has stayed just above 2,000 alerts a year. In 2019, a total of 2,243 measures were circulated in the system[177].

[176] Council Directive 92/59/EEC of 29 June 1992

[177] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/reports/docs/RAPEX.2019.report.EN.pdf

Figure 2: Number of alerts in Safety Gate/RAPEX for the period 2003-2019



Source: Safety Gate/RAPEX

According to Article 12.4 of the Directive, the **Rapid Alert System remains open to applicant countries, third countries or international organisations**, within the framework of agreements between the EU and those countries or international organisations, according to arrangements defined in these agreements. Based on this article, a specific module of the system has been created to allow for swift flagging of notifications to the Chinese authorities concerning unsafe products from China. The Chinese authorities investigate these cases in order to trace back the manufacturers, exporters and businesses concerned and take measures, which most often consist of making companies aware of product safety rules in Europe. In addition, an exchange of information on unsafe consumer products started with the Canadian authorities in 2019, enabled by the EU-Canada Comprehensive and Economic Trade Agreement (CETA) and an Administrative Arrangement between the European Commission's Directorate-General Justice and Consumers and the Department of Health Canada. The exchanges aim to help EU Member States better target their enforcement efforts and identify emerging product safety risks.

Furthermore, according to Annex II, point 8 of the Directive, the Commission shall regularly update guidelines concerning the joint management of the Rapid Alert System by the Commission and the Member States. A first version of the guidelines was adopted in 2004[178], followed by another version in 2010[179]. The most recent version dates from 2018[180].

[178] Commission Decision 2004/418/EC (OJ L 151, 30.4.2004, p. 84)

[179] Commission Decision 2010/15 (OJ L 22, 26.1.2010, p1-64)

[180] Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system (notified under document C(2018) 7334). OJ L 73, 15.3.2019, p.121–187

When it comes to standardisation work under the General Product Safety Directive, there are currently a total of 67 **standards** that have been referenced under the Directive by the European Commission. In 2019, all referenced standards were included in a new Decision[181], to "create a complete list of references". These standards concern the following product types:

- Furniture
- Gymnastic equipment
- Stationary training equipment
- Child use and care articles
- Bicycles
- Paragliding equipment
- Internal blinds
- Diving accessories
- Lighters
- Roller sports equipment
- Decorative oil lamps
- Children's clothing
- Floating leisure articles
- Cigarettes (ignition propensity)
- Child protective products
- Audio, video and similar (safety requirements)
- Information technology equipment (safety - general requirements)

To date, the Commission applied the procedure provided for in **Article 13** of the Directive on five occasions:

- Firstly, it was used to extend the ban on phthalates in toys[182] during the period up to the adoption of the permanent ban under Directive 2005/84/EC[183]
- The next measure based on this Article was the Decision of 11 May 2006[184] requiring Member States to ensure that cigarette lighters placed on the EU market be child-resistant and to prohibit placing on the market lighters which resemble objects that are particularly attractive to children (so-called "novelty lighters"). In the absence of a suitable revised version of the European standard on child safety requirements for lighters which could be referenced in the Official Journal of the EU as providing a presumption of conformity with the safety requirement of the GPSD, it was necessary to extend the period of validity of this Decision ten times

[181] Commission Implementing Decision (EU) 2019/1698 of 9 October 2019

[182] Commission Decisions 2004/178/EC (OJ L 55, 24.2.2004, p. 66), 2004/624/EC (OJ L 280, 31.8.2004, p. 34) and 2004/781/EC (OJ L 344, 20.11.2004, p. 35)

[183] Directive 2005/84/EC (OJ L 344, 27.12.2005, p. 40)

[184] Commission Decision 2006/502/EC (OJ L 198, 20.7.2006, p. 41)

(extension which was valid until 11 May 2017[185]). A new version of the above-mentioned European standard was referenced in the Official Journal of the EU in 2017.

- Another measure was taken by the Decision of 21 April 2008[186] requiring Member States to ensure that magnetic toys placed or made available on the market display a warning about the health and safety risks they pose. Magnets used in toys have become more powerful, but also detach more easily, thus presenting life-threatening risks if ingested (as they can perforate the stomach or intestines). The Commission adopted this temporary measure which was valid until 21 April 2009, until a relevant safety standard was adopted and referenced by the Commission in the Official Journal of the EU.
- Another measure was adopted on 19 March 2009[187], requiring Member States to ensure that products containing the biocide dimethylfumarate are not placed or made available on the market.
- Finally, on 9 August 2011 a Decision was adopted regarding the compliance of standard EN 16156:2010 and the assessment of the ignition propensity of cigarettes[188].

The enforcement of **the FIPD** has been unequal across the EU as Member States have divergent opinions on its interpretation, in particular its relation with other pieces of sectorial legislation, such as the Toys Safety Directive and the Cosmetic, Detergents and CLP Regulations. The Commission proposed the withdrawal of the FIPD and the inclusion of its provisions within the General Product Safety Regulation in the 2013 Package on Product Safety and Market Surveillance. The Commission has since withdrawn this Package and therefore the FIPD remains in force. More information about the implementation of the FIPD is provided in Appendix 4.

4. METHOD

2.2. Short description of methodology

The evaluation was carried out according to the Commission's evaluation techniques and triangulation methods to ensure robustness of the information obtained. The evaluation received input from consultation activities, official statistics and studies. The evaluation followed several steps to collect both qualitative and quantitative data from the relevant stakeholders and national authorities.

[185] In chronological order: Commission Decision 2007/231/EC (3) until 11 May 2008, Commission Decision 2008/322/EC (4) until 11 May 2009, Commission Decision 2009/298/EC (5) until 11 May 2010, Commission Decision 2010/157/EU (6) until 11 May 2011, Commission Decision 2011/176/EU (7) until 11 May 2012, Commission Implementing Decision 2012/53/EU (8) until 11 May 2013, Commission Implementing Decision 2013/113/EU (1) until 11 May 2014, Commission Implementing Decision 2014/61/EU (2) until 11 May 2015, Commission Implementing Decision (EU) 2015/249 (3) until 11 May 2016 and Commission Implementing Decision (EU) 2016/575 until 11 May 2017

[186] Commission Decision 2008/329/EC (OJ L 114, 26.4.2008, p. 90)

[187] Commission Decision 2009/251/EC (OJ L 74/32)

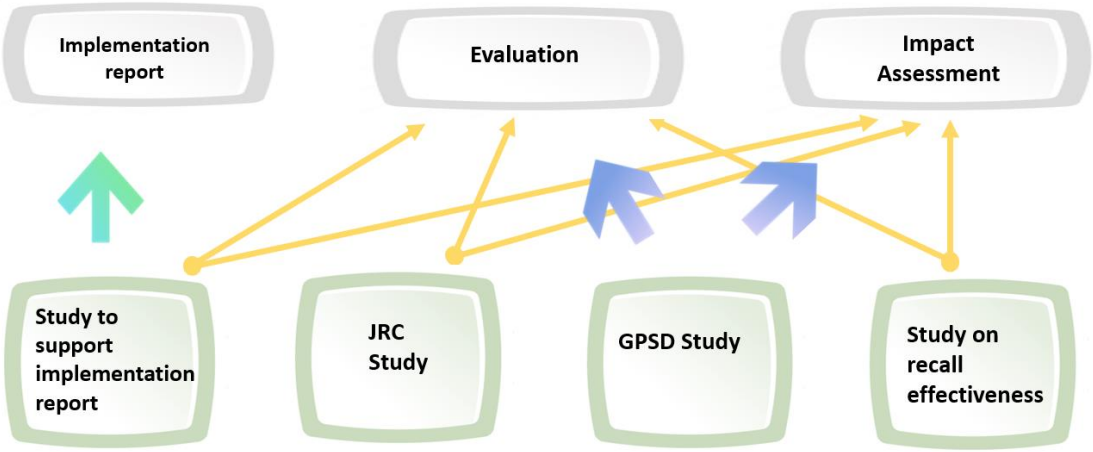
[188] Commission Decision 2011/496/EU (OJ L 205, 10.8.2011, p. 31–32)

2.3. External studies

This Evaluation is based on two main building blocks:

1) An external study on the Directive aimed to assess its functioning and performance and to identify potential shortcomings and whether improvements should be envisaged.
2) Complementary studies and research. This includes the following:
    a. A study on product recall effectiveness
    b. A study to support the preparation of the Implementation report of the Directive, which ran from August 2019 to March 2020.
    c. The European Commission's Joint Research Centre's study on the assessment of the opportunities for increasing the availability of EU data on consumer product- related injuries[189].

Figure 3: External studies supporting the GPSD initiative



2.4. Open public consultation (OPC) and stakeholders' workshops

The **public consultation on the EU's New Consumer Agenda**, that included a specific section on the Directive, ran between 30 June 2020 and 6 October 2020. The consultation was available in 24 official EU-languages and respondents could reply in any of these languages.

The objective of this consultation was to gather the views of the public on the new European consumer policy for the next period, the so-called 'New Consumer Agenda', including a questionnaire on the Directive. These views provided input into the evaluation and impact assessment of the General Product Safety Directive. The questions on the review of the Directive were tailored to two main categories of stakeholders, respectively the general public and stakeholders who are familiar and have certain experience with market surveillance and product safety rules. There were 257 respondents that answered at least one question related to the General Product Safety Directive. The majority of respondents were business associations and EU citizens (each 26%), followed by company/business organisations (15%). Other respondents included

[189] https://injuryprevention.bmj.com/content/early/2020/09/28/injuryprev-2020-043677.full

public authorities (11%), consumer organisations (8%), non-governmental organisations (NGOs) (7%), academic/research institutions (3%), non-EU citizens (1%) and other respondents (3%).

Moreover, the Commission set up a **Sub-group of the Consumer Safety Network on artificial intelligence, connected products and other new challenges on product safety**. The Sub-group's tasks were to assess whether and to what extent existing product safety frameworks are adapted to emerging market realities (connected products, AI, software, etc.) and, in particular, to assist the Commission in developing an EU-wide assessment on the need for the possible adaptations of the General Product Safety Directive in this regard. The Sub-group was established in November 2019.

The Commission also organised a **series of workshops** as part of a broader engagement with stakeholders and evidence-collection strategy, supporting the evaluation of the E-Commerce Directive and the impact assessment for the Digital Services Act as well as the revision of the General Product Safety Directive. The workshops aimed to gather information on the role online marketplaces are playing in the current online supply chain and views on their role for the future. The main findings of the workshops are detailed in Annex 13.

Finally, the Commission also engaged with different stakeholders from around the world in the frame of the **International Product Safety Week** in November 2020, for the discussion of different topics including products recalls and traceability.

2.5. Limitations and robustness of findings

One important limitation of this evaluation is the **difficulty to differentiate data between harmonised and non-harmonised products**. The Directive plays a complementary to the product harmonisation legislation, and consequently it is extremely complicated to isolate the effects and impacts of the Directive. Moreover, although market surveillance rules differ for harmonised and non-harmonised products, in practice Member States organise their investigations and enforcement actions in a comprehensive manner, without distinguishing its legal basis, rendering almost impossible to evaluate both frameworks separately. As a mitigating measure, these aspects were addressed in the consultations activities.

Moreover, it is worthwhile to mention that **data coming from the Safety Gate/RAPEX should be interpreted cautiously**. Measures reported in the system might be affected by multiple factors, in particular inspection priorities of authorities, perceived risks, etc. Besides, notifications only reflect injury events if these are communicated to the market surveillance authorities, which is not systematically the case and not based on the actual frequency of injuries. Notifications also refer to products, but not the exact number of articles or items affected by the measure. This does not in any way limit the value of the system, but shows that **its data cannot be simply used as proxy for product safety trends** or for analysing the preventive potential of enhanced product design or safety features. Consequently, the evaluation has considered data from Safety Gate/RAPEX as one indicator among several, and it is complemented by other datasets and sources.

During the consultations activities, considerable efforts were made to reach out **SMEs**. Otherwise explicitly mentioned, opinions of SMEs do not significantly differ from the opinion of other business stakeholders.

Information related to the product safety aspects of **emerging digital technologies**, i.e. Internet of Things (IoT) and Artificial Intelligence (AI), is scarce and often not sufficiently mature, since some of these technologies are still under evolution. The conclusions of the evaluation in this aspect are based on information collected from stakeholders, studies, media sources and forecasts.

Notwithstanding the specific limitations mentioned above, which could at least partially be compensated by the answers obtained during the consultation activities, the overall **availability and reliability of data and the approach taken is generally considered satisfactory**.

5. ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

5.1 Relevance

5.2.1. General relevance of the Directive

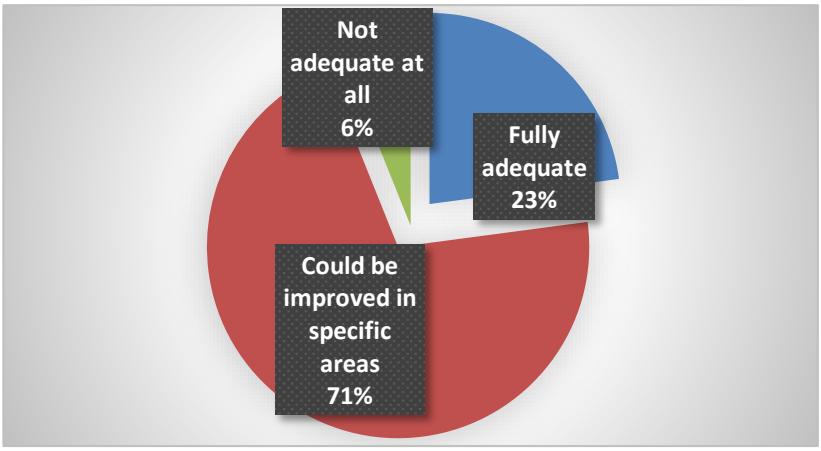
The Directive was adopted in order to respond to the following needs:

- Consumer products placed on the EU market for consumers do not cause harm to the safety and health of people.
- Free movement of goods in the Single Market.

These original needs remain relevant and match the general objectives of the Directive. However, it is important to consider whether the specific tools and provisions provided by the Directive continue to be relevant and future-proof.

A large majority of respondents of the OPC expressed that the current EU safety rules for non-food consumer products covered by the Directive could be improved in specific areas to be more adequate to protect consumers (see figure 4). Nearly one in four respondents held that the current rules were fully adequate, whereas only a small minority considered them not to be adequate at all.

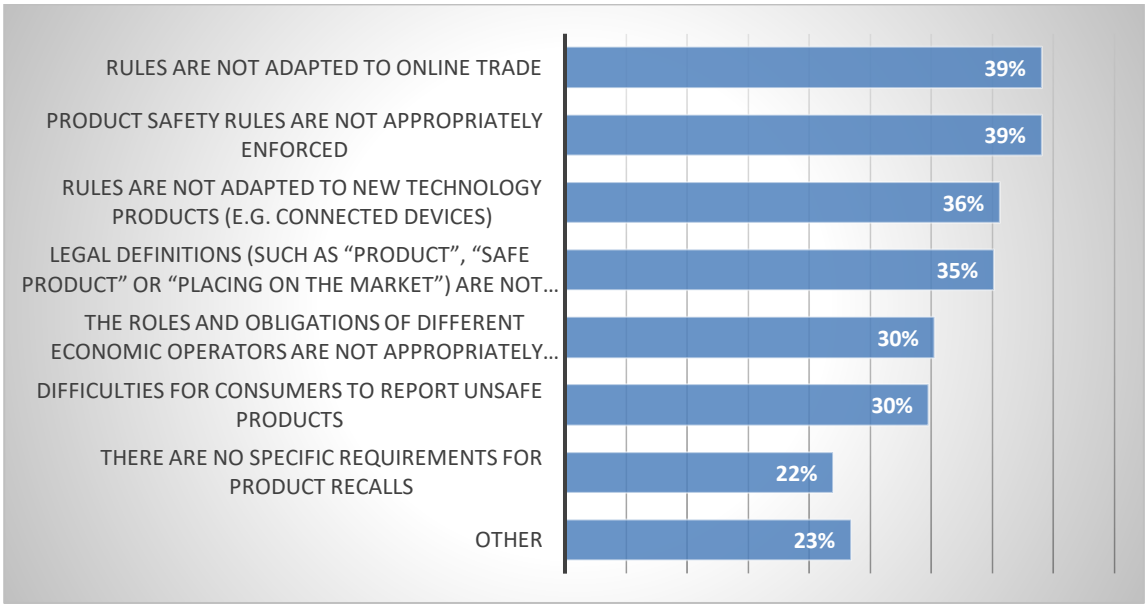
Figure 4: Replies to the OPC question: "In your view, to what extent are current EU safety rules for non-food consumer products covered by the GPSD adequate to protect consumers?"



Source: OPC. Total no. of respondents: 214, Single-choice question

When asked about problems related to the implementation of safety rules for products covered by the Directive, respondents of the OPC (see figure 5) most commonly expressed that rules were not adapted to online trade (39%) and that the rules were not appropriately enforced (39%). More than a third also considered the rules not to be adapted to new technologies (36%) and perceived legal definitions as not sufficiently clear or outdated (35%). Slightly less than a third of respondents (30%) reported that roles and obligations of different economic operators were not appropriately defined and that there were difficulties for consumers to report unsafe products. Lastly, approximately a fifth of respondents regarded as problematic that there were no specific requirements for product recalls (22%) or listed other issues (23%).

Figure 5: Replies to the OPC question: "Are you aware of any problems related to the implementation of EU safety rules for consumer products covered by the GPSD?"



Source: OPC. Total no. of respondents: 205, Multiple-choice question

Moreover, some stakeholders indicated in their comments that the COVID-19 crisis has led to emerging needs in relation to product safety. They expressed that consumer safety was a cardinal value, as the COVID-19 crisis has accelerated existing trends, such as the increased use by consumers of online retail for non-food purchases.

In the sub-sections below the relevance of specific aspects and tools provided by the Directive are analysed.

5.2.2. Relevance of of the Directive vis-à-vis E-commerce and direct imports

While the Directive does not establish specific provisions related to online sales, it clearly applies to all sales channels, offline and online. **Case law**[190] has clarified that EU product legislation also applies to cases where online sellers based outside the EU target consumers in the EU. The assessment to determine if an online offer targets EU consumers must be done on a case-by-case basis. The following aspects could be considered: the international nature of the activity, use of a language and currency (for example the euro) of the Member States, a domain name registered in one of the Member States, geographical areas to which dispatch is possible.

At the same time, **the number of consumers buying products online has drastically increased** since the adoption of the Directive. In 2007, less than half of Internet users bought or ordered goods or services for private use in the previous 12 months; in contrast, in 2019 that figured increase to 71%, with five countries (UK, Denmark, Netherlands, Sweden and Germany) exceeding 80%[191]. Furthermore, the COVID-19 crisis has accelerated this trend: in the EU-27, retail sales via mail order houses or the Internet in April 2020 increased by 30% compared to April 2019, while total retail sales diminished by 17.9% (Figure 6)[192].

[190] Judgment of the Court of Justice of the European Union of 12 July 2011, Case C-324/09, L'Oréal/eBay, paragraph 65 and Judgment of the Court of Justice of the European Union of 7 December 2010 in joined Cases C-585/08 and C-144/09 Peter Pammer v Reederei Karl Schlüter GmbH & Co KG, and Hotel Alpenhof GesmbH v Oliver Heller.

[191] Eurostat

[192] OECD - E-commerce in the time of COVID-19, http://www.oecd.org/coronavirus/policy-responses/e-commerce-in-the-time-of-covid-19-3a2b78e8/#biblio-d1e705

Figure 6 - Retail turnover, year-on-year change, EU-27 (July 2019- July 2020)

Source: OECD, E-commerce in the time of COVID-19

Evidence gathered in the context of the evaluation showed that online sales have led to problems in enforcing the Directive for mainly **two reasons**: difficulties for the **enforcement of the control of products sold online** and **unavailability of responsible economic operators** measures could be effectively addressed to in case products are directly imported from outside the EU.

In the frame of the preparation of the Notice on the market surveillance of products sold online[193], as well as discussions held within the Coordinated Activities on Product Safety 2019[194], the following challenges were identified for market surveillance authorities in relation with the safety of products sold online:

- **Sampling**: there is a lack of clear competences for authorities to engage in mystery shopping at the level of the Directive. There are also legal restrictions for authorities in some Member States that prevent them from hiding their identity when making online inspections, which can make online product safety checks ineffective.
- **Testing**: authorities face challenges in conducting risk assessments or safety tests due to the lack of physical access to products.

[193] C/2017/5200 Commission Notice on the market surveillance of products sold online

[194]CASP 2019 Coordinated Activities on the Safety of Products – Online Market Surveillance – Final report
https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/assets/documents/casp/CASP_HA_online_market_final_report.pdf

- **Resources**: the lack of financial resources, or even the lack of credit cards that authorities can use for online sampling, combined with the lack of competence to ask traders for reimbursement of the product price makes online market surveillance difficult. In contrast, during offline market surveillance activities, authorities can usually seize products free of charge.
- **Identification of economic operators**: authorities face difficulties finding and contacting the trader selling through online marketplaces.
- **Product identification**: there is often lack of sufficient data on products available online (no images of labels, bad quality pictures, and no technical data). The Directive does not establish obligations to economic operators on what specific information needs to be provided in an online offer.
- **Reappearance of unsafe products and repeat infringers**: it often happens that offers containing unsafe products that were already removed are re-uploaded on the same or a different online marketplace.
- **Awareness**: there is lack of awareness among consumers and businesses about buying and selling safe and compliant products online.

In addition, e-commerce allows consumers to purchase directly from operators located outside the EU. This makes it more difficult for authorities to check the safety of products entering the single market. These **direct imports** have increased in the latest years: around 150 million small consignments are imported free of VAT into the EU each year[195] and it has been reported that in 2017 there were 150.000 private consignments coming from China to individual consumers per day[196]. This is a challenge for product safety as, in the case of non-harmonised products[197], there is often no economic operator within the EU available that market surveillance authorities could turn to for enforcement measures in the EU. As noted above, the Directive imposes obligations on the producer as well as on distributors. In practice this means:

- The manufacturer's representative and the importer might be considered as producers according to Article 2(e) of the Directive.
- Where the producer is domiciled in a non-EU/EEA country, it is in most cases outside the reach of the market surveillance authorities of the Member States to impose measures on them. Market surveillance authorities may be able to cooperate with the authorities of the non-EU/EEA country where the producer is

[195] European Commission , Memo 2017 - Modernising VAT for e-commerce https://ec.europa.eu/commission/presscorner/detail/en/MEMO_16_3746

[196] Eurocommerce – Creating a level-playing field for retail in Europe – August 2019

[197] For a certain number of harmonised products, Article 4 Regulation 2019/1020 foresees the figure of the responsible economic operator in the EU.

domiciled (which is the exception[198]), but in principle they cannot take measures themselves.

- Moreover, if the producer sends non-harmonised products directly to the consumer, there is no (other) economic operator with product safety obligations involved in the EU.

The only supply chain actor that is often involved before the consumer gets the product is an online platform. However**,** it seems that **online marketplaces** do not fall under the definition of distributor under the Directive and therefore they are not subject to product safety enforcement measures in a way that is foreseen for producers and distributors. Moreover, even where Member States have taken measures to recall unsafe products, evidence from different investigations carried out by stakeholders show that recalled products often continue to be sold or to reappear on the market in online sales channels.

The European Commission already identified these challenges and took some non-legislative measures to try to tackle the issue. First, it adopted a **Notice on the market surveillance of products sold online**[199] to assist Member State authorities in the enforcement of EU legislation on the safety and compliance of non-food products and to contribute to a more uniform and coherent application of that legislation in the online environment. In addition, the European Commission facilitated the signature by nine online marketplaces of the **Product Safety Pledge**[200]. This initiative, originally signed in 2018 and the first of its kind in the product safety area, sets out specific voluntary actions in 12 different areas by online marketplaces to improve product safety going beyond what is already established in EU legislation. As part of the Pledge, signatory online marketplaces have committed to report to the European Commission every six months on the actions taken to implement the Product Safety Pledge, with the inclusion of key performance indicators.

However, stakeholders have pointed out that these measures, although positive, do not resolve the underlying problems related to online sales. The Notice on the market surveillance of products sold online has proven to be a useful guidance for authorities, but does not solve the issue that in many countries they have legal and practical barriers to carry out online investigations and take appropriate measures. The Product Safety Pledge has set the grounds for an increased cooperation framework between online marketplaces and market surveillance authorities. However, as pointed by authorities and stakeholders, it remains voluntary, so it cannot be enforced in case of infringements, and there are still many actors on the market that have not adhered to the initiative.

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198 Direct cooperation of market surveillance authorities with other relevant authorities in non-EU/EEA countries is only carried out in a minority of countries. Authorities from only five countries (Germany, France, Ireland, Lithuania, United Kingdom) reported cooperating once every three months or more often with non-EU/EEA country authorities, see GPSD implementation study, p 105.

199 C/2017/5200 Commission Notice on the market surveillance of products sold online

200 Product Safety Pledge, available at: https://ec.europa.eu/info/sites/info/files/voluntary_commitment_document_4signatures3-web.pdf

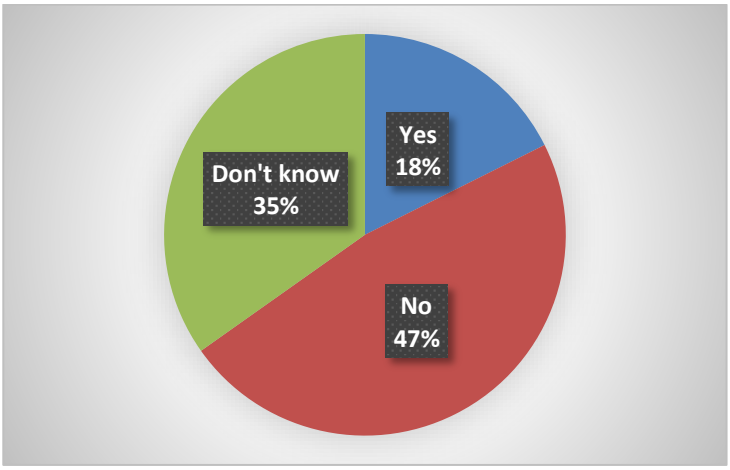
In conclusion, it can be noted **that the Directive is not adapted to the specific challenges posed by online sales**, including the increased level of direct B2C imports towards the EU, facilitated by online marketplaces and fulfilment service providers[201]. Many stakeholders have noted that it would be beneficial to adjust the Directive in relation to these additional economic operators, to address the newly emerged needs related to the online environment and to increase the safety of products sold online to EU consumers.

5.2.3. Relevance of the Directive vis-à-vis new technologies

At the time of the adoption of the Directive the number of consumer products incorporating **new technologies** was scarce. This is not the case anymore. There were 14.2 billion connected devices in 2019 worldwide, a figure that is estimated to go up to 25 billion by 2025, of which 4.9 billion will be in Europe[202].

Almost half the respondents of the OPC considered the safety of products involving new technologies to be not adequately regulated (47%), with only 18 % stating the opposite. The other 35% did not know (see figure 7).

Figure 7: Replies to the OPC question: "Do you think that the safety of products involving new technologies is adequately regulated?"



Source: OPC. Total no. of respondents: 227, Single-choice question

[201] Fulfilment service providers are defined in Regulation 2019/1020 as follows: 'fulfilment service provider' means any natural or legal person offering, in the course of commercial activity, at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services as defined in point 1 of Article 2 of Directive 97/67/EC of the European Parliament and of the Council (31), parcel delivery services as defined in point 2 of Article 2 of Regulation (EU) 2018/644 of the European Parliament and of the Council (32), and any other postal services or freight transport services

[202] Netherlands Entreprise Agency - https://www.cbi.eu/market-information/outsourcing-itobpo/intergrated-internet-things/market-potential

The European Commission published in February 2020 a **report on the safety and liability of new technologies**[203]. The report identified uncertainties linked to the application of the product safety framework with respect to the specific risks posed by AI systems and other digital technologies. It concluded that the current product safety legislation, including the General Product Safety Directive and harmonised product legislation that follows the horizontal rules of the "New Legislative Framework"[204], already supports an extended concept of safety protecting against all kind of risks arising from new technology products. However, there were a number of unclear areas according to the report:

- EU legislation does not comprehensively include explicit provisions regarding some **categories or risks posed by new technologies**, such as cybersecurity risks that affect safety. Such provisions would provide a better protection of users and more legal certainty for businesses.
- While the Union product safety legislation takes into account the safety risks stemming from **software** integrated in a product at the time of its placing on the market and, potentially, subsequent updates foreseen by the manufacturer, there is a lack of specific and/or explicit requirements on standalone software (e.g. an 'app' that would be downloaded). The product safety framework does not provide for additional obligations for manufacturers to ensure that they provide features to prevent the upload of software having an impact on safety during the lifetime of AI products[205].
- Regarding the **concept of "placing on the market"**, as far as the future "behaviour" of AI products can be determined in advance by the risk assessment carried out by the manufacturer before the products are placed on the market, the Union product safety framework already sets out obligations for producers to take into account in the risk assessment the "use" of the products throughout their lifetime. However, there may be also situations in the future where the outcomes of the AI systems cannot be fully determined in advance. In such a situation, the risk assessment performed before placing the product on the market may no longer reflect the use, functioning or behaviour of the product.

Moreover, the **Subgroup on AI, connected devices and other new challenges in product safety to the Consumer Safety Network** reached the following conclusions regarding the relevance of the Directive vis-à-vis new technologies:

- The **legal definition of safe product** of the Directive can be understood as addressing many types of risks by which a product can, directly or indirectly, cause harm to consumers. However, it does not explicitly refer to some risks

[203] Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics COM/2020/64 final

[204] Regulation (EC) No. 765/2008 and Decision (EC) No. 768/2008

[205] The Radio Equipment Directive envisages the possibility to adopt delegated acts under its Article 3(3)(i) that would partially address this issue.

posed to new technologies, such as cybersecurity risks that affect safety ("cyber-safety").

- New technologies can also pose risks not only because they can have a direct impact on the health and safety of the consumers, but also because through connectivity, they can be indirectly used as a tool to put at risk their **personal security**. Having said that, it is unclear under which legal or policy instrument such personal security risks should be tackled so that consumers are effectively protected against such threats.
- Regarding **mental health**, while they are not a new phemonenon, there is evidence that new technologies can have a psychological impact on users[206]. However, the Sub-group agreed that risks to mental health that are not intrinsic to the product, but come from the use of a product in particular ways, should not be considered part of the concept of "safety" in the Directive.
- Despite that the current version of the Directive is in theory broad enough to cover safety risks resulting from **software interacting with the product**, it does not explicitly mention it, creating legal uncertainty in this regard.
- One of the common characteristics of AI and IoT products is the presence of **software that can change/evolve over time**. This challenges the traditional meaning of the concept of placing on the market of the Directive.

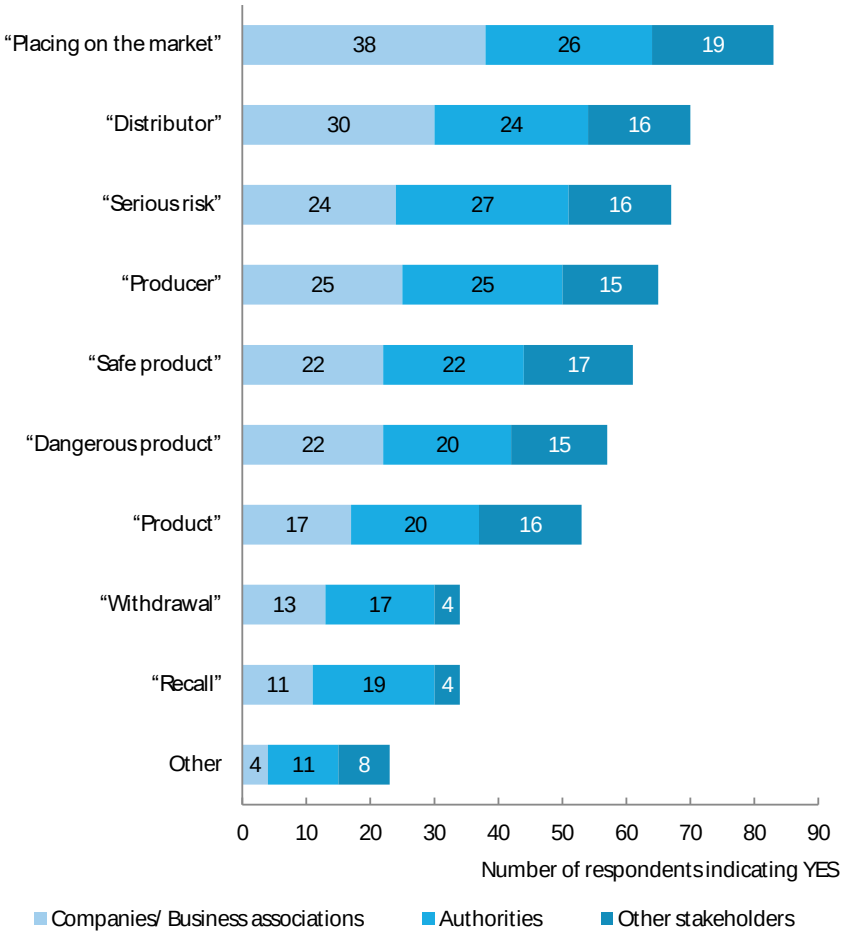
Finally, it was mentioned by one stakeholder of the OPC that **3D printing** could also affect product safety. However, it appears that this technology does not seem to present new safety challenges. 3D printers are already covered by sectorial legislation (Machinery Directive). For the products created by the 3D printer, if they are placed on the market, they need to comply with product safety legislation, as 3D printing is just a new manufacturing technique. Furthermore, there is a similarity between products "printed" by consumers for their own use and traditional DIY products created by consumers.

5.2.4. Relevance of definitions of the Directive

In the context of the GPSD Study, stakeholders were asked whether or not they considered the **key concepts of the Directive** to be still relevant or whether they saw a need for it to be adapted to changed circumstances. Often, comparable numbers of stakeholders even of the same group – companies/business associations, authorities and other stakeholders – suggested that a concept should be changed or kept as it is. Figure 8 provides an overview of results, and indicates the number of respondents that considered that a specific concept needed to be clarified and updated:

[206] Dresp-Langley B. Children's Health in the Digital Age. Int J Environ Res Public Health. 2020 May 6;17(9):3240. doi: 10.3390/ijerph17093240. PMID: 32384728; PMCID: PMC7246471.

Figure 8: Replies to the question of the GPSD Study "Considering the emergence of new technologies and new business models/actors: Is there a need to clarify and update [the following] terms and concepts as currently used in the GPSD? – Number of respondents indicating Yes"



Source: GPSD Study

It appears that most of stakeholders detected that the current definitions for some concepts do not appropriately reflect the needs of the Directive. The reasons highlighted related to divergences with other pieces of EU legislation (see coherence section), but also to the fact that some of the definitions are now outdated due to the development of new technologies and online sales.

5.2.5. Relevance of environmental issues, including chemical risks

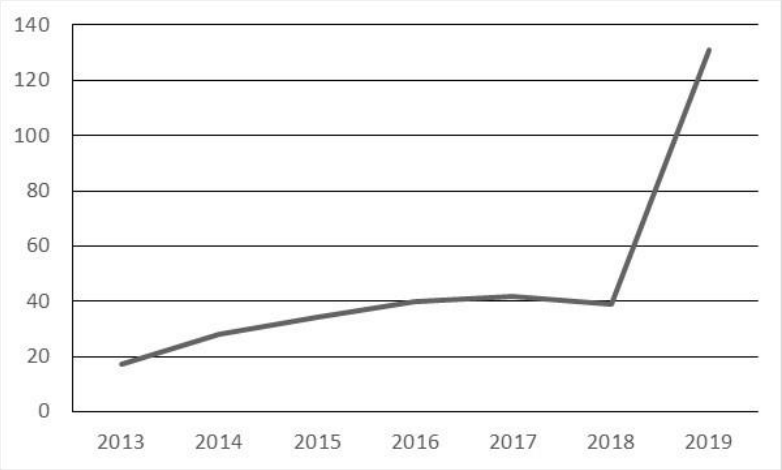
The definition of safety in Art. 2(b) of the Directive covers all product-related risks that can affect the safety and health of persons. This definition therefore also includes risks related to environmental pollutants in products that can affect human health (e.g. heavy metals such as lead and cadmium, phthalates, etc.). A broader scope of risks to be considered in addition to those related to the health and safety of consumers, such as security and **environmental risks**, was only introduced with Regulation (EC) 765/2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products. Since then, the Safety Gate/RAPEX applies to measures which prevent, restrict or impose specific conditions on the marketing and use of products

posing a serious risk to the health and safety of consumers or to measures which prevent, restrict or impose specific conditions on the marketing and use of products posing a serious risk to the health, safety or, for harmonised products, other relevant public interests, including environmental risks.

Data from the Safety Gate/RAPEX shows how the number of notifications indicating "Environmental" as the type risk was slowly increasing, and in 2019 the number of notifications suddenly more than tripled. This rapid rise can be explained by the revision of the guidelines of the Rapid Alert System adopted in 2018 that clarified the cases where risk assessments related to **chemical risks** do not need to be performed in order to consider a product as unsafe. The revised guidelines have indeed set out that if a chemical substance in a product is already banned or restricted by Union legislation, the product can be considered to pose a serious risk, without the need to perform a specific risk assessment. This has simplified the risk assessment process for chemicals, including environmental pollutants with health impact.

Another factor to take into consideration in the surge of notifications on environmental risks concerns the increased focus on motor vehicles' emissions in the aftermath of the "Dieselgate", and the subsequent number of alerts regarding vehicles not satisfying emission standards.

Figure 9: Number of notifications to Safety Gate/RAPEX mentioning "Environment" among the risk types



Source: Safety Gate/RAPEX.

A further analysis of the recent dataset of the system shows that there seems to be a general tendency to identify the risk as "chemical" if the substance in the product poses a direct health risk to the consumer, e.g. acute poisoning. For the years 2013 to 2019, the dataset contains 3 606 notifications (approximately 25% of all notifications in the period) of products presenting a "Chemical" risk, more than ten times the number of notifications that indicate "Environment" as risk type. However, substances presenting a chemical risk will often also have an adverse effect on the environment. In some cases, the products notified in the rapid alert system contain substances that can be dangerous for human health (e.g. cadmium, lead) but that are contained in parts of the product that the consumer will not be in direct contact with (e.g. solders). The risk will thus materialise

during the “end of life” phase of the product, with a possible accumulation of these dangerous substances in the environment. While the definition of safety in the Directive is considered to cover risks related to environmental pollutants in products that can affect human health, this coverage is not explicitly stated. This leaves room for interpretation regarding products posing long-term risks stemming from the toxicity of environmental pollutants. The extent to which the Directive is well adapted to environmental issues with health impact therefore depends on the interpretation of the definition of safety in the Directive and could be clarified.

As regards emerging chemical hazards, the Directive has showed in a number of occasions its particular relevance in being a safety net and the role of the rapid alert system as a ”watchdog” for new chemical hazards. Examples are Dimethilfumarate and Bisphenol A, for which restrictions were triggered after measures against products containing these chemicals were reported in Safety Gate/RAPEX (see above section 3).

It can therefore be concluded that the Directive remains relevant in relation with environmental and chemical risks. However, legal changes might be needed to clarify that risks related to the indirect and long-term health effects of environmental pollution under the scope of the Directive.

5.2.6. Conclusion on relevance

Overall, **the Directive**, its objectives and the product safety framework that it establishes **remain relevant** for the needs of avoiding harm to consumers and building trust on consumer products as a prerequisite for the free movement of goods. However, the growth of **online sales** and the **development of new technologies** show that some of the provisions of the Directive are **not well adapted** to respond to its objectives. In addition, some of the definitions and provisions are now outdated and could be subject to fine-tuning.

5.2 Effectiveness

5.2.1. Extent to which the Directive has been effective in contributing to consumer safety

Several indicators and data sources can be used to assess the extent to which the GPSD and related market surveillance and notification procedures have been effective in achieving a high level of consumer protection through the reduction of unsafe products on the EU market. These include the following indicators/sources:

- Trends in the number of Safety Gate/RAPEX notifications;
- Share of unsafe products found during market surveillance inspections;
- Data on product-related injuries;
- Assessment of consumers and stakeholders concerning the level of product safety achieved.

None of these indicators is without limitations, and to obtain an overall picture they have to be considered together.

First, the number of alerts to **Safety Gate/RAPEX** show a progressive increase over the years; since 2012 the total number of notifications was just above 2,000 alerts a year. In 2019, a total of 2,243 alerts were circulated in the system. The three product categories with the largest number of notifications (toys, clothing and motor vehicles) account for between 1 050 and 1 350 annual notifications with an average of 1 230 notifications per year.

Notifications in the Safety Gate/RAPEX may include information concerning the number of items that are being affected by the measures taken, e.g. the number of items that were rejected at the EU border, or the number of items that were recalled from the market. This information is part of the notification that is only accessible for market surveillance authorities. Table 1 shows an extract of this data, covering a twelve month period from May 2019 to April 2020, and including information for a total of 536 notifications in which more than 1 000 items were affected.

Table 1: Number of notifications and number of items affected by measures taken per product category (May 2019 to April 2020)

Product category	Number of notifica-tions	Number of items affected, with data referring to ...				Total
		National circulation	EU/EEA circulation	Worldwide circulation	Unknown circulation	
Motor vehicles	272	27 240	1 049 811	9 424 961	17 462 909	27 964 921
Construction products	1				4 500 000	4 500 000
Protective equipment	11	4 800	4 290 000		16 545	4 311 345
Electrical appliances and equipment	30	638 177	63 278	1 146 608	210 719	2 058 782
Toys	126[a)]	183 800	539 534		483 901	1 207 235
Other	7		10 700		528 594	539 294
Cosmetics	12		56 560		208 063	264 623
Lighting equipment	11		12 969		231 657	244 626
Lighting chains	**17**	**105 520**			**51 600**	**157 120**
Childcare articles and children's equipment	**9**		**8 111**		**131 817**	**139 928**
Chemical products	4[b)]	2 160			75 073	77 233
Kitchen/cooking accessories	3	5 952			57 249	63 201
Hobby/sports equipment	**6**		**13 197**		**45 734**	**58 931**
Jewellery	**5**	**1 200**			**51 394**	**52 594**
Clothing, textiles and fashion items	**7**	**5 031**	**22 073**		**24 985**	**52 089**
Machinery	3				28 556	28 556
Decorative articles	**4**	**11 000**			**5 052**	**16 052**
Pyrotechnic articles	1		14 400			14 400
Measuring instruments	2	3 648	3 000			6 648
Gas appliances	3				6 140	6 140
Recreational crafts	1				2 953	2 953
Gadgets	1		1 008			1 008
Total	536	988 528	6 084 641	10 571 569	24 122 941	41 767 679

Source: Safety Gate/RAPEX. **Bold** = Non-harmonised product category.

As the table shows, the listed notifications in this twelve-month period affected some 41.8 million items in total or 79 900 items per notification on average. The largest category is "Motor vehicles" with the highest number of notifications (272) and the highest number of items affected (approximately 28 million items). Notifications that concern clearly non-harmonised product categories (marked in bold) account for a total of 169 548 items in this five-month period.

Regarding evidence from **market surveillance activities** of Member States authorities, table 2 presents data on the total number of consumer products inspected by market surveillance authorities in the EU/EEA member countries, as well as the total number of unsafe consumer products found[207]. The share of unsafe products found by market surveillance authorities in their inspections is frequently between 2% and 16% of total consumer products inspected (interquartile range), with the median value being 4%[208]. In some countries this share is much higher: from five countries it was reported that the share of unsafe products of total consumer products inspected is close to 20% or higher. However, the GPSD Study notes that the data has been reported from various sources according to different criteria, so that these figures have to be interpreted with care. As market surveillance authorities often sample according to risk-based criteria (i.e. focusing on risky products, conducting visual inspections to choose for testing products that can potentially be unsafe), this figure is not representative of the incidence of unsafe consumer products on the market[209].

Table 2: Share of inspected consumer products and share of unsafe products found (last available year, mostly 2018 or 2019)

Country	Total number of consumer products inspected	Total number of unsafe consumer products found	Share of unsafe products found (of total products inspected)
Austria	:	:	:
Belgium[a)]	710	283	40%
Bulgaria[p)]	4 624	120	3%
Croatia[q)]	4 475	47	1%
Cyprus[b)]	7 105	301	4%
Czech Republic[c)]	17 088	156	1%
Denmark[d)]	2 500	520	21%
Estonia[e)]	8 317	46	1%
Finland[r)]	85	31	36%

[207] The table includes combined figures for harmonised and non-harmonised products, as separate statistics are rarely available.

[208] The interquartile range is the data between the 25th and 75th percentile of a data series. The median is the middle value, or 50th percentile. In other words, the interquartile range comprises the quartiles below and above the median.

[209] This risk-based approach also affects the type and number of Safety Gate/RAPEX notifications, which may be influenced by changing priorities concerning which risks are considered by authorities when conducting inspections.

France[s)]	3 980	760	19%
Germany[f)]	27 541	12 715	46%
Greece[g)]	850	100	12%
Hungary	:	:	:
Ireland[t)]	492	:	:
Italy	:	:	:
Latvia[h)]	1 144	64	6%
Lithuania[i)]	2 000	59	3%
Luxembourg[j)]	867	15	2%
Malta[k)]	1 313	22	2%
Netherlands	6 500	n.a.	n.a.
Poland[l)]	8 671	440	5%
Portugal[u)]	:	:	:
Romania[m)]	15 245	41	0.3%
Slovenia[n)]	605	9	1%
Slovakia	:	:	:
Spain	:	:	:
Sweden	:	:	:
UK	:	:	:

Source: GPSD Study, from data provided by market surveillance authorities

Furthermore, according to the analysis presented in Annex 4, it is estimated that **consumer detriment** linked to injuries and premature deaths from unsafe products is EUR 76.6 billion per year. This is the sum of detriment caused by non-fatal product-related injuries, and the cost of premature death due to fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) occurring outside of work-related locations[210]. The analysis based on previous research and interviews with product safety experts concluded that 15% is a reasonable and cautious estimate for the proportion of the total detriment that was caused by consumer products, or could have been prevented through better design, instruction or a safety device. On this basis, the preventable detriment suffered by EU consumers and society due to product-related accidents **can be estimated at EUR 11.5 billion per year**.

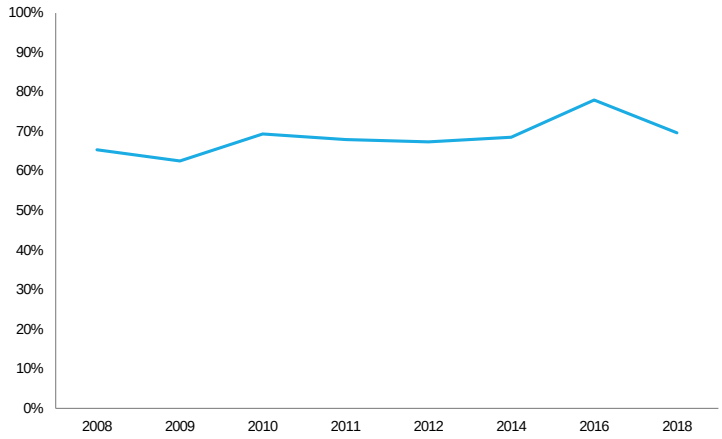
In addition to this injury related detriment, the GPSD Study estimates that the consumers also suffer financial costs of a **total value of EUR 19.3 billion for 2019 arising from the fact they have purchased unsafe products** that they would not have purchased if they knew these products were unsafe[211].

[210] These estimates are based on the best possible approximation of product-related injuries and fatalities. The detriment cannot be estimated separately by categories of products and therefore include all consumer products, harmonised and non-harmonised products.

[211] This relates to non-harmonised consumer products covered by the GPSD. This is based on the assumption that willingness to pay (WTP) for a product depends on the utility of the product for the purchaser. WTP is equal or higher as the price for which a product is purchased by a consumer, as otherwise the transaction would not take place. It is very likely that WTP would be close to zero for an unsafe product (nobody wants to buy e.g., a dangerous childcare product) – so the loss in consumer welfare

Consumer survey data can also provide supporting evidence regarding product safety, at least to the extent that consumers perceive product safety to be an issue relevant to them, based on their own experiences, the experiences of friends and media reports. EU data exists concerning the consumer perception of the level of product safety in the EU. The data derives from the Commission's regular surveys on consumer attitudes toward cross-border trade and consumer protection since 2008 (the last relevant survey was conducted in 2018).

Figure 10: Percentage of consumers who agree that essentially all non-food products are safe or that a small number of non-food products are unsafe (EU average), 2008-2018



Source: Compilation of the GPSD Study based on data from the Commission's 2016 and 2018 survey of consumers' attitudes toward cross-border trade and consumer protection

Figure 10 indicates that **consumer trust in product safety** in the EU has shown a slight increase over time, with the proportion of consumers agreeing that essentially all non-food products in their country are safe (or that only a small number are unsafe) increasing from 65% in 2008 to 78% in 2016, before decreasing again to 70%; a possible explanation provided by stakeholders for this late drop is the increase of unsafe products found online. The largest increase (9 percentage points) occurred between the 2014 and 2016 surveys, before returning in 2018 to slightly above the 2014 level.

During the GPSD study, stakeholders were consulted on their views about to what extent the Directive has been effective in reaching its objective of protecting consumers from unsafe products. Their overall opinion was positive, while SME provided a slightly more negative opinion in this regard than other businesses.

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is at least the price to which the product was purchased. This calculation assumes that the consumers do not get reimbursed for the unsafe product.

The available data also confirms that large numbers of unsafe products that could affect the safety of EU consumers are rejected at the borders, withdrawn from the market or recalled. This implies that a reduction of unsafe products on the market is achieved in practice, in line with the objective of the Directive.

However, there is still a significant number of unsafe products in the EU market, which hint to the fact that the deterrent effect of the Directive might not be effective enough. A plausible explanation for this, suggested by several stakeholders, might be that the maximum amounts of sanctions and penalties for product safety infringements, that are not harmonised across Member States, remain significantly low. Sometimes companies organise product recalls and other measures in jurisdictions first where the level of penalties is higher than in some EU Member States. This damages the effectiveness of the Directive and the EU product safety framework as a whole.

5.2.2. Extent to which the Directive has been effective in contributing to the functioning of the Single Market

According to its recital (2), the Directive pursues the aim of improving the functioning of the internal market. As recital (3) confirms, it has introduced a common legislative framework in order to avoid disparities between Member States that could have emerged in the absence of Union law.

The Directive plays an essential role in the functioning of the Single Market, in line with the legal basis of the legislation, so that producers ensure safety and market surveillance authorities can take actions against products, risks and aspects not covered by sectorial legislation. There is no indication that Member States have tried to stop the income of products for from other EU Countries for which no harmonisation legislation exists and to which the Directive therefore applies fully (non-harmonised products) for other reasons than their insufficient level of safety.

However, stakeholders emphasise that market surveillance authorities of different **Member States may come to different conclusions in relation to the risks posed and safety of a particular product**, and that this in some cases affect their operations and increases administrative burdens, thus having a negative impact on the functioning of the Single Market and the level-playing field for economic operators. Disputes between Member States on risk assessments are discussed within the Safety Gate/RAPEX network. Over recent years, the number of such disputes to better align the risk assessments by different Member States' authorities has been relatively stable, as indicated in table 3. The number of notifications that were subject to disputes has been on average less than 30 per year[212].

[212] The number of actual disputes was slightly higher, as in some cases more than one Member State provided a different risk assessment in a follow-up notification (or "reaction" as it was named previously) compared to the risk assessment by the Member State that submitted the original notification.

Table 3: Number of disputes on risk assessments that needed to be discussed within the RAPEX network

Year	Number of notifications that were subject to disputes	Number of follow up disputes
2013	19	21
2014	39	41
2015	33	39
2016	19	24
2017	24	28
2018	26	27
2019	30	30
Total	***190***	***210***

Source: Safety Gate/RAPEX.

In this regard, it is important to note that over the years, the European Commission has issued a number of guidance documents that support the uniform application of the Directive in the Member States, including the Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' according to Article 12 of Directive 2001/95/EC on general product safety. Moreover, there is evidence that the training programmes that the European Commission organised for the national market surveillance authorities and the EU financing of coordinated market surveillance activities of EU Member States have contributed to a more uniform application of the Directive in the Member States.

Nevertheless, the **lack of a mechanism at EU level to solve divergent positions of Member States** regarding the risk assessment of a specific product remains a challenge for the effectiveness of Directive.

During the GPSD stakeholders were consulted on their views about to what extent the Directive has been effective in reaching its objective of contributing to the functioning of the Single Market. Their overall opinion was positive, while SME provided a slightly more negative opinion in this regard than other businesses.

As conclusion, on a general level the Directive has been effective in contributing to the free movement of goods within the Single Market. The lack of a mechanism to arbitrate disputes on risk assessment contributes negatively to the effectiveness of the Directive.

5.2.3 Effectiveness of the system of market surveillance under the Directive

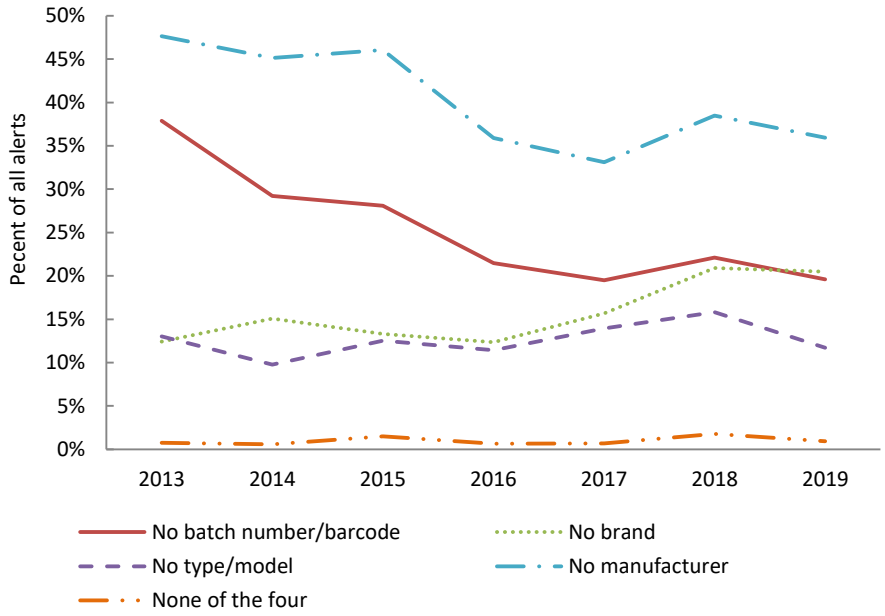
The Directive establishes the obligation for Member States to carry out market surveillance activities to enforce is provisions. This evaluation detected three key factors that have negatively influenced the effectiveness of the market surveillance provisions: traceability of unsafe products as a precondition for market surveillance; the lack of resources of authorities; and the coexistence of two different market surveillance systems for harmonised and non-harmonised products. The latter point is developed in the Coherence section; the other two here below.

The extent to which actions by market surveillance authorities against unsafe products are effective depends on how easily, quickly and precisely products can be identified and traced back to specific producers, importers, distributors, sellers and consumers. An adequate system of **product traceability** allows market surveillance authorities to determine if an unsafe product is on their market, to trace the economic operators who made the product available, and to enforce the appropriate corrective actions. From the perspective of the economic operator, traceability is fundamental for effectively and efficiently managing product risks; increased traceability enables more targeted and less costly corrective actions, e.g. by limiting the size of withdrawals or recalls. Finally, traceability is also important for consumers because if an unsafe product is already purchased, clear product identification is necessary for consumers to respond to a recall.

It appears that at present, the Directive's provisions on traceability are not sufficiently explicit to guarantee that complete information on supply chains and distribution of the product is gathered. The Directive does not contain detailed traceability requirements. Article 5(1) contains a general obligation for producers to provide the necessary information for tracing a product, without asking for specific or minimum identification information. According to article 5(1), this information may for example include "an indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs, except where not to give such indication is justified". Apart from producers, distributors are also required to keep and provide documentation necessary for tracing the origin of the products (article 5(2)). Furthermore, the emergence of online sales poses additional challenges to trace an unsafe product back to where and by whom it was produced and sold from.

The extent to which these requirements based on the Directive achieve adequate product traceability can be demonstrated through the data available in the Safety Gate/RAPEX. From 2013 to 2019 a significant share of the alerts that were submitted for unsafe consumer products involved products with unknown product information items. In 2019 for instance, 36% of alerts for unsafe products did not include information about the manufacturer; 20% concerned products of unknown brand or batch number/barcode; and a share of 12% regarded products with no type or model information. Figure 11 based on alerts registered in the EU Safety Gate shows that only an improvement over time on the availability of information on the manufacturer and batch number/barcode of the product (i.e. a decrease of the number of alerts that did not provide such information). There is no clear trend of improvement over time for the rest of the traceability information.

Figure 11: Share of Safety Gate/RAPEX alerts with unknown product information items (2013-2019)



Source: GPSD Study, from Safety Gate/RAPEX data

The same data also reveal that missing product information is more typical for specific types of products such as laser pointers, lighters, jewellery, decorative articles, etc. What these products have in common is that they all fall within the scope of Directive and are not subject to sector-specific harmonisation rules. It follows that product categories under the Directive are more likely to lack relevant information items that are essential to trace them.

Secondly, the market surveillance system under the Directive (consisting of market surveillance activities by authorities in the Member States, information exchange through Safety Gate/RAPEX and coordination and support measures) appears to be operating under considerable **resource constraints**. In a 2018 evaluation of the product safety-related actions funded under the EU Consumer Programmes[213], authorities indicated limited staff/financial resources for market surveillance and enforcement most frequently as a factor influencing negatively the level of their achievement. A previous study concluded that the total budget available to authorities in 18 EU Member States for which data was available declined annually between 2010 and 2013 in nominal terms, and the total staff resources available to authorities (in full time equivalent units) also showed a negative trend[214]. In a recent survey, both authorities and other stakeholders

[213] See Civic Consulting (2018), Ex-post evaluation of the Consumer Programme 2007-2013 and mid-term evaluation of the Consumer Programme 2014-2020, Part 1 – Mid-term evaluation of the Consumer Programme 2014-2020 and European Commission,

[214] European Commission, Ex-post evaluation of the application of the market surveillance provisions of Regulation (EC) No 765/2008, Final Report, May 2017, p 35-39.

agreed that two of the three top problems affecting the functioning of market surveillance relate to a lack of resources: limited staff resources of market surveillance authorities in general, and in addition, a specific lack of financial resources for product testing[215]. It is widely acknowledged by authorities and other stakeholders that the staff and financial resources of market surveillance authorities are often insufficient, with the fragmentation of responsibilities at national level leading to inefficiencies due to a lack of economies of scale in some cases, and contradictory measures and approaches for risk assessment between authorities in others. Also, the number of inspections can be considered as generally low, with a median of roughly 400 inspections of consumer products per year and million population, based on data from those Member States that provided such information.

Over the last 15 years, the European Commission has co-financed more than 50 coordinated market surveillance activities (the so-called Joint Actions or, since 2018, Coordinated Activities on the Safety of Products or CASP) carried out by Member State authorities, with a total budget around 27 million EUR since the start of the activities. These coordinated activities aim at promoting and coordinating administrative cooperation for the application of Directive and ultimately at ensuring a consistent approach towards the effective enforcement of product safety legislation across the internal market. Most coordinated actions have resulted in the identification of a significant number of unsafe products, with non-compliance rates around 20%[216], leading to consequent notifications in the Safety Gate/RAPEX for 14 categories of products. The implementation of these actions have been considered by authorities extremely useful, as economies of scale allow and the funding provided by the Commission have helped them to carry out inspections for some categories of products that would have been less controlled otherwise.

Finally, it was mentioned by several authorities that some Member States complement product-based market surveillance with a market surveillance of internal processes set up by economic operators to ensure product safety. In those cases, authorities reported an increase of the effectiveness of product safety enforcement.

In conclusion, while the Directive sets an efficient system to ensure the safety of consumer products and contribute to better and more coordinated market surveillance, challenges related to traceability, institutional fragmentation (including regarding market surveillance of harmonised and non-harmonised consumer products) as well as resource constraints limit the effectiveness of the overall system. At the same time, coordinated surveillance activities have proven to be very efficient, contributing to a consistent enforcement of product safety legislation across the internal market.

[215] GPSD implementation study, p.90.

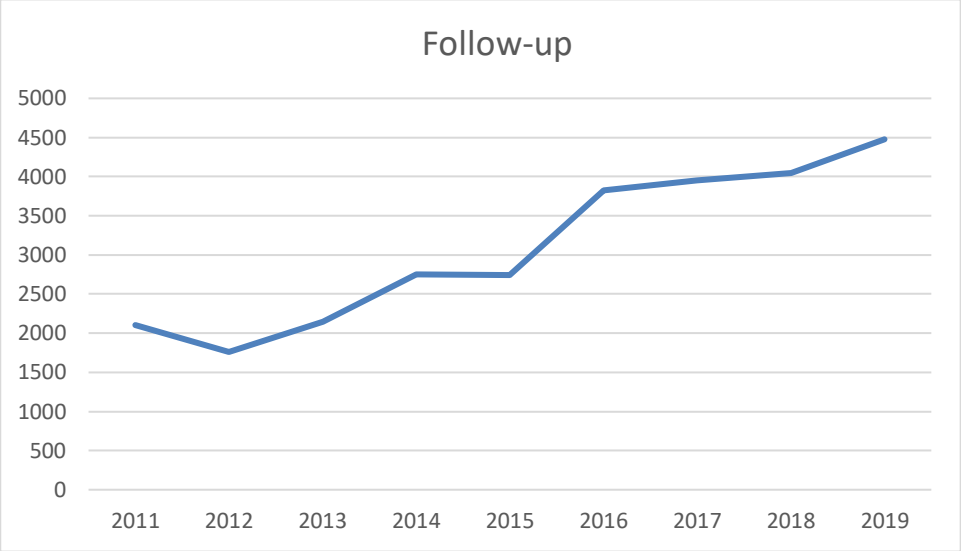
[216] Joint Action reports repeatedly indicate that these high rates of non-compliance were not necessarily representative for the market, as non-random samples were taken and often samples were tested where a visual inspection had suggested possible deficiencies.

5.2.4 Effectiveness of the Safety Gate/RAPEX

The Safety Gate/RAPEX ensures that information about unsafe products withdrawn from the market and/or recalled from consumers anywhere in Europe is circulated between Member States and the European Commission, so that appropriate action can be taken by market surveillance authorities in all EU Member States (and the EEA countries Iceland, Liechtenstein and Norway). **During the period 2005 to 2019 a total of 25 560 notifications were submitted** (close to 5 notifications on average per day), with all Member States participating in the system on a regular basis. The indispensable character of the system is emphasised by the diversity of institutional approaches for market surveillance and the high degree of fragmentation of market surveillance authorities according to sectoral and/or administrative considerations in many in Member States, which requires quick and effective information exchange and distribution, for which the system is a key channel.

The effectiveness of the Safety Gate/RAPEX is also illustrated by the analysis of the number of follow-up measures. Follow-ups can be defined as the feedback received from Member States participating in the Rapid Alert System on actions they have taken following up another country's alerts. As Figure 12 shows, the number of follow-up measures have steadily increased since data started to be gathered in this respect by the European Commission in 2011.

Figure 12: Number to follow-up measures taken by Member States reported to Safety Gate/RAPEX for the period 2011-2019



Source: Safety Gate/RAPEX

The GPSD Study also showed that authorities to a large extent appreciated the functioning of RAPEX, with 65% considering the system to function at least 'moderately well' (48% considered it to be 'rather' or 'very well' functioning). Other stakeholders were even more positive, with 70% finding the system at least 'moderately well' functioning (46% considered it to be 'rather' or 'very well' functioning). Only a small minority provided a negative assessment ('rather not' or 'not at all' functioning).

Despite this general satisfaction with the rapid alert system, there are also **issues that prevent its optimal operation**. In the surveys of authorities and general stakeholders for the GPSD Study, respondents were asked whether they had encountered impediments when using the system. Moreover, the recent GPSD implementation study analysed the average duration between the detection of an unsafe product and its notification to Safety Gate/RAPEX in each Member State. The RAPEX system sets out guidelines setting indicative timeframes for notifications, but these are not compulsory for Member States. In most cases this duration is two weeks or more; in some cases, the duration might be up to 6 months.

Several authorities emphasised that the duration between detection of an unsafe product and its notification to the system depended on the type of product, the risk, the required testing and the behaviour of the economic operator (objections by the relevant economic operator are in some cases reported to lead to significant delays).

Regarding international cooperation, there is high interest both from third countries and from the EU in **exchanging information on unsafe products between the Safety Gate/ RAPEX, and third countries**. This exchange enables more efficient market surveillance in the EU and enhancing product safety worldwide which can also in turn result in a better protection of EU consumers. When it comes to the procedure to set up arrangements to exchange non-public information from the RAPEX system, the Directive does not provide absolute clarity. Indeed, article 12(4) only mentions "access to RAPEX", which must be based on an international agreement. The Directive does not distinguish between the different levels of exchanges between the EU system and third countries. In practice, there is a major difference between:

- a third country becoming a full RAPEX member.
- a third country with which selected non-public RAPEX information is shared.

The current provisions of the Directive clearly cover the first type of cooperation, which consists in full access to Safety Gate/RAPEX and must be based on an international agreement. However, there is no clarity on the procedure for the second type of cooperation.

It can be concluded that the rapid alert system achieves its objective to provide a platform for exchange of information concerning unsafe products. Since its establishment in 2003 in accordance with Article 12 of the Directive, it has become a cornerstone of the EU market surveillance and product safety framework. Market surveillance authorities and other stakeholders therefore consider the Safety Gate/RAPEX mostly to be well functioning and effective. Still, certain issues currently prevent its optimal operation, such as delays between the detection of an unsafe product in a Member State and its notification to Safety Gate/RAPEX, as well as the procedure to set up arrangements for the exchange of information with third countries.

5.2.5 Effectiveness of the standardisation procedure of the Directive

The **standardisation system** established under the Directive has been effective in the sense that standardisation requests have been elaborated under the Directive and these led in most cases to standards which help producers to comply with the general products

safety requirement under the Directive by providing presumption of safety of the product. The list of referenced standards shows the importance of the Directive in this respect, as most of the listed products have a high potential for consumer harm. The GPSD Study showed that referenced standards are widely used by manufacturers, as a conforming product shall be presumed safe. Even a brief Internet research on a major e-commerce website indicates that products falling under the Directive (such as gymnastic equipment, bicycles, carry cots and stands etc.) are regularly advertised as conforming to the relevant standards, thereby providing evidence of their application in practice. Market surveillance authorities also make an extensive use of standards to assess the safety of products and take measures accordingly.

Replies from stakeholders to the GPSD Study have shown that the effectiveness of the standardisation process might be hampered by several procedural issues. In particular, stakeholders have stated that the process is considered to be long and complicated, and sometimes it reduces the possibilities for participation of authorities, SMEs, consumer organisations and other organisations, as well as universities. However, it should be mentioned that the standardisation process must strike a balance between speed and the quality of the outcome, thus, of the standard.

As detailed in Annex 10, the process under the Directive includes one step more than the procedure applied in relation to harmonised standards. The reason is that the harmonisation directives contain essential safety requirements on which standards can be based. In contrast, the wide coverage of the Directive requires specification of the safety requirements for a specific product, which then serves as a guideline for the work of the European standardisation bodies[217]. The addition of Step 1 of the process under the Directive therefore seems to be justified and unavoidable. As the European standardisation organisations attempt to achieve consensus, the duration for elaborating the standard by the ESO (Step 3) also seems to be justified by the nature of the process; while this takes time, the consensus-principle has always been regarded to be an essential element of standard setting procedures. Step 4, the Commission decision to reference standards, has been recently adapted following developments in case law. However, a possible merger of steps 1 and 2 would offer a potential area of improvement (in particular to enhance its efficiency, see section below).

5.2.6 Effectiveness of provisions on product recalls

Product recalls are one of the most common measures to mitigate the risks posed by unsafe products in the EU[218]. Among the over-2000 measures reported each year through the EU Rapid alert system[219] about half concern recalling the products from consumers. The Directive does not contain any specific provisions for recall procedures and

[217] See the GPSD implementation study, at 7.2.1.

[218] The term "recall" refers here to the process aimed at achieving the return of a dangerous product that has already been supplied to consumers, initiated directly by the producer or distributor of the dangerous product, or ordered by authorities.

[219] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

timelines, communication or the remedies to be offered to consumers. Producers undertake voluntary action to organise recalls but authorities can also order a recall on the basis of notifications of unsafe products from other countries or the results of their own market surveillance activities or if producers' actions are deemed insufficient. As shown by the Implementation Study, each Member State follows its own approach, with some common elements, but also diverging practices.

While the effectiveness of product recalls varies considerably depending on factors such as channel of sale[220] and product category[221], the proportion of products successfully recovered from consumers remains generally low, as recognised by a recent OECD report[222]. For instance, one Member State indicated that the return rate (understood as the number of products returned by consumers following the release of a product recall notice and other related communications) rarely exceeds 10%, except when products have been purchased online, which makes it easier for suppliers to contact and alert their customers about a recall[223]. Another national authority estimated that around 80% of products of low value with a short lifespan remain in consumers' hands[224].

The consequences of delayed and ineffective recalls are also exemplified by the deaths and injuries caused by products such as faulty airbags (estimated to have caused 35 deaths and 300 injuries worldwide[225]) and baby sleepers (associated with 59 baby deaths in the US[226]); see Annex 8.

In the interviews with authorities held in the frame of the GPSD Study, few of them were able to estimate recall effectiveness in terms of the percentage of the recalled consumer products that were actually collected. Several authorities also suggested that even though they collect related data, it is difficult to determine the effectiveness of product recalls. At a recent EU workshop, it was concluded that there is no systematic approach by the authorities to monitoring recall effectiveness[227].

The main obstacle to recall effectiveness is the **difficulty of identifying and contacting the owners of recalled products**, which means that many EU consumers are simply not aware that they own a recalled product. The Directive does not contain any requirements

[220] Recalls tend to be more effective if the product was bought online because it's easier to identify and directly contact the buyers.

[221] Recall effectiveness increases with product price and expected lifespan and decreases with product age.

[222] OECD (2018), Enhancing Product Recall Effectiveness Globally, p. 5.[223] Idem, p. 17.

[223] Idem, p. 17.

[224] European Commission, 2021, Behavioural study on strategies to increase the effectiveness of product recalls.

[225] https://www.consumerreports.org/car-recalls-defects/takata-airbag-recall-everything-you-need-to-know/

[226] https://www.washingtonpost.com/gdpr-consent/?next_url=https%3a%2f%2fwww.washingtonpost.com%2fbusiness%2f2019%2f10%2f17%2fstudy-concludes-design-rock-n-play-other-infant-sleepers-led-deaths%2f

[227] EU workshop on strategies to maximize the effectiveness of product recalls, 23 October 2019, p.11. Annex 14

on consumer traceability and authorities interviewed for the Implementation Study mentioned that reaching the final consumer is a challenging task.

For most recalled products, customer data is not available or even if it is available, it is not used to inform affected consumers. Apart from motor vehicles (whose registration with public authorities is mandatory), registration schemes are only available for few higher-value product categories like domestic electric appliances and communication devices, and even in these sectors actual registration rates tend to be rather low[228].. In addition, economic operators are hesitant about using customers' information collected for other purposes (e.g. in the loyalty programmes or online sales) in the event of a recall because of a possible legal uncertainty about the compliance with the General Data Protection Regulation[229]. Limitations on customer data were also notified by online platforms in a Study on contractual relations between online platforms and their professional users[230]. Moreover, there are no systematic sources of indirect recall information for consumers. For instance, only 12 EU/EEA countries publish recall information on their websites[231].

A second obstacle to recall effectiveness is the **consumers' reluctance to return a recalled product even if they are aware about the recall**. An EU-wide survey commissioned by the European Commission showed that over a third of consumers (35%) did not react to a recall that was relevant to them: 31% continued using the product with extra caution, while 4% took no action whatsoever[232]. The corresponding figures in a most recent consumer survey in 10 EU countries were 24% and 13%, respectively[233].

This may be caused by recall notices being unclear and/or minimising consumers' perception of risk. For instance, the analysis of existing recall announcements showed that over half of them used terms and expressions, which could undermine consumers' perception of risk, such as 'voluntary/precautionary recall', 'potential concern/problem', in rare cases'/in specific conditions' or highlighting that there have been no reported injuries[234]. In addition, the procedure for consumers to return the recalled product may be complex and burdensome.

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[228] European Commission, 2021, Behavioural study on strategies to increase the effectiveness of product recalls.

[229] European Commission, Notes from EU Workshop on strategies to maximise the effectiveness of product recalls, 23rd October 2019, p. 2.

[230] Study on contractual relationships between online platforms and their professional users, April 2018.

[231] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

[232] European Commission (2019). Survey on consumer behavior and product recalls effectiveness, p. 20, available at: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/Product.Recall.pdf.

[233] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

[234] Idem.

In addition to the issues mentioned above, behavioural research[235] suggests that **cognitive biases and heuristics may also influence consumers to take suboptimal decisions** regarding how to respond to product recalls and may lead them not to take action. Biases such as information overload and framing effects mean that if recall notices are lengthy and unclear, consumers may ignore them, especially if they lack time. Over-optimism may result in consumers underweighting the risk posed by a recalled product, while inertia and endowment effect (i.e. the emotional bias that causes individuals to value an owned object higher, often irrationally, than its market value) relate to the fact that consumers have an inherent preference for status-quo, which in the case of recalls means keeping the product[236].

To sum up, the increase in the number of product recalls over time and the fact that recalls are currently for most part organised on a voluntary basis can be considered as indications that the Directive has contributed to making recalls more widely used as a corrective measure. However, EU-wide general requirements regarding the recall procedure or communication are missing. This has been repeatedly reported as a **significant shortcoming**, suggesting that existing requirements are in themselves currently not sufficient to ensure effective recalls. The resulting limited effectiveness of recalls may negatively affect consumer safety and the degree to which there is a level-playing field for businesses in the internal market, affecting therefore the extent to which the objectives of the Directive are achieved in practice.

5.2.7 Impact of e-commerce in the effectiveness of the Directive

The evaluation showed that e-commerce poses additional challenges for the control of the safety of products sold online, thus questioning the effectiveness of the Directive in this regard. In particular, there is evidence pointing to the fact that **the control of the safety of products sold online is more problematic than the one for unsafe products found in brick-and-mortar shops**. Data coming from the Safety Gate/RAPEX for the period 2018-2019 show that the share of notifications of products 'sold online' in which one of the four traceability information items was missing (see table 4) was between 29,2% and 57,3% (depending on the item); the share for notifications not indicating 'sold online' in which one of the four traceability information items was missing was considerably lower (between 12,6% and 35%7).

[235] Bernstein A. (2013), 'Voluntary Recalls', University of Chicago Legal Forum, 1: 394 ff., available at: http://chicagounbound.uchicago.edu/uclf/vol2013/iss1/10 and Jacoby J. (1984), 'Perspectives on Information Overload', Journal of Consumer Research, 10(4), pp. 432-435.
[236] See OECD (2018), Enhancing Product Recall Effectiveness Globally, p. 5.

Table 4: Number and share of Safety Gate/RAPEX notifications concerning unsafe consumer products with unknown product information items (by sales channel, 2018-2019)

	Total number of notifications	Number of notifications regarding products not indicating 'online'	Share : Notifications not online missing information / Total notifications not online	Number of notifications regarding products indicating 'online'	Share : Notifications online missing information / Total notifications online
Total number of notifications for consumer products 2018-19	3 864	3590	-	274	-
Notifications in which information item is missing					
- No manufacturer	1437	1 280	**35,7%**	157	**57,3%**
- No brand	800	700	**19,5%**	100	**36,5%**
- No type/model	531	451	**12,6%**	80	**29,2%**
- No batch number/barcode	805	667	**18,6%**	138	**50,3%**
- None of the four	52	17	**0,5%**	35	**12,8%**

Source: Prepared with Safety Gate/RAPEX data.

Furthermore, recent investigations from market surveillance authorities, consumer organisations and industry associations show worrying levels of unsafe products in some categories of products sold online:

- A campaign carried out in 2018 by DGCCRF[237], the French market surveillance authority, showed that on average 42.8% of the inspected products online were unsafe. The level of dangerous products reportedly varied a lot depending on the product category: high rates of unsafe products were found for example in low priced jewellery (74%) and some electrical products (66%), while for cosmetics the rate was 16%. The situation also varied greatly considering the marketplace on which the samples were taken (ranging for example from 22% to 58% of unsafe products). The authority concluded that it found a significantly higher share of unsafe products on online marketplaces compared to products sampled across all distribution channels.
- In February 2020, six consumer groups from the BEUC network[238] tested 250 electrical goods, toys, cosmetics and other products bought from a number of online marketplaces. They selected the products based on possible risks and found that 66% of them failed EU safety laws with possible consequences such as electric shock, fire or suffocation.

[237] Direction générale de la Concurrence, de la Consommation et de la Répression des fraudes

[238] https://www.beuc.eu/publications/two-thirds-250-products-bought-online-marketplaces-fail-safety-tests-consumer-groups/html

- Also in 2020, Toy Industries of Europe[239] undertook a project to assess the safety and the legal compliance of toys bought from operators who sell on several online marketplaces present in the EU. The assessment was conducted on toys bought in seven EU markets - Denmark, France, Germany, Italy, the Netherlands, Spain and Sweden. The project showed that more than 97% of the 193 toys assessed did not comply with strict EU toy safety rules and 76% of 134 that were safety-tested had defects that made them unsafe for children. In addition, 83% of the toys bought as part of the project did not include necessary traceability information.

These results support the other evidence provided above. When interpreting the research presented in the previous paragraphs, it is important to recall that all quoted studies are based on risk-based sampling, i.e. they focused on products with a higher probability for non-compliances. While this is a standard approach used by market surveillance authorities, it means that results are not necessarily representative of the market overall, but provide insights into specific problem areas.

As already stated in the section on Relevance, the Commission has taken some actions to tackle this problematic. One major action has been the facilitation of the signature of the **Product Safety Pledge** by 9 online marketplaces. Most market surveillance authorities and the online marketplaces part of the Pledge see the signature of the voluntary commitments as positive, as it sets a cooperation framework and defines possible actions to be carried out by online platforms as an important player in the supply chain. The 3rd Monitoring Report of the Pledge[240], published in November 2020, showed some progress: there are indications that signatories are taking actions to monitor Safety Gate/RAPEX notifications and remove product listings when notified by authorities. However, further than that **it is challenging to analyse the effectiveness of the Pledge to appropriately ensure the safety of products sold online**. The report also showed that there has been a divergence in the way online marketplaces calculated the Key Performance Indicators (KPIs), making it difficult to extract conclusions from those numbers and monitor the effectiveness of the commitments of the Pledge. Further negotiations with marketplaces to enhance the monitoring and accountability of the Pledge have proved to be complex. In addition, authorities, consumer organisations and other stakeholders have signalled that the Product Safety Pledge remains voluntary, so the infringement of those commitments cannot be penalised by authorities. There are also many players on the market that have decided not to adhere to the voluntary commitments, creating also an **uneven level-playing field between online marketplaces** targeting EU consumers.

In addition, **the presence of unsafe products in online channels can have an impact on the level-playing field for businesses**. A study published by Eurocommerce[241] showed estimations on how much lower the purchase price would be if the products did not comply with EU Product Safety Rules. The cost difference between products

[239] https://www.toyindustries.eu/wp-content/uploads/2020/06/Executive-Summary-Online-Marketplaces-6-1.pdf

[240] https://ec.europa.eu/info/sites/info/files/3rd_progress_report_product_safety_pledge.pdf

[241] Eurocommerce – Creating a level-playing field for retail in Europe – August 2019

produced in accordance with EU rules and standards, and produced without taking account of the EU rules was considered as significant. While such calculations cannot be extrapolated to a whole category of products, they give an indication of the possible detriment of the presence of rogue traders.

The evidence described above shows that e-commerce allows for a growing flow of consumer products (both those falling under the Directive and those falling under harmonised legislation) to enter the EU market including unsafe and recalled products, with traders and products being often untraceable. While these problems also do occur in the 'offline' environment, they are more relevant in the online environment which allows products to enter the EU market without having a relevant economic operator in the EU. It can therefore be concluded that on balance, **the emergence of e-commerce has negatively affected the effectiveness of the Directive** in terms of enforcing the general safety and traceability requirements, but also with respect to effective market surveillance by the Member States.

5.2.8 Impact of new technologies in the effectiveness of the Directive

The development of new technologies is also putting into question the effectiveness of the Directive as a safety net for products, aspects and risks not covered by product harmonisation legislation.

As stated in the section on Relevance, the **uncertainties regarding the applicability of the Directive to new technologies**, such as to new risks, have also an impact on its effectiveness. A good example can be the follow up of a Safety Gate/RAPEX notification from Iceland regarding a smartwatch for children[242]. The Icelandic authority argues that this product would not cause a direct harm to the child wearing it, but lacking a minimum level of security, it can be easily used as a tool to have access to the child. As one of the product's intended function is to keep children safe through localisation, a consumer would expect that it would not pose security threats to children that may affect their safety by potentially being tracked and/or contacted by anyone. As measures regarding this product were notified to Safety Gate/RAPEX, authorities in the rest of Member States took follow-up actions.

However, as the surveys for the GPSD Study showed, many of those authorities were unsure if the Directive applied to such risks due to the lack of explicit provisions in that regard. The lack of explicit provisions and/or guidelines with regard to the safety of new technologies has a negative impact on the effectiveness of the Directive. Furthermore, almost half of the interviewed Member States authorities reported that they currently do not carry out inspections on products incorporating new technologies, which could also be due to such lack of clarity. The report on the safety and liability of new technologies[243]

[242] Safety Gate/RAPEX notification from Iceland published in the EU Safety Gate's website (A12/0157/19)

[243] Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and robotics COM/2020/64 final

also concluded that EU product safety legislation would need to be further clarified for legal certainty.

The example of consumer products using new technologies illustrates both the strengths and the weaknesses of the general safety requirement of the Directive. It confirms the advantage of a general requirement that products need to be safe independent from the technology used, i.e. the safety requirement being technology-neutral. However, it also has shown its weakness in that certain key definitions, such as "safe product" and "product", which are broad and unspecific to apply in a wide range of situations, can be ambiguous in the context of new technologies, and therefore **create practical difficulties for the application of the Directive, which reduce its effectiveness**.

5.2.9 Effectiveness of the Food-Imitating Products directive

The number of Safety Gate/RAPEX notifications of **food imitating products** is small. Between 2013 and 2019, a total of 114 notifications (less than 20 per year on average) that relate to food imitating products, as table 5 shows. Moreover, it seems that the product category "Food-imitating products" was only used up to 2015; afterwards, the products have been categorised according to their use (cosmetics, clothing, etc.), and aspects related to the imitating nature of the product were incorporated in the risk assessment of the product itself (but not in a systematic manner by all Member States).

Table 5: Notifications to Safety Gate/RAPEX related to food-imitating products

Product category	Year							Total
	2013	2014	2015	2016	2017	2018	2019	
Cosmetics				3	1	28	1	33
Decorative articles	1			1		4	17	23
Food-imitating products	26	12	8					46
Other							2	2
Stationery							2	2
Toys		1				4	3	8
Total	***27***	***13***	***8***	***4***	***1***	***36***	***25***	***114***

Source: Safety Gate/RAPEX

To address this issue, in 2019 the Commission circulated a questionnaire to Member States on the implementation of the FIPD. Its outcome showed that there are very different interpretations of the FIPD (and notably whether food-imitating products should be banned per se or be subject to a risk assessment). **These divergences rendered the FIPD ineffective in practice**, as there is not a harmonised approach for this category of products in the EU.

During a meeting of the Consumer Safety Network organised in November 2019, Member States agreed that the development of guidelines would not enhance the effectiveness of the FIPD and legal changes might be needed to address the diverging interpretations of this directive.

5.2.10 Conclusion on effectiveness

The Directive appears overall to have met its objectives of ensuring a high level of safety of consumers, while ensuring an effectively operating internal market for goods. **Overall, the Directive has reached a reasonable uniformity in its implementation and the set of its rules makes it effective**.

However, **certain provisions of the Directive have proven to affect negatively its effectiveness**, resulting in a continuing influx of new unsafe products on the market. This relates, as highlighted above, to the lack of a mechanism to arbitrate disputes on risk assessment, challenges on the traceability of unsafe products, lack of resources of market surveillance authorities, as well as the impact of e-commerce and new technologies on the effectiveness of the Directive. Furthermore, more clarity could be sought with regards to product recalls and other key definitions. The current divergences of interpretation of the FIPD among Member States has also resulted to be inefficient, so actions in that respect should be pursued.

5.3 Efficiency

5.3.1. Analysis of costs

The current **costs of compliance** with the Directive are directly accruing to businesses and market surveillance authorities, and indirectly to consumers in the form of costs of consumer goods and taxes.

5.3.1.1 Costs for businesses

The Directive applies fully to consumer products for which no specific EU harmonised legislation exists. It does not apply to industrial/professional products. While the Directive is also applicable to harmonised consumer products to the extent that there are no specific provisions with the same safety objective in the EU harmonised legislation, the significance of this 'residual effect' of the Directive depends on several factors, most notably on the extent to which EU harmonised legislation reflects the same level of protection. As the residual effects on manufacturing and distribution of harmonised products are in any case expected to be minor compared to the effects in the area of non-harmonised products, this assessment focuses on the latter. In other words, the following assessment only considers the costs of compliance with the Directive for manufacturers and distributors of non-harmonised consumer products.

Following this approach, the estimation of business costs is based on the following steps and detailed in Appendix 2:

- *Step 1: Estimation of EU companies' total annual turnover from the production and/or sales of non-harmonised consumer products in the EU* - Based on this approach, the total EU turnover from non-harmonised products in the selected sectors amounts to EUR 773 billion for EU manufacturers, EUR 750 billion for EU wholesalers and EUR 581 billion for EU retailers.
- *Step 2: Deduction of extra-EU export* – This results in an estimation of an annual EU turnover related to non-harmonised products of EUR 655 billion for EU

manufacturers, EUR 707 billion EUR for EU wholesalers and approx. EUR 485 billion EUR for EU retailers.

- *Step 3: Deduction of industrial and professional products* - As a result, the total annual EU turnover of EU companies from non-harmonised consumer products is estimated at EUR 1032 billion EUR.
- *Step 4: Derivation of empirical estimates for companies' product safety-related costs* – These estimates take into account activities such as managing product safety, testing for product safety, and product recalls.
- *Step 5: Extrapolation of EU companies' annual costs related to the Directive including business-as-usual costs that occur also in absence of regulation.*
- *Step 6: Deduction of business-as-usual costs and extrapolation of EU companies' annual compliance cost related to the Directive*

As indicated in table 6, the estimated costs for EU businesses to comply with the Directive amount to EUR 1.1 billion per year, of which EUR 343 million accrue to EU manufacturers, EUR 321 million to EU wholesalers and EUR 439 million to EU retailers.

Table 6: Estimated annual cost for businesses to comply with the GPSD, by company size class, in million EUR

	Cost by company size			**Total costs**
Company size (employees)	*From 0 to 49*	*50 – 249*	*250 or more*	*All size categories*
Total of manufacturing	79	101	163	343
Total of wholesale	118	81	122	321
Total of retail	232	44	163	439
Total	**428**	**226**	**448**	**1 102**

Source: GPSD Study, based on company costs survey and Eurostat data.

With regards to SMEs, companies with less than 50 employees are estimated to have GPSD-related costs (after business-as-usual costs such as costs related to general due diligence activities have been subtracted) of approx. 428 million EUR per year, and companies with 50 to 249 employees are estimated have GPSD-related costs of approx. 226 million EUR per year (see Table 6 above). Accordingly, SMEs account for 59% of the total of GPSD-related compliance costs in the EU, in line with their overall share in the market. It should be noted that due to the relatively high number of EU SMEs that engage in wholesale and (particularly in) retail sectors compared to manufacturing sectors (and compared to large EU companies which are more engaged in manufacturing activities), GPSD-related measures that impact on the distribution chains of non-harmonised consumer products can be expected to have a higher aggregate impact on EU SMEs than measures that impact on manufacturers.

5.3.1.2 Costs for authorities

Assessing the costs for market surveillance authorities to comply with the Directive is complicated due to organisational differences across Member States. Market surveillance systems for consumer products differ in the extent to which market surveillance is conducted by authorities with broader or with narrower sectoral responsibility, as well as

to the degree of centralisation of the administration of each country. These organisational features affect how market surveillance of non-harmonised consumer products is organised, and in some cases the share of staff working on market surveillance of non-harmonised products is unknown.

To overcome this limitation, the estimate of market surveillance costs has been based on comprehensive staff data for 20 EU Member States obtained through interviews and surveys. Consequently, the estimation for total EU27 staff-related costs for market surveillance of non-harmonised consumer product amount to approximately EUR 122 million per year. Of this amount, EUR 14 million accrue in countries where responsibility for market surveillance is centralised and EUR 108 million in countries where responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations (for more info see Appendix 2). Non-staff related costs of market surveillance activities for non-harmonised consumer products in the EU can be considered negligible (EUR 0).

5.3.2. Analysis of benefits

The main benefit of the Directive is the consumer protection and its consequential **reduction of consumer detriment**. The GPSD Study provided an analysis of detriment due to product-related injuries and fatalities in the EU (see Annex 4). The analysis concluded that the preventable detriment suffered by EU consumers and society due to product-related accidents (and related injuries and pre-mature deaths) can be estimated at **EUR 11.5 billion per year**. In addition to this injury related detriment, the consumers also suffer financial costs of a total value of **EUR 19.3 billion for 2019** arising from the fact they have purchased unsafe products that they would not have purchased if they knew these products are unsafe While it is not possible to estimate the detriment suffered by EU consumers and society that is avoided by EU product safety legislation, including the Directive, it is reasonable to assume that in absence of the general safety requirement, the standards referenced and other provisions under the Directive, the detriment suffered due to product-related accidents and financial costs for consumers would be substantially higher, thereby outweighing the related costs for companies, market surveillance authorities and consumers.

Furthermore, the Directive has contributed with additional benefits:

- Increased **consumer trust**: as reflected in Figure 10, there has been an increase of consumer trust from 65% in 2008 to 78% in 2016;
- Increased **business revenue** (e.g. due to increased reputation /brand value);
- Improved **quality / lifecycle of products**;
- **Better information** on unsafe products/measures taken by authorities provided through the Safety Gate/RAPEX (more than 25,000 notifications since the establishment of the system);
- **Better supply chain management** due to traceability of products;
- Greater **legal certainty**;
- **Lower operational risk** for businesses;
- **Deterrent effect** on rogue traders;

- More **level-playing field** among businesses;
- **Better functioning of the EU Single market**;
- Higher level of **protection of the environment** due to reduction of unsafe products that also have environmental impacts (e.g. lead in PVC, siloxanes, Nonylphenol);
- **Better access to the market in non-EU/EEA countries**.

2.5.1. 5.3.3. Balance and distribution between costs and benefits

About nine in ten respondents that had an opinion considered the costs due to product safety requirements of the GPSD to be at least "moderately proportionate" to the resulting benefits. Close to six in ten respondents that had an opinion even found these costs to be "largely proportionate" or "very proportionate".

This **largely positive assessment** is consistent with the analysis of compliance costs (see table 7). A large part of costs related EU product safety legislation for consumer products are considered as business-as-usual costs (BAU), i.e. costs that companies would incur anyway (i.e. even in absence of product safety legislation, for example because these costs relate to their due diligence procedures). Compliance costs due to the safety requirements of the Directive that exclude business-as-usual costs are therefore limited, compared to the benefits the Directive brings, including in terms of contributing to the functioning of the internal market.

Table 7: Assessment of costs and benefits

Type	Assessment of cost/benefits
Costs	
Companies' compliance costs	Consumer product safety-related compliance costs are estimated at 0.59% of turnover for manufacturing sectors and 0.14% for retail and wholesale services sectors. Subtracting costs that companies would incur anyway (i.e. even in absence of product safety legislation, e.g. because these costs relate to due diligence), the estimated costs for businesses to comply with the GPSD amount to **EUR 1.1 billion** per year, of which EUR 343 million accrue to EU manufacturers, EUR 321 million to EU wholesalers and EUR 439 million to EU retailers
Member States' costs for market surveillance costs	Total EU27 staff-related costs for market surveillance of non-harmonised consumer product amount to approximately **EUR 122 million** per year. Of this amount, EUR 14 million accrue in (smaller) countries where responsibility for market surveillance is centralised and EUR 108 million in (often larger) countries where responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations
Benefits[a)]	
Better information on unsafe products through Safety Gate /RAPEX	In the period 2005 to 2019, a total 25 850 publicly available notifications were transmitted through Safety Gate/RAPEX, including **25 051 notifications** concerning products with serious risks. In a 12 months period 2019/20, the analysed notifications affected some **41.8 million items** in total
A better functioning internal market	The aim of free movement of (non-harmonised) goods within the internal market has been achieved. There were only few cases where Member States prohibited or hindered the import of products from other Member States that had been certified in line with EU product safety law, and these cases all related to specific harmonised legislation but not to the GPSD. There is **no indication that Member States try to stop imports** from other Member States for reasons of their insufficient level of safety. Standardisation has contributed to the uniform application of product safety law in the Member States. So far, a total of **80 standards** were referenced under the GPSD
Increased consumer trust	Consumer trust in product safety in the EU has shown a **slight increase over time**, with the proportion of consumers agreeing that essentially all non-food products in their country are safe (or that only a small number are unsafe) increasing from 65% in 2008 to 78% in 2016, before decreasing again to 70%. The largest increase (9 percentage points) occurred between the 2014 and 2016 surveys, before returning in 2018 to slightly above the 2014 level
Reduced occurrence of products presenting health and safety risks & reduced number of accidents/injuries caused by unsafe products	Based on data from the European Injury Database (IDB) an estimated **11 million product-related injuries**, in which consumers visited a hospital emergency department due to the injury, occur in the EU each year. The related detriment is estimated at EUR 76.6 billion per year. This is the sum of detriment caused by non-fatal product-related injuries, and the cost of premature death due to fatalities caused by mechanisms relevant for product safety (such as tools, strangulation, electric current, or fire) occurring outside of work-related locations. The preventable detriment suffered by EU consumers and society due to product-related accidents can be estimated at **EUR 11.5 billion** per year. In addition, consumers also suffer financial costs of a **total value of EUR 19.3 billion per year arising from the fact they have purchased unsafe products** that they would not have purchased if they knew these products are unsafe. It is reasonable to assume that in absence of the general safety requirement of the GPSD, and the standards referenced under the Directive, detriment suffered due to product-related accidents and financial costs would be considerably higher.

Source: GPSD Study

5.3.4. Conclusion on efficiency

This evaluation therefore concludes that the **costs of the Directive are proportionate to the benefits it brings**.

However, it should be highlighted that several of the factors that affect the effectiveness of the Directive may also influence its efficiency:

- Complexity of the legal framework for product safety, in particular the co-existence of two systems of rules on market surveillance;
- Difficulties on enforcement by market surveillance authorities the provisions of the Directive, in particular due to challenges posed by E-commerce and traceability;
- Lack of a mechanism to solve differences in risk assessment of authorities in different Member States;
- Outdated/unclear terms and concepts used in the Directive, in particular with regards to new technologies;
- Delays in notification of unsafe products through Safety Gate/RAPEX;
- Challenges related to the standardisation process;
- Suboptimal effectiveness of product recalls.

Consequently, actions aimed to address those issues would contribute to further enhance the efficiency of the Directive.

5.4 Coherence

5.4.1 Internal coherence of the Directive

This evaluation did **not identify discrepancies or inconsistencies between the provisions of the Directive**. This has been backed by stakeholders interviewed for the preparation of the GPSD Study. However, certain stakeholder have signalled that certain provisions of the Directive lack clarity. In particular, Art 5(1) of the Directive, that sets obligations for producers to provide necessary information for tracing the origin of a product, is considered to be very vague and subject to multiple interpretations. This vagueness has led to slight differences in implementation in Member States and a lack of certainty for economic operators.

5.4.2 Coherence with product harmonisation legislation and market surveillance

Article 1.2 of the Directive provides that the provisions of the Directive "shall apply in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned". This definition of the scope of the Directive as *lex generalis* ensures its coherence with product harmonisation legislation, as there are no overlaps between the Directive and a specific instrument. This role of **"safety net"** is considered by stakeholders consulted for this evaluation as an unquestionable element and **cornerstone for the protection of consumers in the EU**, as well as an essential element for the free movement of goods in the Single Market. The interlinks of the Directive with sectorial legislation has also been acknowledged by the Court of Justice of the EU[244].

Nevertheless, despite the full coherence of the Directive with product harmonisation legislation, some stakeholders state that there are in practice **some uncertainties** when

[244] Judgment of the Court (Eighth Chamber) of 30 April 2009. Lidl Magyarország Kereskedelmi bt v Nemzeti Hírközlési Hatóság Tanácsa. Case C-132/08

determining the applicable legislation to a specific category of products. However, as the GPSD Evaluation and IA shows, the reasons for these practical challenges are not necessarily linked to the scope of the Directive, that by definition plays a residual role for harmonised products, but rather by the sometimes unclear scope of specific pieces of EU product harmonisation legislation or by the lack of guidelines or supporting documents to provide clarity to businesses.

An additional aspect that can contribute to such uncertainty is the existence of **discrepancies between some of the definitions of the Directive and definitions of the product harmonisation legislation**, in particular legislation following the New Legislative Framework (NLF) set by Decision 768/2008/EC[245] (see Table X). While the divergence of those terms is not significant, a lack of alignment has a negative impact on the coherence of the EU product safety framework.

Table 8: Comparison of key concepts in the Directive and Decision No 768/2008/EC

Concept	Directive 2001/95/EC (GPSD), Article 2 e-h	Decision No 768/2008/EC, Annex I, Article R1, points 3, 6, 14, 15
Producer	"producer" shall mean: (i) the manufacturer of the product, when he is established in the Community, and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product; (ii) the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product; (iii) other professionals in the supply chain, insofar as their activities may affect the safety properties of a product;	'manufacturer' shall mean any natural or legal person who manufactures a product or has a product designed or manufactured, and markets that product under his name or trademark;
Distributor	"distributor" shall mean any professional in the supply chain whose activity does not affect the safety properties of a product;	'distributor' shall mean any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a product available on the market;
Recall	"recall" shall mean any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor;	'recall' shall mean any measure aimed at achieving the return of a product that has already been made available to the end user;
Withdrawal	"withdrawal" shall mean any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer.	'withdrawal' shall mean any measure aimed at preventing a product in the supply chain from being made available on the market.

Source: GPSD Study

[245] Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (Text with EEA relevance OJ L 218, 13.8.2008, p. 82–128

It also needs to be signalled that Decision 768/2008/EC is not yet aligned with Regulation 1020/2019 on market surveillance, that has incorporated new definitions such as "fulfilment service provider". The Decision is also currently under evaluation.

The respondents have pointed out that the **interlink between the Directive and legislation on chemicals**, notably Regulation (EC) No 1907/2006 (REACH), sometimes lacks clarity. For instance, the term "product" is not used in REACH, as it refers instead to "articles", while it uses "substances" for a chemical element and its compounds. Some respondents suggested that this can cause confusion, when the measures refer to, respectively a "dangerous product" (Article 2(c) and (g), Article 8(1)(e) and (f), Article 10(2)(a) and (d), Article 13(3) GPSD) and a "dangerous substance" (mainly Title VIII REACH). In particular, the question of whether the presence of a dangerous substance would always lead to the finding of a dangerous product pursuant to the Directive was raised. This issue has been tackled in the revision of the guidelines on the operation of the Rapid Alert System RAPEX in 2018. The revised guidelines set out that *"[t]he risk level of a product may be considered to be serious if it contains a chemical substance either banned or in a concentration above the limit established by European legislation. Therefore, in cases where measures are taken against products containing a chemical substance subject to a restriction contained in EU Legislation, a notification may be submitted without a detailed risk assessment*" [246]. By presuming the serious nature of the risk when a product contains a substance either banned or in a concentration above the established limit, the work of market surveillance authorities is facilitated and this ensures the consistency of measures among Member States.

Due to the fact that chemical limits in sectorial legislation often concern specific categories of products, it is important to correctly classify a product, which can prove difficult for borderline cases. The consistency of chemical limits for products that present similarities but fall under different legislations (e.g. toys and childcare articles) can thus be raised, as well as the possibility to proceed by analogy when establishing a risk assessment for the products not covered by such restrictions.

In relation with **food contact materials**, the Evaluation observed that these products generally fall under the purview of food law[247], however, some food contact materials may require an evaluation in line with the General Product Safety Directive. This may have implications that are not comprehensively addressed in the legal framework e.g. regarding which authority is responsible for a specific problem and also whether to notify the safety issue through Safety Gate/RAPEX or the Rapid Alert System for Food and Feed.

[246] Commission Implementing Decision (EU) 2019/417 of 8 November 2018 laying down guidelines for the management of the European Union Rapid Information System 'RAPEX' established under Article 12 of Directive 2001/95/EC on general product safety and its notification system.

[247] Food Contact Material Framework Regulation (EC) 1935/2004 and the General Food Law Regulation (EC) 178/2002

Regarding **market surveillance**, as already stated above, there are **two different systems established by the EU legislation**: one applicable to product harmonisation legislation as established in Regulation 2019/1020 on market surveillance and the one set by the Directive for non-harmonised products. The existence of these two systems exacerbates the risk of weakening the general coherence of the product safety framework. The majority of respondents of the OPC confirmed having experienced problems with the divergence of rules between harmonised and non-harmonised products. Furthermore, some stakeholders stated that the implementation of two different set of rules is not even justified; a consumer organisation provided the paradoxical example that there are different market surveillance provisions for a baby doll bed that for an actual baby bed.

This has also been considered by market surveillance authorities as a major challenge, as the investigation and enforcement powers granted to them are different depending on each system. The **maintenance of both systems** also entails internal **administrative costs and inefficiencies** for Member States.

5.4.3 Coherence with standardisation policies

The evaluation identified that there is a **divergence between the standardisation procedures set by Regulation (EU) No 1025/2012**[248] and the Directive, as the latter counts with an additional step. However, this **divergence is justified** and corresponds to the fact that the Directive does not contain specific safety requirements in the legal text, so it requires an additional step for the setting up of such safety requirements.

However, the inter-links of both instruments can result in some inefficiencies. In line with this Regulation, after the decision on safety requirements by the GPSD Committee, the decision on the standardisation request is adopted by a different Committee, the Standardisation Committee, which is also the responsible for standardisation procedures in case of harmonised products. The involvement of two different Committees with Member States representatives is considered by the different actors involved to be not efficient and burdensome. Consequently, this has an impact on the coherence of the standardisation process of the Directive with the general framework provided by Regulation (EU) No 1025/2012. This is an area that could be subject to administrative simplification.

5.4.4 Coherence with consumer protection and product liability legislation

Some stakeholders have mentioned the lack of consistency between consumer rights under the Directive and other **EU consumer protection framework** with respect to redress options. For example, the Unfair Commercial Practices Directive 2005/29/EC

[248] Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council Text with EEA relevance - OJ L 316, 14.11.2012, p. 12–33

(UCPD)[249] could provide remedies for the victims of unfair commercial practices in cases involving the purchase of unsafe products, such as a right to compensation. Furthermore the Consumer Sales Directive 1999/44/EC[250], as well as the newly adopted Sale of Goods Directive 2019/771/EU[251], could provide remedies for victims of non-conforming products, such as a right to a termination of contract. The General Product Safety Directive does not award such rights to consumers, which may not only limit the involvement of stakeholders in monitoring product safety, but also weaken the coherence of the consumer protection framework against unsafe products. However, the recently adopted Directive on representative actions for the protection of the collective interests of consumers[252], includes Articles 3 and 5 of the General Product Safety Directive in the list of consumer legislation, a breach of which will entitle the qualified national entities to bring forward a representative action in case such breach harm or may harm the collective interests of consumers.

Directive 85/374/EEC concerning the **liability for defective products**[253] lays down common rules for strict liability (i.e. "liability without fault") of producers for damage caused by defective products at European Union level. It allows parties that have been injured by defective products to claim financial compensation for death, personal injuries or for damage caused to an item of property intended for private use with a threshold of 500 EUR. In order to successfully claim compensation, the injured person has to prove the damage, the defect and the causal relationship between defect and damage. The evaluation of the Product Liability Directive[254], published in May 2018, concluded on its persistent correspondence to the general expectations the public can have from product safety legislation, such as the General Product Safety Directive. The EU product safety rules describe the safety levels that products placed on the EU market must meet. In turn, they represent the safety levels for these products that an injured person is entitled to

[249] As amended by Directive (EU) 2019/2161 of the European Parliament and of the Council of 27 November 2019 amending Council Directive 93/13/EEC and Directives 98/6/EC, 2005/29/EC and 2011/83/EU of the European Parliament and of the Council as regards the better enforcement and modernisation of Union consumer protection rules, which added a new Article 11a to the UCPD on redress rights for consumers. This will be applicable as from 28 May 2022.

[250] Directive 1999/44/EC of the European Parliament and of the Council of 25 May 1999 on certain aspects of the sale of consumer goods and associated guarantees, OJ L 171, 7.7.1999, p. 12–16

[251] Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC - PE/27/2019/REV/1 - OJ L 136, 22.5.2019, p. 28–50

[252] Directive (EU) 2020/1828 of the European Parliament and of the Council of 25 November 2020 on representative actions for the protection of the collective interests of consumers and repealing Directive 2009/22/EC, OJ L 409, 4.12.2020, p. 1–27

[253] Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products, as modified by Directive 1999/34/EC of the European Parliament and of the Council of 10 May 1999 (OJ L 210, 7.8.1985, p.29 and JO L 141 4.6.1999, p. 20)

[254] COMMISSION STAFF WORKING DOCUMENT SWD(2018) 157 final - Evaluation of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

expect under the Product Liability Directive. Moreover, the General Product Safety Directive states in its recital (36) that its provisions should not affect victims' rights within the meaning of the Product Liability Directive, which remains an autonomous legal regime. However, the evaluation of the PLD also noted that as technological changes will bring about corresponding changes in the economy, the relevance of the PLD to these new needs will have to be ensured.[255]

5.4.5 Coherence with E-commerce rules

The **E-commerce Directive**[256] establishes the general legal framework for electronic commerce in the EU. The obligations set out apply, inter alia, to online sellers of products and services or online advertisers, as long as they are providers of an information society service that fall within the scope of that Directive.

Under the E-commerce Directive, Member States cannot impose a general obligation on online intermediaries to monitor the content or a general obligation to actively seek the facts or circumstances indicating illegal activity.

Intermediary service providers carrying out hosting activities may benefit under certain conditions from an exemption of liability for illegal information provided by third parties using their networks or illegal activities initiated by third parties. However, the liability exemption is subject to specific conditions. It only applies if the intermediary service providers have no actual knowledge or awareness of the illegal activity or information hosted or, upon obtaining such knowledge or awareness (for instance by a 'sufficiently precise and adequately substantiated' notice[257]), they act expeditiously to remove or to disable access to it. If hosting service providers do not fulfil these conditions, they are not covered by the liability exemption and thus can be held liable for the content they host.

While the E-commerce Directive does not define the concept of illegal information or activity, based on the General Product Safety Directive as well as product harmonisation legislation, this concept can also cover the offer of unsafe products. In that sense, it can be established that the E-commerce Directive is coherent with the Directive.

However, stakeholders have signalled in the different consultations that the principles mentioned above related to the prohibition of general monitoring and the liability system make difficult the implementation of the provisions of the Directive. Participants at the workshop on online marketplaces (see Annex 13) agreed that online marketplaces play an essential role in the supply chain, and that more responsibilities and cooperation with market surveillance authorities would help to effectively control the safety of products sold through their platforms. This issue has been partially tackled by the recent proposal

[255] *Ibidem*, page 49 and ff.

[256] Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (E-commerce Directive) (OJ L 178, 17.7.2000, p. 1).

[257] In Case C-324/09, L'Oréal vs. eBay, the European Court of Justice clarified that the relevant question relating to the conditions for benefiting from a liability exemption was whether eBay was aware of facts and circumstances from which the illegal activity was apparent (paragraphs 120 to 123).

of the Commission for a **Digital Services Act**[258], a comprehensive set of new rules, which regulate the responsibilities of digital services that act as intermediaries, including online marketplaces. In particular, the proposal sets out clear due diligence obligations for online intermediaries such as a harmonised notice and action mechanism, transparency obligations, measures to deter rogue traders, cooperation with competent authorities and an obligation for online marketplaces to gather information on the identity of traders using their platforms.

5.4.6 Coherence with wider EU policy

The evaluation shows that there are no coherence problems of the Directive with wider EU policy and priorities. However, some of the stakeholders in the consultations of the GPSD Study mentioned a few areas where frictions remain. Those issues cannot be considered as coherence problems of the Directive *per se* and they cannot be solved by a single instrument. However, they are worthy to be mentioned below.

As explained in the effectiveness section, the Directive is considered to be effective with regards to its objective to allow the **free movement of goods** within the Single Market. However, stakeholders mentioned that there might coherence problems with regard to **mutual recognition**. Stakeholders indicated their uncertainty as to whether a particular product, and its producers or distributors, could enjoy the free movement of goods, if there was an option for the Member States to adopt voluntary national certification systems. According to stakeholders, various Member States have such voluntary national certification systems in place for various products. Whilst the presence of such certification systems does not make the market prohibitive for products from outside this Member State, as there is no obligation to comply with the potential additional safety requirements, it may make the market more difficult to succeed in without that certification mark, in particular for SMEs.

With regard to **sustainability**, several stakeholders highlighted that in their view the emerging circular economy implied the need for legal certainty with regard to reused, refurbished and repaired products, and in particular in relation with who within the circular supply chain should bear the responsibility for the safety of the re-sold products. In the context of the Sub-group on new technologies and product safety, several stakeholders mentioned that for harmonised products, concepts such as 'substantial modification' already provided clarity in this respect, and such provisions were missing for non-harmonised products.

2.5.2. 5.4.7 Conclusion on coherence

It results from this evaluation that overall, **the Directive shows a high degree of internal coherence**, as there are no major contradictions among its provisions, as well as external (i.e. with other pieces of EU legislation), playing a key role in the Single Market framework. Further coherence however could be sought through more clarity.

[258] COM(2020) 825 final Proposal for a Regulation of the European Parliament and of the Council on a Single Market For Digital Services (Digital Services Act) and amending Directive 2000/31/EC

As regards coherence with other pieces of legislation, this evaluation has detected a **major shortcoming regarding the coherence of market surveillance provisions**. While rules for harmonised and non-harmonised are clear and do not overlap between each other, in practice the coexistence of two systems has an impact on the coherence of the legal framework, and has implications for market surveillance authorities.

5.5. EU added value

The GPSD Study shows that both authorities and companies/business associations see on average a **"significant added value"**. While other stakeholders provide a somewhat less positive assessment, they consider the Directive to provide still more than "moderate added value". A considerable number of respondents across all stakeholder groups found the Directive to even have "very significant added value"; namely 42 of 141 stakeholders had this opinion. In contrast, only 9 respondents to our surveys found the GPSD to have "no" or only "minor" added value. SMEs were also slightly less positive than other business stakeholders.

The reasons for such positive assessment are clear. Action at EU level is important to **protect consumers** and to ensure obligations on the EU businesses evenly. Furthermore, common rules established under the Directive ensuring **rapid circulation of information** among Member States on unsafe products are essential to protect consumer and ensure a fair internal market. Products freely circulate across the Internal Market. When an unsafe product is identified in a certain Member State it is very likely that the same product could be found in other Member States too. This shows the clear cross-border effect of product safety, which cannot be sufficiently achieved by the Member States' individual actions because they cannot ensure cooperation and coordination by acting alone.

Since the adoption of the Directive there have been no procedures in the EU courts related to national measures in the area of the health and safety of products that fall under its scope of application.

The Directive has also contributed to **economies of scale** with regard to market surveillance. The Directive allows the performance of joint market surveillance action and exchange of sensitive information.

Furthermore the **Safety Gate/RAPEX system** established by the Directive allows faster and more efficient circulation of information between Member States, ensuring a level playing field. The circulation of information through the Safety Gate/RAPEX allows to spread information on unsafe products among both Member States Authorities and consumers.

At **international level**, the common set of provisions established by the Directive has also allowed the EU to be stronger in promoting high level of safety at a more global level, very important nowadays with the increasing circulation of goods via online selling.

Repealing the Directive would lead to fragmentation and differing levels of consumer protection. The safety of consumer products is so intrinsically linked to the

internal market that such fragmentation of rules would create a very critical obstacle for the internal market and for the European consumer.

Therefore, this evaluation concludes that the **EU added value of the Directive is undeniable**. Nevertheless, it needs to be recognised that the added value of the Directive and its harmonious application in the Member States could be further improved by clearer rules and/or guidance documents.

6. CONCLUSIONS AND LESSONS LEARNT

The role of the Directive as a cornerstone of consumer safety and the functioning of the Single Market is uncontested. Its objectives remain fully relevant, and its EU added value cannot be denied. The role of safety net of the Directive remains essential for consumer protection, as it provides a legal basis aimed to ensure that no dangerous products end up in the consumer's hands. The establishment of the Rapid Alert System for dangerous non-food products under the Directive has proven to be a success, and consequently expanded via Regulation 765/2008 first and Regulation 2019/1020 afterwards to other categories of products, such as professional products, and to other risks, such as risks to the environment, security and other risks to other interests to the Union.

However, this evaluation has exposed a number of factors that put into question the extent to which some provisions of the Directive contribute to the proper achievement of the goals that it pursues.

In the first place, the growth of **E-commerce** has negatively influenced the relevance and effectiveness of the Directive. As repeatedly stated through this report, the Directive applies to all consumer products regardless if they are sold in brick-and-mortar shops or online. However, it can be taken as a lesson learnt that the lack of explicit provisions of the Directive to address the specificities of online selling, in particular the appearance of new actors in the online supply chain, has negatively affected to the safety of EU consumers as well as the level-playing field for compliant EU businesses. New rules regarding E-commerce, in particular the Digital Services Act, are likely to contribute to partially address this issue. However, explicit provisions directly related to E-commerce and product safety could be envisaged.

The rapid development of **new technologies** is also questioning the relevance of some of the key concepts of the Directive. The appearance of some new risks linked to connectivity, the applicability of the Directive to software updates and downloads as well as the evolving functionalities of AI-powered products raise the question whether the Directive is clear enough to provide legal certainty for businesses and protection to consumers. While legislative measures should be sought in product harmonised legislation to address the particularities of these technologies, this evaluation has also showed a need to ensure that the Directive remains as the safety net for all consumer products, including those incorporating new technologies.

The evaluation has also identified the problems for the coherence of the EU legal framework and the existence of two different sets of rules on **market surveillance** for

harmonised and non-harmonised products, that have also clear implications for the effectiveness and efficiency of the Directive. An alignment between both frameworks, as well as in the definitions of the Directive with product harmonisation legislation, should be sought.

Finally, it is also apparent from this evaluation that it would be necessary to fine-tune some of the provisions to improve the effectiveness of the Directive. In particular, legislative changes or further actions are needed to improve the effectiveness of **product recalls**. There is a need for mechanism to arbitrate disputes between Member States regarding risk assessments. The **traceability system** under the Directive and the **resources constraints of market surveillance authorities** are challenges that make it difficult to effectively control the safety of products, and consequently need to be tackled to ensure a proper protection of consumers and functioning of the Single Market. Provisions of the FIPD on **food-imitating products** are currently not enforced in a harmonised manner among Member States, so a solution to address this challenge is needed.

Appendix 1: Procedural information

1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

- Lead DG: Directorate General for Justice and Consumers (DG JUST)
- Decide/Planning: PLAN/2019/6283 Review of the general product safety directive - Proposal for a regulation on general product safety.
- REFIT (Evaluation)

2. ORGANISATION AND TIMING

- An Inter-service Steering Group oversaw the process to ensure coherence and comprehensiveness with the Commission's overall responsibilities and activities in related policy areas.
- This GPSD ISSG held 5 meetings times (one informal meeting on 14/02/2020 and four formal meetings on 12/06/2020, 08/10/2020, 18/11/2020 and 07/12/2020). DG JUST consulted the ISSG on the different steps of this initiative: Roadmap/Inception Impact Assessment, Consultation strategy, open public consultation questionnaire, the study underlying the evaluation and impact assessment (ISSG provided comments on all study steps and reports) and finally on the draft evaluation.
- Publication in EUROPA of the Roadmap on the evaluation, 30 June 2020
- Launch of the Open public consultation, 30 June 2020 - 6 October 2020 (14 weeks)

3. EXCEPTIONS TO THE BETTER REGULATION GUIDELINES

This Evaluation has been conducted back-to-back to the Impact assessment.

4. CONSULTATION OF THE RSB (IF APPLICABLE)

This Evaluation report is one of the annexes to the Impact Assessment report, on which the RSB has been consulted.

5. EVIDENCE, SOURCES AND QUALITY

Studies commissioned or supported by the European Commission

- Study to support the preparation of an evaluation of the General Product Safety Directive as well as of an impact assessment on its potential revision, Civic consulting, December 2020
- Study for the preparation of an Implementation Report of the General Product Safety Directive, Civic consulting, July 2020
- Study on the assessment of the opportunities for increasing the availability of EU data on consumer product- related injuries, European Commission's Joint Research Centre's, May 2020
- Behavioural Study on strategies to improve the effectiveness of product recalls, LE Europe, December 2020
- Survey on consumer behaviour and product recalls effectiveness, April 2019
- Implementation of the new Regulation on market surveillance: indication of origin, VVA Europe, May 2015

External Expertise

- Consumer Safety Network (CSN)
- Sub-group on Artificial Intelligence, connected products and other new challenges in product safety to the Consumer Safety Network

Selective bibliography

- Bernstein A. (2013), 'Voluntary Recalls', University of Chicago Legal Forum, 1: 394 ff., available at: http://chicagounbound.uchicago.edu/uclf/vol2013/iss1/10 and Jacoby J. (1984), 'Perspectives on Information Overload', Journal of Consumer Research
- OECD (2020)- 'E-commerce in the time of COVID-19', available at http://www.oecd.org/coronavirus/policy-responses/e-commerce-in-the-time-of-covid-19-3a2b78e8/#biblio-d1e705
- OECD (2018), 'Enhancing Product Recall Effectiveness Globally', available at https://www.oecd-ilibrary.org/science-and-technology/enhancing-product-recall-effectiveness-globally_ef71935c-en

Other Sources

- Eurostat
- European Injury Database (IDB)
- Safety Gate/RAPEX
- WHO CHOICE

Appendix 2: Analytical methods

This Appendix shows the analytical methods additionally used for the preparation of the Evaluation. For more general information about the Analytical methods, please see Annex 4.

5.1. Estimation of costs of compliance with the Directive for EU businesses (for efficiency criterion)

Firstly, there is a need to calculate the estimation of the baseline market size, i.e. the total turnover of EU businesses from manufacturing and/or selling non-harmonised consumer products in the EU[259], before analysing company level compliance cost data, and extrapolating it to EU level, based on the estimated baseline market size. The analysis is structured according to six steps:

Step 1: Estimation of EU companies' total annual turnover from the production and/or sales of non-harmonised consumer products in the EU

Based on NACE industry codes and sector descriptions, those manufacturing sectors were identified (NACE Rev. 2, B-E), wholesale services sectors and retail sectors (NACE Rev. 2, G) in which consumer products are produced and/or sold, i.e. sectors that clearly focus on the production and sales of industrial products were excluded. Sectors related to motor vehicles have been excluded, in line with the focus on non-harmonised consumer products. While retail sale can be assumed to be largely related to consumer products (although retailers may also sell to professional users, and may sell services), the wholesale and manufacturing in the listed areas clearly also contain industrial/professional products, an issue considered in Step 3 below. To arrive at the share of non-harmonised products produced and/or sold in these sectors, it was applied the estimate provided in the 2017 EU impact assessment for the new Market Surveillance Regulation, which estimated that about 54% of products circulating within the European Single Market are harmonised products and 46% are non-harmonised products[260].

Step 2: Deduction of extra-EU export

To calculate the net turnover for non-harmonised consumer products that are only sold in the EU, the share of extra-EU exports from the total turnover of EU companies was deducted. The calculation is based on an approximation of sector-specific export shares. The extra-EU trade by enterprise characteristics data provided by Eurostat do not exactly match the sector classification of turnover data by enterprise size class. Therefore the

[259] All estimates in this section refer to the EU27 as of 2020.

[260] SWD (2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM (2017) 795.

extra-EU export shares of manufacturing, wholesale and retail sectors were approximated on the basis of those sectors[261]. The estimated extra-EU export shares of manufacturing, wholesale and retail sectors were subtracted from the annual turnover of EU companies with non-harmonised products in the selected sectors.

Step 3: Deduction of industrial and professional products

The EU turnover derived in Step 2 was corrected by the percentage shares of turnover that can be attributed to the production and/or sales of consumer products in manufacturing, wholesale and retail sectors. For this purpose, a different dataset was drawn, namely the final consumption expenditure of households by consumption purpose[262]. There was a correction for the share of harmonised products, and arrived at an estimate for total household consumption of non-harmonised products. For the following analysis it was assumed that this consumption of non-harmonised consumer products is equivalent to the total turnover from non-harmonised consumer products sold by EU retailers. The estimated retail turnover from non-harmonised products indicated before was adjusted accordingly, and the resulting amount was allocated between the three enterprise size classes. Due to data limitations, the same methodology could not be applied for manufacturing and wholesale sectors[263]. For manufacturing and wholesale sectors, it was estimated the share of turnover that can be attributed to consumer products on the basis of the share of "consumer-oriented" wholesale services in total wholesale services. It is assumed that the same share reflects the portion of consumer products produced and/or sold by manufacturers. Based on this approach, the total annual EU turnover of EU companies from non-harmonised consumer products was calculated.

Step 4: Derivation of empirical estimates for companies' product safety-related costs on the basis of survey responses

In the GPSD study, businesses were asked to indicate staff time used for managing product safety, testing for product safety, recalls and other consumer product safety related activities. Respondents were asked to consider all costs for ensuring product safety of both harmonised and non-harmonised consumer products (excluding pharmaceuticals, medical devices or food), as the identification of costs for non-harmonised products only was not considered to be feasible. In addition to staff requirements, companies were asked to provide estimates for other costs to comply with safety requirements for consumer products (e.g. costs for external legal advice, costs for

261 These sectors are: "Manufacture of textiles, Manufacture of wood and of products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials", "Manufacture of paper and paper products", "Manufacture of computer, electronic and optical products", "Manufacture of electrical equipment", "Manufacture of furniture", "Wholesale trade, except of motor vehicles and motorcycles", and "Retail trade, except of motor vehicles and motorcycles".

262 Eurostat, Final consumption expenditure of households by consumption purpose (COICOP 3 digit) [nama_10_co3_p3].

263 Eurostat data do not allow to extract "pure" consumer products for manufacturing and wholesale sectors, i.e. final products that are consumed by households.

external safety testing, costs for certification of safety of products etc.)[264]. The cost estimates provided by the respondents also include business-as-usual costs, which would incur even in absence of product safety regulation (see Step 6). These estimates were used to estimate companies' annual regulatory compliance costs in Euro terms. The calculation of Euro-denominated costs for staff was based on the EU's (weighted) average wage for the business economy, which in 2019 was 27.50 Euro per hour[265]. To account for overhead costs, a 25% mark-up was added to staff-related costs. Subsequently, the costs for each company were related to the EU turnover for consumer products, i.e. companies' annual cost resulting from activities to comply with safety requirements for (all) consumer products as a share of the related turnover.

Step 5: Extrapolation of EU companies' annual costs related to the Directive including business-as-usual costs that occur also in absence of regulation

For each enterprise size class, the empirical median values for companies' relative product safety-related costs (Step 4) were multiplied by the annual turnover of EU companies that can be attributed to the production and/or sales of non-harmonised consumer products in the EU (Step 3). The results of this calculation still include business-as-usual costs.

Step 6: Deduction of business-as-usual costs and extrapolation of EU companies' annual compliance cost related to the Directive

In the GPSD Study, businesses were asked to indicate the share of the total product safety-related costs that they would incur anyway (i.e. even in absence of product safety legislation, e.g. because these costs relate to due diligence), hereafter referred to as business-as-usual costs, BAU. These estimates reflected the self-assessment of the companies that are part of the sample, and are therefore subjective in nature. However, as concerns differences between manufacturers, on the one hand, and wholesalers and retailers, on the other, it was considered that the estimates to be in line with expectations and a credible basis for the final step of the assessment. The empirical median values of these shares were applied to the product safety-related cost estimates derived in Step 5. Excluding business-as-usual costs, compliance costs of EU companies were obtained that can be attributed to non-harmonised consumer products, i.e. the costs for businesses to comply with the Directive.

5.2. Estimation of costs of compliance with the Directive for Member States (for efficiency criterion)

The estimation of market surveillance authorities' staff-related costs related to market surveillance activities for non-harmonised consumer products in the EU was based on the following three steps:

[264] Business stakeholders were asked to estimates average costs per month in EUR.

[265] Labour cost for LCI (compensation of employees plus taxes minus subsidies), provided by Eurostat.

Step 1: Identification of authorities' annual FTEs for market surveillance activities related to non-harmonised consumer products

The number of full time equivalent (FTE) staff for market surveillance of consumer products as provided in the country research was used. Where the available country estimates related to the market surveillance of non-harmonised consumer products, this figure was directly used in the calculation. Where estimates related to the total staff for market surveillance of both harmonised and non-harmonised consumer products, staff was allocated according to the 54%/46% ratio for harmonised/non-harmonised products circulating within the European Single Market to derive an estimate for related market surveillance activities[266]. It should be noted that a share of 46% in staff time for market surveillance of non-harmonised consumer products is 12 percentage points higher than the empirical median share indicated by authorities for activities devoted to non-harmonised products in the stakeholder survey (34%), potentially causing an estimate at the higher end of authorities' actual costs that can be attributed to market surveillance activities for non-harmonised consumer products. For seven countries, no information on staff numbers was available at all.

Step 2: Approximation of annual FTEs for market surveillance activities related to non-harmonised consumer products for countries for which data was not available

For the seven countries, for which no staff data was available (Croatia, Germany, Hungary, Italy Slovenia, Slovakia, and Spain) it was estimated the number of FTEs on the basis of the data for the remaining 20 Member States. To account for institutional differences with regard to the level of centralisation, it was considered that two clusters of countries, in line with the characteristics of the respective market surveillance systems as described above: Cluster 1: responsibility for market surveillance is centralised (no sub-national administrations involved); Cluster 2: responsibility for market surveillance is (partly) delegated to or competence of sub-national administrations, in line with the administrative structure of the country.

To derive estimates for the number of FTEs per million population for Slovenia and Slovakia (more centralised market surveillance), the sample median of 3.5 FTEs per million population was applied. To derive FTE estimates for the number of FTEs per million population for Croatia, Germany, Hungary, Italy and Spain (more decentralised market surveillance), the sample median of 4.6 FTEs per million population was applied.

[266] As mentioned before, the 2017 EU impact assessment for the new Market Surveillance Regulation estimated that about 54% of products circulating within the European Single Market are harmonised products and 46% are non-harmonised products. See SWD (2017) 466 final PART 2/4 Commission Staff Working Document Impact Assessment Accompanying the document COM(2017) 795.

Step 3: Calculation of annual staff costs for market surveillance activities related to non-harmonised consumer products

In the final step, it was calculated that the EUR equivalent of the estimated number of staff required for market surveillance of non-harmonised consumer products by multiplying the number of FTEs per million population by:

- The size of population for each country (in million);
- The number of person-hours per year (1 720) [267]; and
- The average wage of 28.00 EUR, which corresponds to the EU27 average wage of "administrative and support service activities" (18.70 EUR) and "professional, scientific and technical activities" (37.30 EUR) for 2017 (latest figure available in Eurostat database).

5.3. Methods for other supporting estimations (for effectiveness criterion)

Other supporting estimations include the analysis of data from the rapid alert system. Data from Safety Gate/RAPEX was used for the analysis of the baseline situation and the related problem analysis. For this purpose, a full dataset covering the years 2005 to 2019 was retrieved. The dataset consisted of a total of 25 850 notifications that are publicly available. The dataset included 25 051 notifications concerning products with serious risks, 738 notifications of products with other risk levels, and 61 other types of alerts. This dataset was merged with a second dataset covering notifications in the period 2011 to 2019, which included complementary (not publicly available) data.

[267] Following EU Horizon 2020 guidelines, one person year corresponds to 1 720 person-hours per year. See, e.g. the H2020 Programme: User's Guide for the Personnel Costs Wizard.

Appendix 3: Evaluation questions

Relevance

To what extent the initial objectives of the GPSD correspond to the current needs?
To what extent is there a need to clarify concepts set out in the GPSD, such as "product", "safe product", "serious risk" and "placing on the market"?
How well adapted is the GPSD to online sales?
How well adapted is the GPSD to challenges posed by new technologies, such as cybersecurity risks in relation to safety, self-evolving products and stand-alone software or emerging safety issues in the post-market phase of the product?
How well is GPSD adapted to increased level of direct imports towards the EU?
How well adapted is the GPSD to environmental issues with health impact? In particular, how this health impact is considered by taking into account the assessment done under REACH related to chemicals?

Effectiveness

To what extent does the GPSD meets its objectives of achieving a high level of consumer protection through the reduction of unsafe products and contributing to the functioning of the Single Market? Which are the main elements that have contributed to this? Is there anything missing?
To what extent has the market surveillance system established by the GPSD (in particular the Rapid Alert System for dangerous non-food products) been effective?
How has the development of e-commerce affected the effectiveness of the GPSD?
How has the development of new technologies, such as Artificial Intelligence, Internet of Things and connected devices, affected the effectiveness of the GPSD?
How effective has been the development and use of the standards supporting the implementation of the GPSD?
How well is GPSD adapted to ensure efficient corrective actions are taken, in particular recalls?
How well is GPSD adapted to ensure effective market surveillance?
Are there any aspects/means/actors that render certain aspects of the Directive more or less effective than others (including product recalls), and if there are, what lessons can be drawn from this?
What are, if any, the consequences or effects (either positive or negative) that were not originally planned?

Efficiency

What are the regulatory (including administrative) costs of the GPSD for the different actors involved (Member States authorities, businesses, consumers) and for the society overall? In particular, what is the economic cost for businesses to comply with the GPSD?
What are the benefits of the GPSD for the different actors involved (Member States authorities, businesses, consumers) and for the society overall?
To what extent are these costs proportionate to the benefits?
What factors influenced the efficiency of reaching the objectives which the GPSD sets out?

Coherence

Are there any discrepancies and/or inconsistencies between the provisions of the GPSD?
Are there overlaps and/or complementarities between the GPSD and any other Union legislation with similar objectives, in particular regarding market surveillance, product harmonisation legislation, including horizontal legislation on chemicals and food contact materials legislation, standardisation, consumer protection law and product liability, and also other union legislation such as the E-commerce Directive?
To what extent is the Directive coherent with wider EU policy, such as rules on free movement of goods, mutual recognition, customs, competition, industrial policy, sustainability (environmental protection) and trade?

EU added value

What is the added value of the GPSD compared to what could reasonably have been expected from Member States acting at national level?
What would be the most likely consequences of withdrawing the GPSD? How would it affect the functioning of the Single Market and the health and safety of consumers?

Appendix 4: Implementation of the Food Imitating Products Directive (FIPD)

Council Directive 87/357/EEC (the Food-Imitating Products Directive) was adopted to address the lack of harmonisation amongst national measures trying to ensure product safety of products 'appearing to be other than they are'. Before the adoption of the Directive, there were legal provisions or regulations in force in several Member States concerning certain products which, appearing to be other than they are, endanger the safety or health of consumers. However, these provisions differed in content, scope and field of application. In particular, these provisions concerned in certain Member States all products which resemble foodstuffs while not being such whilst in other Member States they concern products likely to be confused with foodstuffs, especially confectionery. This situation created significant barriers to the free movement of goods and unequal competitive conditions within the Community without ensuring effective protection for consumers, especially children.

The products covered by the FIPD possess, pursuant to Article 1(2), a 'form, odour, colour, appearance, packaging, labelling, volume or size' that consumers, especially children, could confuse with foodstuffs, and endanger health of safety of consumers (Article 1(1)). The fact that these products imitate foodstuffs could then lead to consumers putting such products in their mouths, sucking or ingesting them, which could be dangerous. This led the European legislator to provide that Member States should take all measures necessary to prohibit the marketing and introduction of such products on the market[268] through the above-mentioned Directive. The justification for the adoption of this measure was twofold: to improve consumer protection, especially the protection of children, as well as to ensure a level-playing field on the Internal Market of such products. The latter goal aimed at eliminating barriers to the free movement of goods that could imitate other products, but which would not create serious risks to consumer protection.

While most Member States have implemented the Food-Imitating Products Directive into national legislation as in the Directive, without additional provisions, there are differences in interpretation. Some authorities perceive products in this category as dangerous per se, whilst others are of the opinion that any serious risks need to be proven through an appropriate risk assessment procedure. Indeed, the Food-Imitating Products Directive has been adopted before the GPSD, which sets out the principle of the necessity of risk assessment of the product safety before taking appropriate measures against products and some Member States started to apply to food-imitating product the GPSD logic while others stayed at the primary interpretation of the Food-Imitating Products Directive as a ban of these products. This had then led to differences in the national assessment whether a particular food-imitating product should be prohibited from the market. However, the number of Safety Gate/RAPEX notifications of food-imitating

[268] Article 2 Food Imitating Directive.

products is small. Between 2013 and 2019, a total of 114 notifications that relate to food-imitating products[269]. The table below shows the product categories for these notifications in the period 2013 to 2019. The number of notifications of food-imitating products is fairly small – up to 36 notifications out of the approximately 2 000 notifications annually. The number has varied significantly over the years, from 1 to 36 notifications annually.

Table 9: Notifications to Safety Gate/RAPEX related to food-imitating products

Product category	Year							Total
	2013	2014	2015	2016	2017	2018	2019	
Cosmetics				3	1	28	1	33
Decorative articles	1			1		4	17	23
Food-imitating products	26	12	8					46
Other							2	2
Stationery							2	2
Toys		1				4	3	8
Total	***27***	***13***	***8***	***4***	***1***	***36***	***25***	***114***

Source: Safety Gate/RAPEX

The table shows that the product category "Food-imitating products" was only used up to 2015. Afterwards, the products have been categorised according to their use (cosmetics, clothing, etc.). This seems to indicate that a change of practice has occurred in the Member States to remove the overlap between the category "food-imitating products" and other product categories. Most of these notifications makes reference to the Food-Imitating Products Directive in the description of the risk and include a statement like "The product does not comply with the Food-Imitating Products Directive." Apparently, many authorities ban a food imitating product because the Food-Imitating Products Directive directly bans such products without the need for a risk assessment. However, this raises questions regarding the proportionality of such measures.

The vast majority of the notifications related to food-imitating products (87%) mentions or includes choking in the description of the risk associated with the product, presumably because the product is or contains small parts. The second-most common risk type is "chemical" (12%).

There is little evidence available regarding the adverse effect of food-imitating products. A 2011 opinion by the Scientific Committee on Consumer Safety concluded that "Few cases of accidental ingestion of food-resembling or child-appealing products are reported. This may be due to the lack of sufficient registered information to discriminate these

[269] These are identified in different ways, and some cases meet several of the criteria at the same time: The parameter "Category" includes "Food imitating products" (46 notifications); The parameter "Product" includes the text "imitat" (6 notifications); The parameter "Description" contains the text "imitat" (46 notifications); The parameter "Risk" contains the text "imitat" (57 notifications). Cases that were identified using the filtering term "imitat" have subsequently been reviewed manually to remove cases that did not refer to food (e.g. notifications related to "leather imitation", "imitation of gun", etc.)

types of products. Data from poison centres and scientific literature on accidental ingestion of cosmetics or liquid household products suggest that the majority of such ingestions result in mild gastrointestinal effects. […] The weight of evidence from accidental ingestion of cosmetics suggests that there is a low risk of acute poisoning in either children or the elderly. For household products, there is a slight increase of a more serious outcome". From the opinion, which focused on chemical consumer products resembling food and/or having child-appealing properties', it appears that these food-imitating products rarely represent serious or high risks. However, the opinion also concludes that "there is a lack of specific data on accidental ingestion from consumer products resembling food and/or having child-appealing properties".

It can therefore be concluded that while a majority of Member States seems to apply the provisions of the Food-Imitating Products Directive only in cases where the risks are serious, there are also countries that consider products in this category as dangerous per se. In other words, the legal framework for food-imitating products is applied differently in different countries.

Annex 6: Effects of the COVID-19 crisis in the context of the policy options and their expected impacts

The analysis of the impact of COVID-19 in the Study underlying the GPSD Evaluation and Impact assessment is based on macroeconomic data and a series of interviews conducted with companies active in (also) non-harmonised consumer products. The Study explored the companies' views on the policy options and potential effects of COVID-19 in this respect, as well as expectations concerning relevant long term, structural changes.

In terms of **structural changes** that would need to be considered for changes in the EU legislative framework in general, interviewees expected:

- A change in consumer behaviour towards **more quality products** that are also **more eco-friendly**;
- **Energy efficiency** will be an important topic and people will likely buy more **sustainable and environmentally friendly products**;
- **Promoting the reuse, refurbishment and recycling of used products**;
- **A stronger focus on hygiene** is expected, and the safety of these products will have a more prominent role for consumers.

Furthermore, in the short-term, interviewees expected **practical difficulties in conducting market surveillance for authorities due to COVID-19 restrictions.** An interviewee noted that COVID-19 had led to a reduction in controls. Accordingly, this interviewee considered that the need for a clearer GPSD has increased as it would help conducting market surveillance more effectively in the 'new normal' with less visits of inspectors.

Interviewees also expected in the medium-term to long-term that reduced public budgets (due to potential austerity measures after the pandemic) would mean that the **downward trend in market surveillance capacities in Member States** that they had noted after the financial crises would continue. According to their view, this would increase the need for a less complex legal framework and a (resulting) more efficient market surveillance, more efficient recall procedures, and increased support through EU programmes.

Concerning the impacts of the options for a possible revision of the GPSD, interviewees emphasised the **overall impact of COVID-19 on the baseline situation**, i.e. the increased importance of e-commerce, including with third countries, which was expected to put additional demands on authorities in terms of online market surveillance. **Safety of products sold online** is therefore expected by interviewees to become more important, which would make **Options 3 and 4** (and especially the suggested changes regarding online sales and online marketplaces) **more relevant**. All interviewees stressed the importance of having a **common set of rules in the EU**, and of **reducing administrative burdens**, e.g. to explore differences in legislation between countries. Interviewees also emphasised that **good guidance** would help in decision-making of companies.

The Study concludes that the **COVID-19 crisis has increased the need for reducing existing, and avoiding additional administrative burdens, while the growing**

importance of online sales channels has emphasised the need to close related legislative and enforcement gaps.

Annex 7: SMEs Test

The results of the SMEs test, based on the data from the GPSD Study and other consultation activities, are summarised in the following table:

(1) Preliminary assessment of businesses likely to be affected
All businesses handling consumer non-harmonised products are likely to be affected, including SMEs. For **SMEs**, the estimated annual **costs to comply with the GPSD today** (after subtraction of business-as-usual costs) are **EUR 428 million per year** (companies < 50 employees) and **EUR 226 million per year** (companies 50 to 249 employees). The median value for consumer product safety-related costs in proportion of the total annual turnover appears to decrease with the company's size/turnover. This is likely due to scale effects. This general pattern is confirmed by SMEs' replies to the business stakeholder survey in the GPSD Study. Accordingly, SMEs account for 59% of the total of GPSD-related compliance costs in the EU, in line with their overall share in the market. (See section 5 of the Impact Assessment Report, baseline scenario)
(2) Consultation with SMEs representatives
EU SMEs and SMEs associations have been consulted during the preparation of the Evaluation and Impact assessment. For the GPSD Study, considerable efforts were made to reach out to businesses, including SMEs and their representatives. The survey questionnaires were widely distributed amongst SMEs and other business stakeholders as follows: questionnaires were sent to more than 1000 SMEs and other businesses and more than 300 relevant business associations (including UEAPME, BusinessEurope, Digitaleurope, EMOTA, EuroCommerce, etc) in all EU27 Member States (plus UK). Only relatively low number of direct responses were received from SMEs in the GPSD Study (6 survey responses from SMEs, 2 interviews with SMEs, 37 survey responses from business associations, which often also represent SMEs (e.g. Toy industry, furniture Industry, etc.). However, no response was received from business associations that only or specifically represent SMEs. Business associations representing SMEs also provided feedback on the GPSD Roadmap/Inception Impact Assessment and replied to the Open Public Consultation (16 replies received from SMEs and 68 from business associations). ***Consultation results:*** In the survey conducted for the GPSD Study SMEs did by large provide similar assessments to companies in general. However, SMEs responding to the survey only reported 'minor' additional costs due to differences in the safety requirements in Member States that are caused by differences in the national implementation of the GPSD (e.g. regarding traceability requirements). In contrast to larger companies, none of the SME respondents indicated 'moderate' or 'significant' additional costs due to differences in the national implementation of the GPSD. A possible reason is that larger companies are more likely to operate in several EU Member States than SMEs, and therefore experience relevant legislative differences more often. Also notable is that in the assessment of the effectiveness of options, as well as concerning the benefits they bring, business associations often provided considerably lower assessments than companies, including SMEs, especially regarding policy options involving legislative change. **Specific views of SMEs on the impact of COVID 19 crisis include:** • Regarding the question of how the COVID-19 pandemic has in any way affected how product safety in companies is safeguarded and any related supply chain issues, an SME respondent mentioned that testing for new devices is taking longer due to delays related to the pandemic.

Such delays for example in supply chain functioning can have a particularly detrimental effect on business activity of SMEs.

- A SME respondent also stated that the pandemic is likely to have an impact on long-lasting, structural changes of the 'new normal' in behaviour and economy that are significant for SMEs. For example, people are expected to buy more sustainable and environmentally friendly products.
- Regarding the question of how the COVID-19 crisis affects the policy options and their expected impacts, one SME respondent stressed that it was a bad time to be bringing in additional regulations for businesses. The interviewee mentioned that many businesses are really struggling, and that this is especially the case for SMEs. He continued that these challenges, including for SMEs, also arise from changing consumer habits.
- However, one SME respondent also argued that better clarification of rules would reduce costs significantly. Cost reductions would take place on the sales level, i.e. less explanation to buyers and insurance companies, and the design and manufacturing level, i.e. less explanation of product safety requirements to engineers. But the SME respondent also stated that one-off costs would generally increase for all regulatory options except for Option 1 due to familiarisation costs occurring in the organisation, i.e. explaining the new rules internally and externally. And these costs are especially significant for SMEs, according to the interviewee.

(3) Measurement of the impact on SMEs

The Impact assessment comes to the following conclusions regarding the impacts on SMEs of the different options (see Section 6 of the Impact assessment Report):

Option 1: No significant **firm-level impacts** are to be expected due to the implementation of Option 1 for SMEs. Option 1 does not foresee any legislative changes to the GPSD and therefore no new requirements but also no possibilities for more costs efficiencies for SMEs.

Option 2:
Total costs for SMEs in the EU27 in the first year of implementation are estimated at **EUR 21 million**. They would fall in **subsequent years** down to **EUR 16.6 million**.
Estimated **benefits for SMEs** linked to cost **savings**, that are currently **caused by differences in the national implementation** of the GPSD and would be partly solved if a the new instrument is a Regulation under the Option 2, would amount to **EUR 34 million annually**, compared to the baseline. Idem for Options 3 and 4 which already foresee the choice of Regulation as legal instrument replacing GPSD.
SMEs generally estimate that a revision of the product safety requirements of the GPSD according to Option 2 would bring a variety of **at least 'minor' to 'moderate' benefits**[270]. At the same time Option 2 would impose **additional adjustment** (e.g. **familiarisation cost**) as well as **compliance costs on SMEs**[271], in particular for manufacturers. Data show that SMEs would likely face relative higher compliance costs than large companies from the implementation of the proposed policy measures.
Even though the relative cost increases are generally higher for SMEs, t**he net impact on SMEs overall costs depends on the benefits** that can result from a revised GPSD aligned to the market

[270] Significant benefits due to improved quality/lifecycle of products and a deterrent effect on rogue traders, relatively strong benefits are increased consumer trust, better supply chain management due to improved traceability of products and better access to the market in non-EU/EEA. These areas are seen as benefits that SMEs assess to be 'moderate' to 'significant'. This is also the case for lower operational risks for businesses and easier compliance with product safety requirements. By contrast, SMEs considered several benefits to be less than 'moderate', including a more level playing field among businesses and greater legal certainty.
[271] This is particularly the case for SMEs that (voluntarily) decide to install and operate customer registration systems. Similarly, mandatory elements for product recalls (product description with a photograph, description of risk, instructions on what to do, link to a recall website and free phone number or online service for queries) would increase the cost of SMEs that have put unsafe consumer products to the market.

surveillance rules and traceability requirements in Regulation (EU) 2019/1020. We expect the **SMEs could save some of the costs that currently arise from inconsistencies in the implementation and enforcement of the GPSD across the EU**. Taking into consideration these benefits and the fact that the changes in SMEs' costs from Option 2 are very small, we expect that the **overall net effect from Option 2 on SMEs' costs is rather low** and therefore unlikely to affect SMEs' operations. This is also confirmed by cost data above.

Option 3:
Total costs for SMEs in the EU27 in the first year of implementation are estimated at **EUR 111 million**. They would fall in **subsequent years** down to **EUR 99.9 million**.
Estimated **benefits for SMEs** linked to cost **savings** that are currently **caused by differences in the national implementation** of the GPSD and would be partly solved by the choice of Regulation and would amount to **EUR 34 million annually**, compared to the baseline.
As concerns the benefits for **SMEs**, the GPSD Study shows that ***small companies*** generally estimate that Option 3 would bring a variety of at least 'minor' to 'moderate' benefits, especially due to its **deterrent effect** on rogue traders and **better detection of unsafe product**s. However, Option 3 is considered by small companies as less beneficial when it comes to reducing legal complexity or making compliance with product safety requirements easier for SMEs. In the case of ***medium-sized companies***, Option 3 is seen as a **suitable contribution to an increased level-playing field** among businesses and to have a significant benefit linked to reducing the occurrence of unsafe products and for contributing to a better functioning of the EU internal market. Finally, moderate benefits are expected regarding the potential to increase business revenue or consumer trust.
Even though the relative **cost increases are generally higher for the SMEs**, the impact on SMEs overall costs is still considered moderate when measured against the benefits that would result from a greater level of regulatory harmonisation and reduced regulatory complexity through the choice of a Regulation. The changes in SMEs costs are estimated to be limited and Option 3 would not be expected to affect operations considerably[272].

Option 4:
Total costs for SMEs in the EU27 in the first year of implementation are estimated at **EUR 187.1 million**. They would fall in **subsequent years** down to **EUR 166.3 million**.
Estimated **benefits for SMEs** linked to cost **savings** that are currently **caused by differences in the national implementation** of the GPSD and would be partly solved by the choice of Regulation and would amount to **EUR 34 million annually**, compared to the baseline.

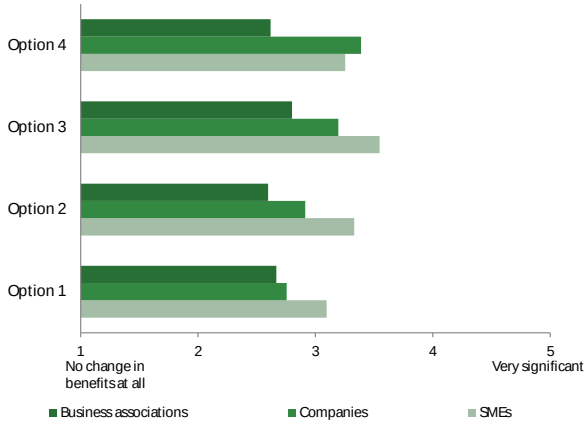
Overall, under **options 2 to 4**, the effects of additional compliance costs will have a **larger relative cost impact on SMEs** than on large companies. Even though the relative cost increases are higher for SMEs, the impact on SMEs overall costs is **still considered moderate when measured against the benefits** that would result from a greater level of regulatory harmonisation. The changes in SMEs costs are small and implementation of any of the options would not be expected to significantly affect SMEs.

Figures 1 and 2 below show that SMEs assess Option 3 as addressing the best the challenges for product safety and bringing the highest additional benefits among all the options:

[272] This consideration is also true for specific information obligations, such as the obligation for actors across the online supply chain to provide all safety information online that is also required to be provided with a product in 'brick and mortar' stores, and the related obligation for online platforms to make sure that third-party sellers, such as SMEs, provide this information. We expect these costs to be relatively minor for companies selling consumer products on these platforms, including SMEs.

Figure 1: In your view, to what extent would Option [...] effectively address the following challenges for product safety? – Average across all challenges, by business stakeholder group (Source GPSD Study)

Figure 2: Where do you see the greatest additional benefits that would result from the implementation of Option […]? – Average across all benefit categories, by business stakeholder group (Source GPSD Study)



Options 3 and 4 are seen as providing most benefits by companies overall, as well as SMEs as specific sub-group, which assessed these benefits on average between 'moderate' and 'significant'. While SMEs consider Option 2 to also bring more than 'moderate' benefits, companies as a whole and business associations are more sceptical, with an assessment on average across benefit categories of less than 'moderate' benefits regarding Option 2. In general, business associations tend to see less benefits than companies and SMEs. Note however, that the sample of SMEs responding to the survey is very small, so that results have to be interpreted with care.

4) Assess alternative options and mitigating measures

The **SMEs and micro-SMEs are not exempted** from any of the obligations foreseen under the different options analysed in this Impact Assessment. Indeed, EU product safety legislation does not allow for "lighter" regimes for SMEs since a consumer product must be safe whatever the characteristics of its supply chain to meet the general objective of product safety and consumer protection. However provisions are foreseen in the EU legislation e.g. to facilitate access for SMEs to EU safety standards including those adopted under the GPSD (see Article 6 of Regulation (EU) 1025/2012). (See Section 5 of the Impact Assessment Report)

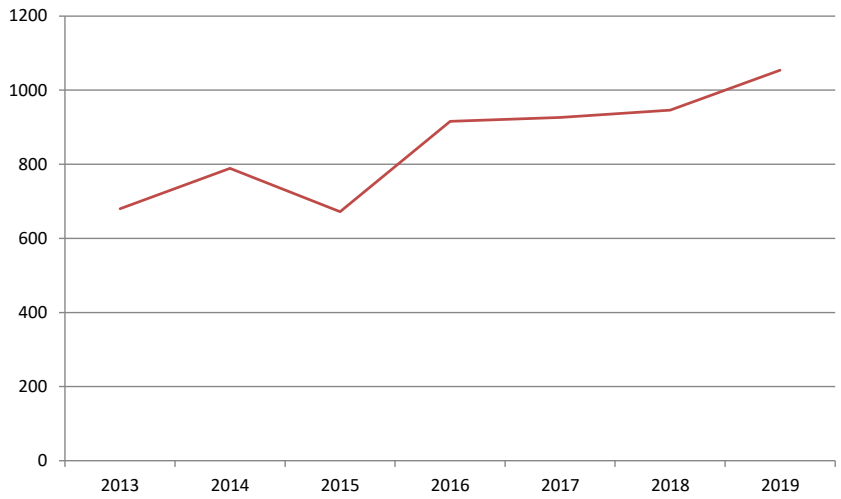
Annex 8: Effectiveness of recalls of consumer products

1. CONTEXT

1.1. Prevalence of recalls in the EU

Product recalls are one of the most common measures to mitigate the risks posed by dangerous products in the EU[273]. Among the over-2000 measures reported each year to the Safety Gate/RAPEX[274], about half concern recalling products from consumers. A total of six thousand recalls have been notified in the system from 2013 to 2019, with an overall increase of approximately 35% (see Figure 1). These figures are likely an underestimation, as not all recalls in a country are necessarily notified at EU level[275].

Figure 1: Number of recalls registered in the Safety Gate/RAPEX in 2013-2019



The increasing trend can to a large extent be attributed to the increase in the number of recalls concerning motor vehicles, which grew by a factor of more than 3 from 159 recalls in 2013 to 507 (i.e. 48%) in 2019. Apart from motor vehicles, the five most frequently recalled product categories according to Safety Gate/RAPEX alerts were toys; clothing and textiles; electrical appliances and equipment; lighting equipment; and childcare articles and children equipment.

[273] By the term "recall" we refer to the process aimed in particular at achieving the return of a dangerous product that has already been supplied to consumers, initiated directly by the producer or distributor of the dangerous product, or ordered by authorities.

[274] https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/content/pages/rapex/index_en.htm

[275] As regards products posing a less than serious risk, notification is encouraged but not mandatory in the case of voluntary measures taken against products covered by the GPSD and in the case of both voluntary and compulsory measures taken against products subject to EU harmonised legislation. In addition, Member States are not required to notify corrective measures in cases where the effects of the product risk cannot go beyond the territory of the Member State.

1.2. Legal provisions

Under the GPSD, producers and distributors have to inform immediately the competent national authorities when they become aware that a product they have placed on the market is dangerous, giving details of the actions taken to prevent risks to consumers[276].

Producers have the primary responsibility for the safety of products they place on the market. If necessary to avoid risks to the health and safety of consumers, they have the obligation to take appropriate action (including withdrawing the dangerous product from the supply chain, warning consumers or, as a measure of last resort, recalling products that have already been supplied to consumers)[277].

Distributors have to act "with due care" and must not supply products which they know are unsafe. They also have to cooperate in the action taken by producers and competent authorities to avoid the risks and pass on information on product risks[278].

Member States authorities have the power to order a recall or to coordinate or, if appropriate, to organise it together with producers and distributors[279]. In general, authorities shall encourage and promote voluntary actions by producers and distributors, including where applicable by the development of codes of good practice. However, if voluntary action is unsatisfactory or insufficient, they shall order the measures or organise them themselves[280].

There are no specific rules at the EU level on how a recall should be organised. The GPSD only states that "recall shall take place as a last resort, where other measures would not suffice to prevent the risks involved, in instances where the producers consider it necessary or where they are obliged to do so further to a measure taken by the competent authority" and that it "may be effected within the framework of codes of good practice on the matter in the Member State concerned, where such codes exist".

In fact, few Member States have established such codes of good practice or guidelines on recalls (see table 1 below). In addition, most consist of a very brief description of the recall process with little further requirements.

Table 1: National guidance documents on recalls

Country	Website
Austria	https://www.sozialministerium.at/Themen/Konsumentenschutz/Produktsicherheit/Gefaehrliche-Produkte-und-Rueckrufe.html
Belgium	https://economie.fgov.be/fr/themes/qualite-securite/securite-des-produits-et/rappel-dun-produit-ou-autre
Denmark	https://www.sik.dk/erhverv/produkter/vejledninger/generelle-vejledninger-om-produkter/tilbagetraekning-og-tilbagekaldelse-produkter
Finland	https://tukes.fi/en/products-and-services/dangerous-products
France	A guide on product recalls is being developed
Germany	https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-

276 GPSD Art 5 (3).
277 See GPSD Art 5 (1), (b) of the third subparagraph, and last paragraph.
278 GPSD Art 5 (2).
279 GPSD Art. 8(1)(f)(ii).
280 GPSD Art. 8(2).

	Produkte/Produktsicherheit/Rueckrufmanagement/Handlungsempfehlungen.html https://www.baua.de/DE/Themen/Anwendungssichere-Chemikalien-und-Produkte/Produktsicherheit/Rueckrufmanagement/Rueckrufmanagement_node.html
Norway	https://www.dsb.no/lover/produkter-og-forbrukertjenester/veiledning-til-forskrift/veileder-om-meldeplikt-ved-farlige-produkter/
Sweden	https://www.konsumentverket.se/for-foretag/produktsakerhet/salt-farlig-vara/

In the absence of EU-wide rules on recall procedure, communication or remedies, each Member State follows its own approach, with some common elements (e.g. in most countries, voluntary recalls are more common than mandatory ones), but also diverging requirements.

The increase in the number of product recalls over time and the fact that most recalls take place voluntarily can be considered as an indication that the GPSD has contributed to making recalls more widely used as a corrective measure. On the other hand, the lack of minimum EU-wide requirements regarding recall communication, remedies or monitoring has been repeatedly reported as a significant shortcoming, with negative impacts on consumer safety and on level-playing field for businesses.

2. ASSESSMENT OF RECALL EFFECTIVENESS

The effectiveness of product recalls varies considerably depending on factors such as customer traceability and product type. Recalls tend to be considerably more effective, if affected consumers can be identified and contacted directly (e.g. because the product was registered, bought online or delivered to customer's home). Recall effectiveness also increases with product price and expected lifespan and decreases with product age. In the automotive sector, up to 100% success rates have been reported, thanks in particular to mandatory motor vehicle registration[281]. Likewise, Samsung's recall of over 4.6 million Galaxy Note7 phones resulted in 90% return rate within four months and a further 7% within 7 months thanks to the sending of over 23 million alerts and push notifications to the company's customers and a software update that reduced battery capacity up to 0%[282].

Success rates tend to be much lower for cheaper products and when it is not possible to reach out to affected consumers. In general, the proportion of products successfully recovered from consumers remains low, as recognised by a recent OECD report[283]. For instance, one Member State indicated that the return rates for recalled products rarely exceed 10%, except when products have been purchased online[284]. Another national authority estimated that around 80% of products that have relatively low value and short lifespan remain in consumers' hands[285].

Recall participation also depends on consumers' characteristics. Socially disadvantaged, relatively young and less safety-conscious consumers are less likely to both participate in recalls (especially if such participation is time-consuming) and to register their products

281 German Federal Motor Transport Authority (KBA) presentation at the Interrnational Product Safety Week, 11/10/2010, https://youtu.be/S-RGd4jVhvQ, iTWire (2021). Car manufacturers complete 99.9% of Takata airbag recall, https://www.itwire.com/automotive/car-manufacturers-complete-99-9-of-takata-airbag-recall.html.

282 OECD (2018), Measuring and maximising the impact of product recalls globally, p. 9.

283 OECD (2018), Enhancing Product Recall Effectiveness Globally, p. 5.

284 Idem, p. 17.

285 European Commission, 2021, Behavioural study on strategies to increase the effectiveness of product recalls.

(making them more difficult to contact in case of a recall)[286].The EU-wide societal cost of recalled products remaining in consumers' hands have been estimated at approximately €378 million in 2019 due to healthcare costs, productivity losses and losses of quality of life.[287]

The consequences of delayed and badly managed recalls are also exemplified by the deaths and injuries caused by products such as faulty Takata airbags (estimated to have cause 35 deaths and 300 injuries worldwide[288]) and Fisher-Price rock 'n play baby sleepers (associated with 59 baby deaths in the US[289]).

3. REASONS FOR LIMITED RECALL EFFECTIVENESS

3.1. Many consumers are not aware of product recalls

The main obstacle to recall effectiveness is the difficulty of reaching out to the owners of recalled products, which means that many EU consumers are simply not aware that they own a recalled product.

3.1.1. Limited direct communication with consumers

There is a general agreement that direct communication with consumers (e.g. via email, telephone, SMS or connected devices) is more effective not only in reaching affected consumers but also in encouraging consumer response compared to indirect methods such as press releases or recall announcements published on companies' and authorities' websites. In an online experiment carried out by the European Commission 72% of respondents who were presented with a direct recall notification acted on it compared to 31% of respondents who saw a generic notification with the same description of hazard, action to take and remedy. Based on these figures, the EU-wide cost savings from using direct recall communication have been estimated at €73 million in 2019, i.e. a fifth of the overall estimated cost of recall ineffectiveness[290].

Effectiveness of generic vs direct recall notification

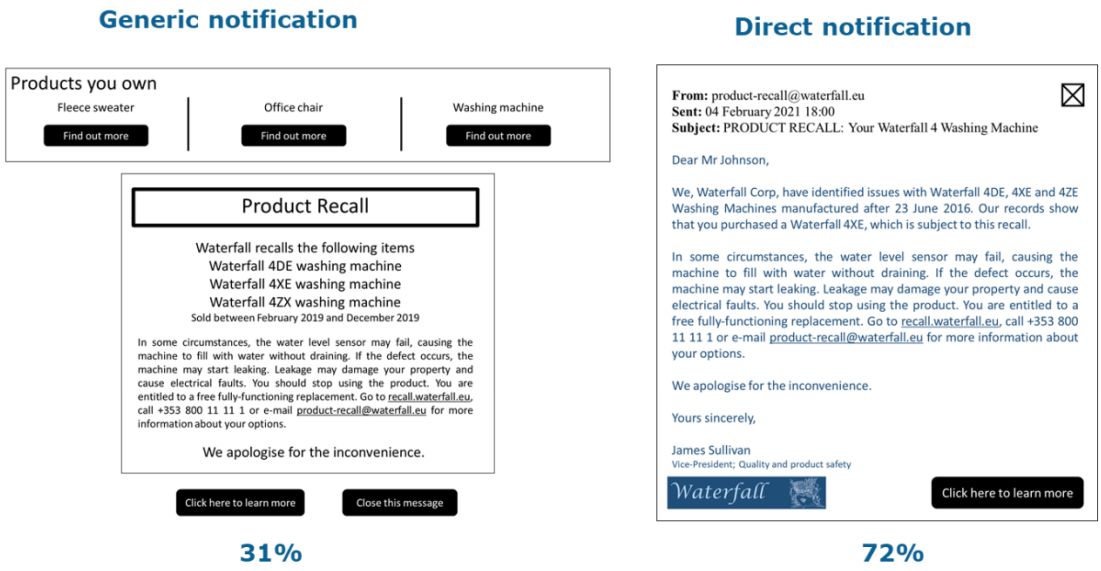
[286] Idem.

[287] Idem.[288] https://www.consumerreports.org/car-recalls-defects/takata-airbag-recall-everything-you-need-to-know/

[288] https://www.consumerreports.org/car-recalls-defects/takata-airbag-recall-everything-you-need-to-know/

[289] https://www.washingtonpost.com/gdpr-consent/?next_url=https%3a%2f%2fwww.washingtonpost.com%2fbusiness%2f2019%2f10%2f17%2fstudy-concludes-design-rock-n-play-other-infant-sleepers-led-deaths%2f

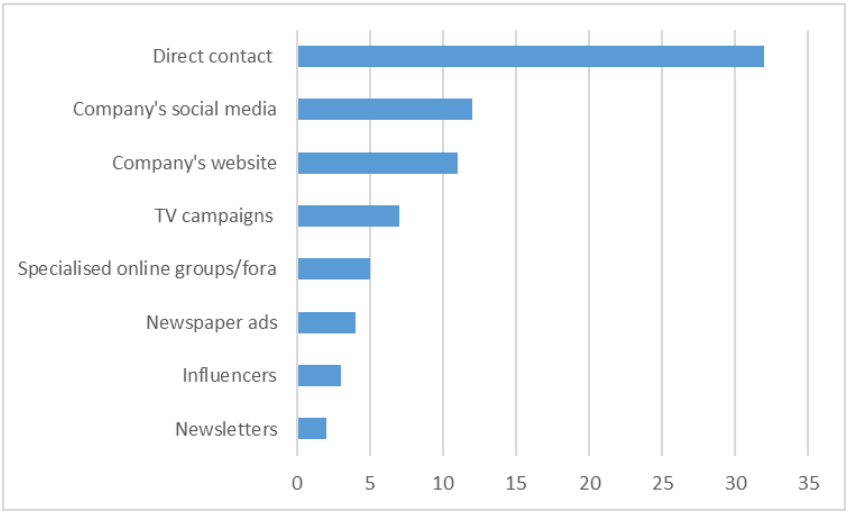
[290] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.



Source: Online experiment

Direct contact is also seen as the most effective communication channel by industry stakeholders[291] and indicated as the preferred communication method by all consumer groups[292].

Effectiveness of different communication channels (sum of replies: 'effective' and 'very effective')



Source: Online industry survey

These findings are corroborated by actual recall monitoring data from the US Consumer Product Safety Commission (CPSC), which found that direct recall alerts result in an

291 Idem.

292 European Commission (2019). Survey on consumer behavior and product recalls effectiveness, p. 20, available at: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/Product.Recall.pdf.

average return rate of 50% compared to 6% for joint press release issued by the CPSC and the recalling company[293].

Yes, authorities interviewed for the GPSD Implementation Study recognised that identifying and directly reaching out to affected consumers is a challenging task. The Directive does not contain any requirements on consumer traceability. As for national guidance documents, Finnish and Belgian ones require that affected consumers be contacted directly, whenever feasible, but in most countries there are no similar requirements.

For most recalled products, customer data is not available and even in situations when it is available, it is not always used to reach out to the owners of recalled products because of data protection concerns.

3.1.1.1.Suboptimal use of product registration schemes

When a consumer registers a product, he or she provides information (e.g. an email address) that personally links them to this product and allows for direct contact in case of product recalls or safety warnings. Yet, apart from motor vehicles (whose registration with public authorities is mandatory), registration schemes are only available for few higher-value product categories like domestic electronic appliances and communication devices[294]. In addition, even in these sectors actual registration rates tend to be rather low. In a recent consumer survey, declared registration rates were 37% for communication devices, 33% for domestic electrical appliances, 24% for childcare articles and 8% for toys[295].

The main barriers to product registration include:

- **No link between product registration and safety:** Research on existing EU registration schemes indicated that product safety is in general not highlighted in the analysed registration schemes and the main benefit of registration is framed in terms of general customer support or marketing. Only 4 out of the 40 analysed schemes mentioned product safety as a sole or one of the benefits of product registration in the invitation to register[296]. As a consequence, consumers seldom see the safety benefit of registering their products. Only 40% of consumers across the EU indicated they are aware of the possibility to register their products for safety purposes[297]. In a more recent consumer survey, the most frequently-reported reasons for not registering a product were not knowing that registration was possible (42%) and not seeing the

293 CPSC (2017), CPSC Defect Recall Data Carol Cave Deputy Director, Office of Compliance and Field Operations July 25, 2017, available at: https://www.slideshare.net/USCPSC/cpsc-recall-effectiveness-workshop-recall-data. (The US CPSC classifies a case as a 'recall alert', if the company is able to contact 95% of affected consumers using direct notification channel, in which case no press release is required).

294 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

295 Idem

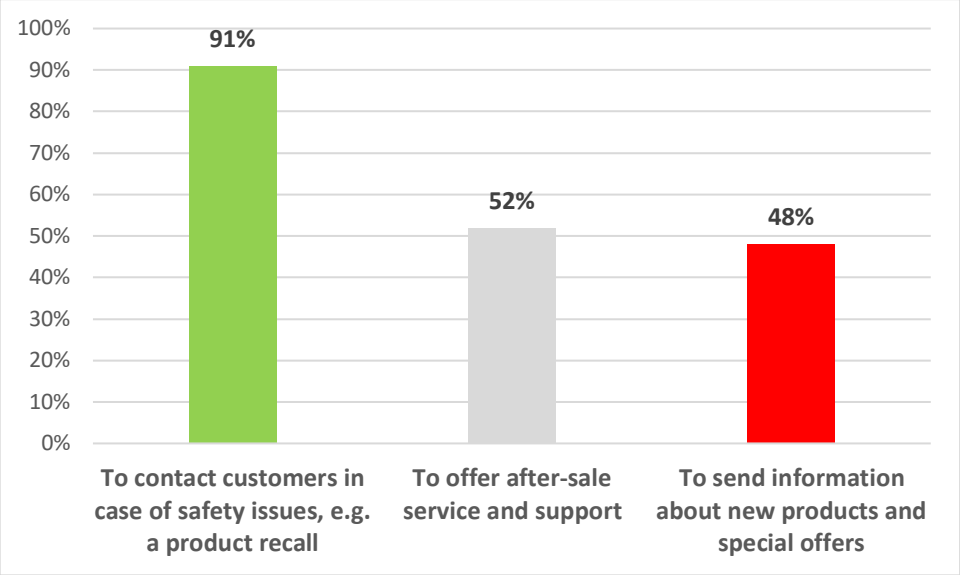
296 Idem

297 European Commission, 2019, Survey on consumer behaviour and product recalls effectiveness. Final Report https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/ Product.Recall.pdf

benefit of registration (25%)[298]. Likewise, in consumer focus groups, participants associated product registration with warranty or after-sales support but did not make a link between registration and safety[299].

- **Data protection concerns:** While the majority of 40 analysed registration schemes did envisage the use of registration data for safety notifications or general product support in their privacy/data notices, in all but two cases, the notices also mentioned marketing/after-sales communications in addition to safety communications. In addition, only in a minority of cases consumers were given the choice to opt in or out from marketing communications[300]. In the online industry survey, half of respondents said that they used customer information received through product registration to send marketing information.

Use of customer information obtained through product registration (N=23)



Source: Online industry survey

At the same time, concerns about how their personal data will be used is a major concern for consumers. In the EU focus groups, a key reason participants provided for not registering their products was that they felt uncomfortable about providing personal data, which they feared would be used for targeted advertising (profiling) and other marketing purposes[301]. Likewise, in a US survey, 59% of respondents were concerned about unwanted communication from the company after registering a product and 79% said they would be more likely to register products if companies were prohibited from contacting consumers for non-safety-related issues[302].

298 European Commission (2021), Behavioural study on strategies to improve the effectiveness of product recalls.

299 Idem

300 Idem

301 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

Schoettle, B., Sivak, M. (2015). Consumer Preferences Regarding Product Registration. (Report No. UMTRI-2015-26), available at:

The possibility to use product registration data for marketing purposes has been limited in some third countries. For instance, the US mandatory product registration card for childcare products needs to provide clear reassurance to consumers that the information provided will only be used in case of safety alerts and recalls[303]. Likewise, the UK code of practice recommends that consumers should be asked to consent to their contact details being recorded exclusively for product safety purposes, without having to opt in or out of marketing communication[304].

- **Effort required:** While most products are registered (with the manufacturer) after the actual purchase, the point of sale has been identified as the key moment during which consumers can be prompted to register their products[305]. In an online experiment carried out by the European Commission, considerably more respondents clicked on an invitation to register a product when they saw it at the check-out (45%) than when they saw it after completing the purchase, either as part of the packaging (14%) or as a general registration campaign (10%)[306]. The amount of information that needs to be retrieved and/or filled in can also act as a deterrent. In the online experiment, when the product information was pre-filled (mimicking for instance QR code scanning), 87% of respondents completed the registration compared to 63% when they needed to fill in the information themselves[307]. Finally, time limits for registration or the requirement to provide a proof of purchase may make it more difficult or even impossible to register many products, in particular those received as gifts or bought second-hand[308].

3.1.1.2. Other sources of customer data not routinely used for recalls

Data allowing to link customers to specific purchases is also routinely collected by companies through other sources. While customarily intended for marketing promotion, loyalty programmes and other data (e.g. digital receipts or delivery records) held by retailers can also enable identification of consumers in case of product recalls. A third source of consumer data that could be used for recall purposes is the consumer information provided in the context of online purchases. Purchasing a product directly from the online seller implies that customer's contact details are is registered automatically and the online seller can hence easily use the information provided in the event of a product recall. When the purchase takes place through an online marketplace, depending on its business model, the marketplace can either notify consumers directly or request the sellers to do so in the event of a recall campaign. Similarly, the data held by

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http://deepblue.lib.umich.edu/bitstream/handle/2027.42/116020/103219.pdf?sequence=1&isAllowed=y[303]See:https://www.cpsc.gov/Regulations-Laws--Standards/Rulemaking/Final-and-Proposed-Rules/Consumer-Registra-tion-of-Durable-Infant-or-Toddler-Products/

[303]See:https://www.cpsc.gov/Regulations-Laws--Standards/Rulemaking/Final-and-Proposed-Rules/Consumer-Registra-tion-of-Durable-Infant-or-Toddler-Products/

[304] UK Department for Business, Energy & Industrial Strategy (BEIS), 2018, Supporting better product recalls: Code of practice on consumer product safety related recalls and other corrective actions https://www.bsigroup.com/en-GB/pas7100-supporting-better-product-recalls/

[305] Notes from EU expert workshop on recall effectiveness of 23/10/219, p. 3, U.S. Consumer Product Safety Commission (CPSC), 2017, Transcript of Recall Effectiveness Workshop, 25 July 2017, pp. 21-29. https://www.cpsc.gov/Recall-Effectiveness.

[306] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

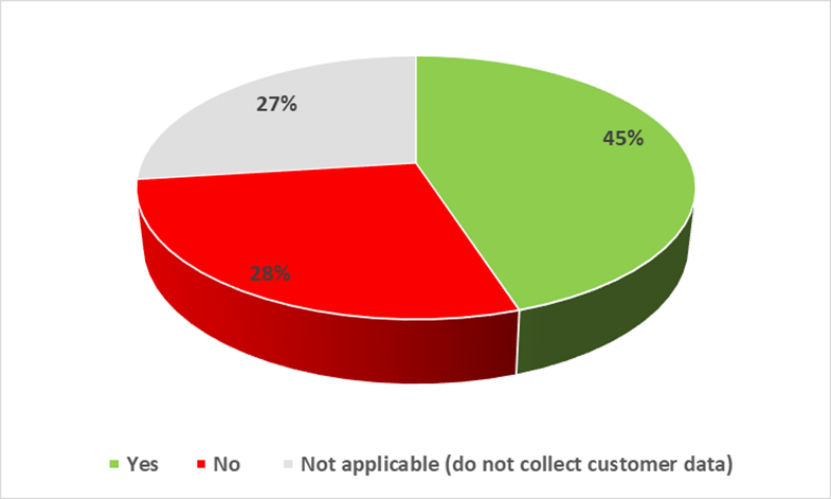
[307] Idem

[308] Idem

payment card providers or insurance companies could also be used to inform consumers about relevant recalls.[309]

However, economic operators are hesitant about using customers' information collected for non-safety purposes in the event of a recall because of a possible legal uncertainty about the compliance with the General Data Protection Regulation.[310] Even though safety-conscious companies were likely overrepresented in the survey[311], 28% of respondents in an online survey carried out by the European Commission indicated that they do not use customer data (collected e.g. through loyalty schemes, online sales, digital receipts etc.) to contact customers in case there is an issue with their product[312].

Do you use customer data collected for other purposes (e.g. loyalty schemes, online sales, digital receipts etc.) to contact customers in case there is a safety issue with their product? (N=147)



At the same time, consumers may provide "dirty data" (e.g. fake contact details or an email address that they do not regularly check) when signing up for loyalty programmes to avoid receiving marketing information. A possibility for consumers to provide separate contact details only for the purpose of safety notifications has been put forward as a good practice to increase the usefulness of loyalty programmes for recall purposes[313].

3.1.2. No comprehensive sources of public information to consumers

In most cases, it will not be possible to directly reach all consumers affected by a recall. In such situations, using a multitude of communication channels is recommended as the best approach to increase the visibility of the recall message and appeal to different

309 Notes from EU expert workshop on recall effectiveness of 23/10/2019, pp. 2-5.
310 Notes from EU expert workshop on recall effectiveness of 23/10/2019, p. 2.
311 Mostly companies interested in product safety might have participated, especially that the survey was promoted in the Safety Gate weekly reports.
312 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.
313 Notes from EU expert workshop on recall effectiveness of 23/10/2019, p. 4.

consumer categories[314]. These channels may include company's website, social media and newsletters, paid announcements in newspapers, TV or radio as well as point-of-sale information. Social media ads have been identified as particularly cost-effective not only in targeting specific audience but also in activating the word of mouth, people being able to share recall information with their contacts who they think may be using a recalled product[315]. At the same time, online communication channels may be less effective in reaching older and less Internet-savvy consumers[316].

At the moment, there are no rules on public sources of recall information to consumers in the GPSD. Likewise, in most EU/EEA countries, the recalling company has no legal obligation to put the recall notice on their website, social media, newsletter or retail outlet. In response to the consultation on the GPSD Roadmap/Inception Impact assessment, it was highlighted that some countries demand printed advertising as part of the recall communication, while in other countries, this is reportedly not the case.

Even though safety-conscious companies were likely overrepresented in the survey[317], less than one in three respondents in an online survey carried out by the European Commission indicated that their recall procedure envisages the use of newspaper articles to encourage recall participation and slightly over a half said the same for company's social media[318].

[314] Bond, C., Ferraro, C., Luxton, S., & Sands, S. (2010). Social media advertising: An investigation of consumer perceptions, attitudes, and preferences for engagement. In P. Ballantine, & J. Finsterwalder (Eds.), *Proceedings of the Australian and New Zealand Marketing Academy (ANZMAC) Conference 2010 -'Doing More with Less'* (pp. 1 - 7). University of Canterbury.

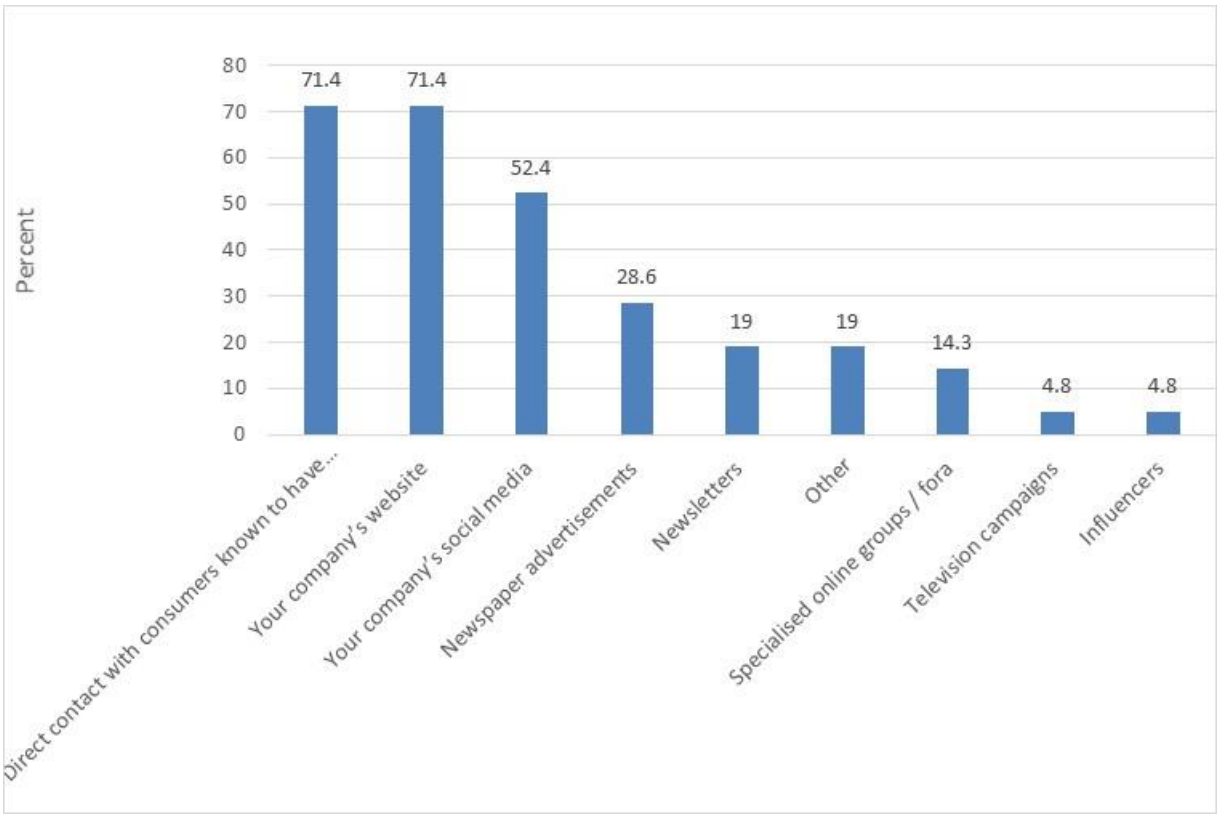
[315] U.S. Consumer Product Safety Commission (CPSC), 2017, Transcript of Recall Effectiveness Workshop, 25 July 2017, pp. 7-12, 32-4, https://www.cpsc.gov/Recall-Effectiveness.

[316] European Commission, 2019, Survey on consumer behaviour and product recalls effectiveness. Final Report https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/Product.Recall.pdf

[317] Mostly companies interested in product safety might have participated, especially that the survey was promoted in the Safety Gate weekly reports.

[318] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

Does your recall procedure envisage the use of one of the following channels to encourage customer participation in a product recall? (N=21)



In addition, not all authorities engage in spreading recall information on their website and/or social media (in addition to notifying recalls to the Safety Gate/RAPEX[319]). Identified national central recall portals are listed in the table below[320].

Table: National central recall portals

Country	Website
Austria	https://www.ages.at/produktwarnungen/ (also a related app)
Bulgaria	https://kzp.bg/opasni-stoki-v-bulgaria?f_category=0&f_year=2020&f_search= (mandatory recalls) https://kzp.bg/novini/dekatlon-balgariya-eood-predpriema-dobrovolni-merki-vav-vrazka-s-ustanovena-opasnost-pri-izpolzvane-na-detski-shorti-za-bord-500kid-olaian (voluntary recalls)
Denmark	https://www.sik.dk/farlige-produkter
Estonia	Estonia: https://www.ttja.ee/et/tarbijale/ohutus
Finland	https://marek.tukes.fi

[319] However, not all recalls need to be notified to Safety Gate/RAPEX. As regards products posing a less than serious risk, notification is encouraged but not mandatory in the case of voluntary measures taken against products covered by the GPSD and in the case of both voluntary and compulsory measures taken against products subject to EU harmonised legislation. In addition, Member States are not required to notify corrective measures in cases where the effects of the product risk cannot go beyond the territory of the Member State.

[320] In addition, specialised portals for motor vehicles exist in Finland (https://recall.trafi.fi/#vclass=&mark=&model=) and the Netherlands (https://terugroepregister.rdw.nl/Pages/Terugroepregister.aspx)

France	https://www.economie.gouv.fr/dgccrf/securite/avis-rappels-produits
Germany	www.rueckrufe.de
Hungary	https://fogyasztovedelem.kormany.hu/#/veszelyes_termekek_
Iceland	https://www.neytendastofa.is/neytendur/solubonn-innkollun-voru/
Ireland	https://www.ccpc.ie/consumers/product-safety/product-recalls/
Latvia	https://www.ptac.gov.lv/lv/jaunumi?category%5B103%5D=103
Luxembourg	https://portail-qualite.public.lu/fr/alertes.html
Malta	https://mccaa.org.mt/Section/Content?contentId=4407
Norway	https://farligeprodukter.no/
Poland	http://publikacje.uokik.gov.pl/hermes3_pub/
Romania	https://anpc.ro/categorie/44/retrageri-voluntare-de-produse
Slovenia	https://www.gov.si/zbirke/seznami/nevarni-proizvodi/
Sweden	https://www.konsumentverket.se/aktuellt/aterkallelser-av-varor/

3.2. Consumers fail to respond to recalls

The extent to which a product recall will be successful and prevent harm depends also on whether consumers respond, once they become aware that a product they own is being recalled.

An EU-wide survey on recall effectiveness by the European Commission found that over a third of consumers (35%) did not react to a recall that was relevant to them: 31% continued using the product with extra caution, while 4% took no action whatsoever[321]. The corresponding figures in a most recent consumer survey in 10 EU countries were 24% and 13%, respectively[322]. Lack of consumer responsiveness was also pointed out by several MSAs interviewed for the Implementation Study.

Consumers' propensity to respond to recalls depends on several **external factors**. Product characteristics, such as **product value, expected lifespan, age and type**, all play a role. Low product value typically decreases consumers' motivation to participate in a recall[323]. The US CPSC data show that return rates increase with the price of the product[324]. Likewise, in a recent survey by the European Commission, self-reported recall participation rates ranged from 73% for motor vehicles and 63% for furniture to 39% for clothing and footwear and 31% for children's toys[325]. MSAs interviewed for the Implementation Study also highlighted the importance of product value. In particular, recalls of low-priced products from Asia, distributed on open-air markets, Asian shops or online marketplaces, were reported to be very ineffective. On the contrary more consumers are inclined to return expensive products such as cars[326]. Consumers will also be more motivated to respond to a recall, the newer the product and the longer they

321 European Commission (2019). Survey on consumer behavior and product recalls effectiveness, p. 20, available at: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/Product.Recall.pdf.

322 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

323 OECD (2018), Enhancing Product Recall Effectiveness Globally, p. 17.

324 CPSC (25th July 2017), Recall effectiveness workshop meeting minutes, p. 41.

325 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

326 Implementation Study.

expect it to last.[327] Furthermore, consumers tend to underestimate the risks associated with leisure products (e.g. for sports, recreational vehicles) as they are often linked with positive emotions[328]. In addition to product characteristics, **cconsumers' socio-economic status** also plays a role, disadvantaged and younger consumers being less likely to respond to a recall.[329]

However, consumers' propensity to respond to a recall also depends on the recall internal characteristics: the clarity and persuasiveness of recall communication, the ease of the recall process and the attractiveness of the remedies offered.

3.2.1. Unclear recall communication

The way in which recall announcements are formulated and presented can affect consumers' understanding, perception of risk and motivation to act.

3.2.1.1.Content and layout of recall notices not specified in the EU

Lengthy and complex recall notices may lead to information overload and disengagement, especially among lower-educated and time-poor consumers. It is therefore important for recall announcements to use plain and concise language, avoiding legal terms and jargon. The inclusion of a product picture and further product identifiers (as well as a clear visual indication of where to find them on the product) can also help consumers immediately determine if they own the recalled product. Finally, the inclusion of colour and graphic elements may also help draw consumers' attention to the recall.[330]

A number of jurisdictions outside the EU defined the main elements that need to be included in a recall notice, with the aim of making them clearer and more salient. A standardised template for recall notices has been set out in Australia and the UK (see below). In the EU, elements that need to be included in a recall notice are specified in the Finish and Norwegian guidance documents but in most countries there are no requirements in this regard.

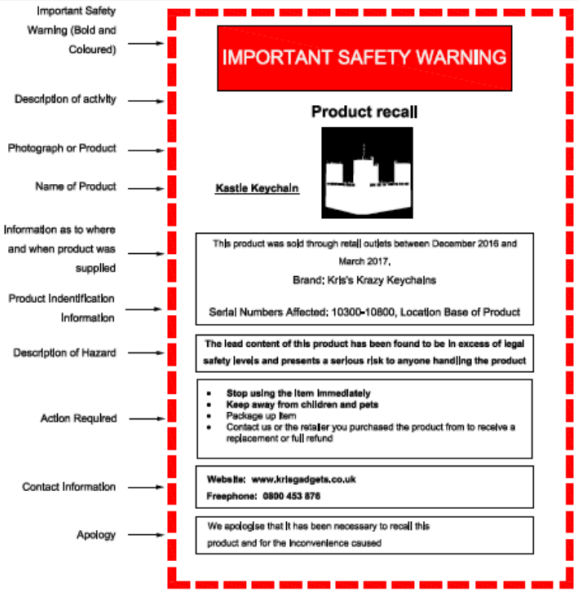
Australian and UK template for recall announcements

[327] European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

[328] U.S. Consumer Product Safety Commission (CPSC); XL Associates; Heiden Associates, 2003.

[329] Idem, European Commission (2019). Survey on consumer behavior and product recalls effectiveness, p. 20, available at: https://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/alerts/repository/tips/Product.Recall.pdf.

[330] OECD report, Notes from EU expert workshop on recall effectiveness of 23/10/2019, p.



In the focus groups carried out by the European Commission, participants preferred shorter paragraphs with clear subheadings over a single body of text with the same information. They also appreciated the inclusion of product picture. The red frame received more mixed feedback. While some participants considered it as "eye-catching", others felt that it was exaggerated and made the notice look like spam email. However, eye-catching imagery might work better for indirect communication.[331]

Moreover, stakeholder interviews suggested that defining key elements to be included in all recall notices would be beneficial for the companies too who would have clarity as to what information is required and in what format.[332]

3.2.1.2.Downplaying perceived risk

Consumers' perception of the likelihood and severity of the risk posed by a recalled product is another important factor influencing their decision to participate in a recall[333]. It is therefore crucial that recall notices clearly explain the hazard associated with the recalled product, avoiding euphemisms (such as 'overheating' or 'thermal event' instead of 'fire hazard') as well as any other terms that may decrease consumers' perception of risk (such as 'voluntary' or 'precautionary')[334]. Some third jurisdictions have banned this kind of terms in their guidance documents (Australia, South Africa, UK).

In focus groups carried out by the European Commission, participants felt that a good recall message needs to show a sense of urgency, underlining the risk to the consumer. The phrase "voluntary product recall" in the heading was viewed as to weak, self-evident

331 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

332 Idem

333 CPSC, XL Associates and Heiden Associates (2003), 'Recall effectiveness research: a review and summary of the literature on consumer motivation and behavior', p. 17 ff, available at: https://www.cpsc.gov/s3fs-public/RecallEffectiveness.pdf.

334 Idem

or confusing because participants were unsure to whom "voluntary" referred or what it meant. [335]

At the same time, the analysis of existing recall announcements showed that more than half of them (35 out of 55) used terms that could downplay consumers' perception of risk, for example:

'voluntary/precautionary recall' or 'voluntary replacement programme' (27 cases)
'in rare cases'/'in specific conditions' (20 cases)
highlighting that there have been no reported injuries (2 cases).[336]

3.2.2. Burdensome recall procedure

If participating in a recall is costly and does not outweigh the compensation proposed, this will serve as a disincentive to respond to a recall. The costs associated with recall participation may include financial costs (e.g. of shipping back the product), opportunity costs/loss of time, required effort, loss of product use etc. In a recent consumer survey, recall process taking too much time and effort was the second-top reason for not responding to a recall (after the product being cheap)[337].

Some of the best practices to minimise consumer effort identified through European Commission's mapping of existing recall campaigns and expert workshop include:

the company picking up any bulky items (like washing machines) from consumer's home or arranging for in-home repair,
offering a pre-paid postage, if the product needed to be sent back,
allowing customers to return the product in any shop that supplies the product (rather than the one where they purchased the product) or at a neighbourhood collection point,
accepting the return without a proof of purchase (which consumers are unlikely . to keep, especially in the case of cheaper purchases).[338]

The setting up of a free hotline or other two-way communication mechanism with consumers to answer any queries about a recall was also identified as a good practice[339].

Furthermore, it was suggested that in some cases, the recalled products could be disposed of or repaired by consumers themselves instead of being returned to the recalling company[340].

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335 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.
336 Idem.
337 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.
338 Idem
Notes from EU expert workshop on recall effectiveness of 23/10/2019, pp. 8-9.
339 Idem.
340 Notes from EU expert workshop on recall effectiveness of 23/10/2019, pp. 8-9.

3.2.3. Insufficient remedies

Consumers' likelihood to respond to a recall will also depend on the attractiveness of the compensation offered.[341] Tardy or insufficient remedies may reduce consumers' propensity to act upon a recall.

At EU level, the General Sales Directive guarantees the right to repair, replacement or refund in case of product non-conformity for a minimum period of 2 years after the delivery of the goods. However, many products are recalled after the expiry of the obligatory guarantee period.

The European Commission's mapping of existing recall campaigns found that in some cases the description of the remedy in the recall notice was unclear or missing. In addition, sometimes the remedy was seen as inadequate. This included cases when consumers were offered a discount to buy a new product from the same company rather than a proper remedy such as a repair, replacement or refund (detected in two US campaigns) or when the remedy involved providing consumers with free replacement parts for self-repair but the instructions were not very user-friendly and the process itself was time-consuming.[342]

In consumer focus groups, some participants mentioned that they would like a compensation for the period during which they cannot use the product.[343]

3.2.4. Behavioural biases

Behavioural biases may also negatively impact consumers' propensity to return a recalled product. The box below includes a comprehensive overview of such biases identified by the OECD.

Consumer behavioural biases applied to product recalls[344]

Information overload: If recalls contain too much information or consumers feel overwhelmed with information on recalls, they may disengage and not take action, especially if they are also time poor. With the growing number of product recalls in countries, consumers may suffer from "recall information" *fatigue*, and may not pay attention to the recall alerts that are relevant to them.

Framing effects: Consumers are influenced by how information is presented. Presenting an option in a certain way may induce consumers to evaluate the choice from a particular reference point. For example, consumers are less likely to respond to voluntary recalls if the potential hazards are not clearly stated. They are also less likely to follow instructions, including the steps they should follow to return the product, if such instructions are presented in a complex and lengthy message.

341 OECD (2018), Enhancing Product Recall Effectiveness Globally, p. 21.

342 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

343 European Commission, 2021, Behavioural study on strategies to improve the effectiveness of product recalls.

344 OECD (2018), Enhancing Product Recall Effectiveness Globally, p. 34.

Inertia: With an inherent fear of the unknown, when consumers face complex products or a bewildering array of choices, they may ignore possible choices or choose not to choose. Consumers may also rely on simple "rules of thumb" to avoid change or are guided by the values, actions and expectations of a particular society or group.

Endowment effect: Consumers often demand much more to give up an object than they would be willing to pay to acquire it. A consumer's value of a product increases when it becomes part of their endowment, so if the perceived inconvenience associated with returning a recalled product outweighs the compensation (i.e. return, refund or replacement), consumers are less likely to return it. This is because naturally humans tend to be loss averse, even if it is in relation to a recalled product.

Over-optimism: Consumers tend to think that they are more likely to experience an outcome that is better than the average expected outcome. This may cause them to miss or ignore warnings, or negative messages. Consumers may also be more inclined to keep using unsafe products, particularly if these products have been used for a long time without injury caused to them or to someone they know.

Time inconsistency: Consumers may make choices that are not consistent across time periods due to conflicts between short-term urges and long-term interests.

Annex 9: Cooperation activities under GPSD

The GPSD is one component of a broader consumer product safety framework. Apart from legislative texts (which also include harmonised legislation), it comprises non-legislative initiatives aimed at advancing the safety of consumer products, via cross-border and international cooperation, as well as cooperation with stakeholders.

1) Cross-border cooperation

The Consumer Safety Network and RAPEX contact point network

The Consumer Safety Network (CSN) is the expert group gathering product safety authorities of EU/EEA countries to discuss about ongoing and emerging product safety issues.

The RAPEX contact point network gathers all national RAPEX contact points to discuss questions related to the operation of the rapid alert system Safety Gate- RAPEX.

These networks are important fora for authorities to discuss about the challenges they face and exchange best practices. They also offer the possibility to foster cooperation with stakeholders: in December 2018, a CSN workshop was organised on the cooperation between national product safety authorities and consumer organisations. Similarly, in November 2019, a CSN workshop took place on the cooperation between authorities and online marketplaces.

Coordinated activities on the safety of products (CASP)

The European Commission helps market surveillance authorities (MSAs) responsible for the enforcement of non-food consumer product safety across Europe work together, pool resources and share best practices. It does so by organising coordinated market surveillance and coordinated activities on the safety of products (CASP). These projects provide EU/EEA authorities with the financing tools needed to jointly test products, determine their risks and take the necessary measures against any identified dangerous products in order to keep all European consumers safe.

CASP projects can focus on the analysis of a single product or a group of products (product specific activities) or on the exchange of best practices on market surveillance (horizontal activities).

The MSAs work on resulting recommendations, which are converted into communication material to be disseminated among economic operators and consumers. At the end of each project cycle, the CASP Closing Event presents the outcomes of the projects and launches a European wide communication campaign, contributing to greater awareness about product safety.

Over the last 15 years, the European Commission has co-financed more than 50 activities with a total EU budget around 27 million EUR since the start of the activities. Most coordinated actions have resulted in the identification of a significant number of

dangerous products, with non-compliance rates around 20%[345], leading to consequent notifications in the Safety Gate/RAPEX for 14 categories of products.

2) International cooperation

Cooperation with China

In recent years, about half of the alerts on Safety Gate have given China as the dangerous product's country of origin. This is mainly due to the volume of Chinese products imported into Europe. Since 2006, the European Commission has had formal cooperation on product safety with the Chinese authorities, which follow up on dangerous products from China notified in the rapid alert system and report to the Commission about the follow-up measures they take. Cooperation with this major producer country helps improve product safety "at source", so that fewer dangerous products reach European markets.

Information exchange with Canada

Given the increasingly global nature of supply chains, cooperation is also key with countries that have the same or similar products on their market. This allows for more timely identification of emerging product safety issues and enables EU Member States to better detect dangerous products. Exchanges of information on dangerous consumer products started with the Canadian authorities in 2019 under the EU-Canada Comprehensive and Economic Trade Agreement (CETA). The exchanges aim at helping EU Member States better target their enforcement efforts and identify emerging product safety risks.

Multilateral cooperation

Given the global nature of most product safety challenges (e.g. the safety of products sold online, the safety of artificial intelligence and connected products), it is paramount that the EU position is voiced in international discussions on these subjects to better protect its consumers. The Commission is actively participating in the OECD and UNCTAD Working Groups on Consumer Product Safety. The European Commission has also become an ex-officio board member of the International Consumer Product Health and Safety Organisation (ICPHSO) board. ICPHSO is an international, not for profit and neutral forum for product safety stakeholders, which offers regular occasions for product safety stakeholders to meet, discuss about major global challenges and share good practices in this field.

3) Cooperation with businesses to go above and beyond minimum legal requirements

Product Safety Pledge

In June 2018, four online marketplaces (AliExpress, Amazon, eBay and Rakuten France), signed a Product Safety Pledge. They were later joined by Allegro, CDiscount, Wish.com, Bol.com and eMAG.

[345] Joint Action reports repeatedly indicate that these high rates of non-compliance were not necessarily representative for the market, as non-random samples were taken and often samples were tested where a visual inspection had suggested possible deficiencies.

The conclusion of this Pledge was facilitated by the European Commission with the objective of increasing the safety of products sold online by third-party sellers through online marketplaces. This initiative, which is the first one of its kind in the product safety area, sets out specific voluntary actions in 12 different areas by online marketplaces that go beyond what is already established in EU legislation. As part of the Pledge, signatory online marketplaces have committed to report to the European Commission every six months on the actions taken to implement the Product Safety Pledge, with the inclusion of key performance indicators.

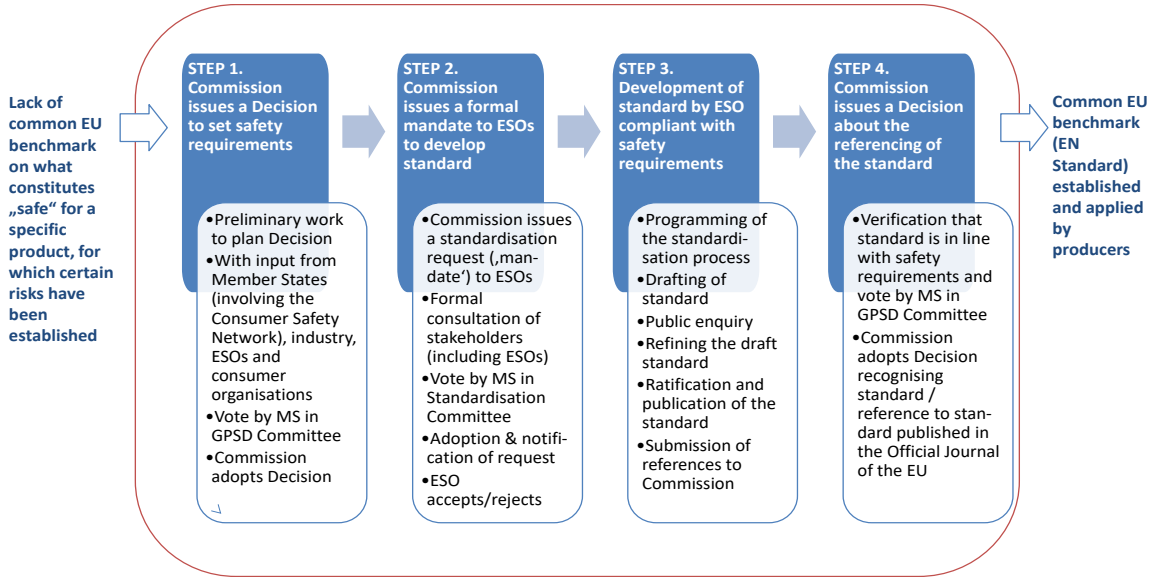
EU Product Safety Award

In 2019, the European Commission launched the first EU Product Safety Award, rewarding businesses that go the extra mile to protect consumers, beyond the minimum requirements laid down in EU law.

Annex 10: Standardisation procedure

The GPSD requires producers to put only safe products on the market. This requirement may be difficult to apply because of the lack of a common benchmark on what constitutes a safe product. Standards can respond to this need and they play an important role in EU product safety law. In the framework of the GPSD, they facilitate market access and ensure the safety of products.

The European Commission can request the European Standardisation Organisations (ESOs) to develop standards to support product safety legislation. In the case of the GPSD, the Commission first needs to issue a Commission decision on safety requirements to be met by the standard and then issue a standardisation request (mandate) to the ESOs to develop the standard. When the requested standard is developed, the Commission checks the compliance of the standard with the safety requirements. If the outcome is positive, the reference of the standard is published in the Official Journal of the European Union. Products compliant with the standards referenced in the OJ EU are presumed to be safe. This helps businesses to know what to comply with and the market surveillance authorities by providing a benchmark to assess safety of a product. Ultimately they contribute to safer products on the market for the benefit of consumers. The procedure is represented in the following scheme:



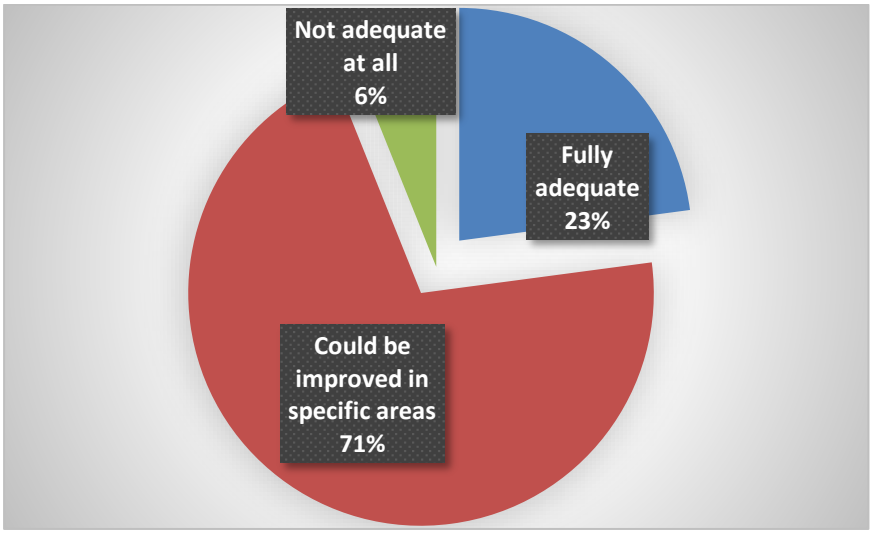
The overall process can be quite long and burdensome. However, the standardisation process must strike a balance between speed and the quality of the outcome, thus, of the standard.

The process under the GPSD includes one step more than the procedure applied in relation to harmonised standards. The reason is that the harmonisation directives contain essential safety requirements on which standards can be based. In the case of the GPSD, its wide coverage calls for specification of the safety requirements for a specific product, which then serves as a guideline for the work of the European standardisation bodies. There is room for improvement especially as regards Step 2. The GPSD Study found that there seems to be room to streamline the process that currently requires the involvement of two different committees. This appears to duplicate work, and leads to inefficiencies, as the members of the two committees are not necessarily the same.

Annex 11: Summary of replies to the open public consultation

Q1 In your view, to what extent are current EU safety rules for non-food consumer products covered by the GPSD adequate to protect consumers?

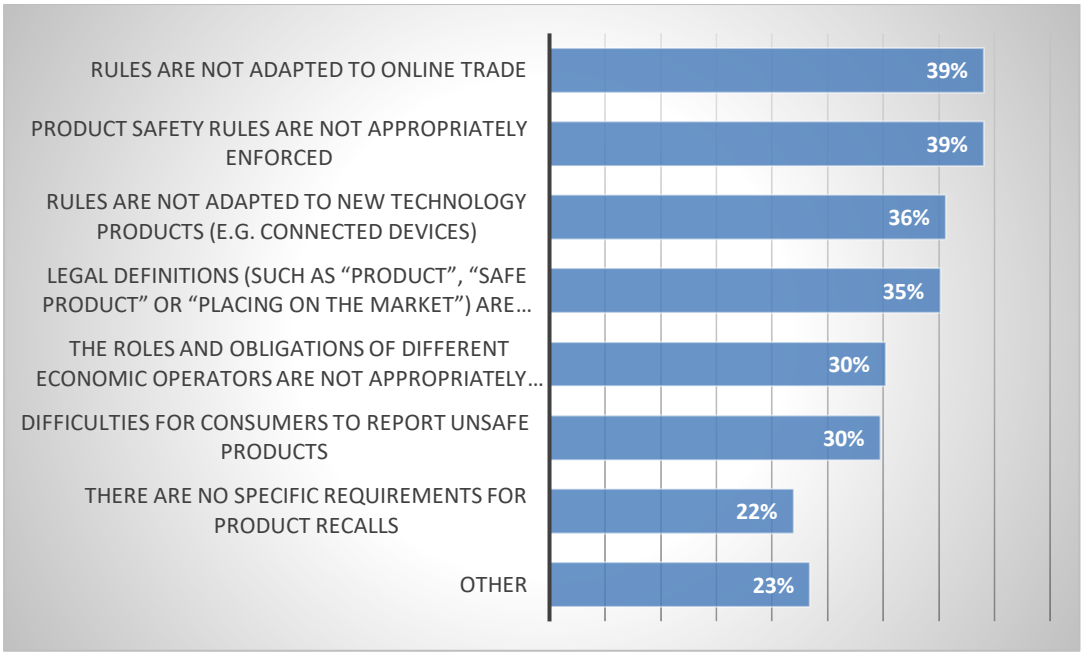
A large majority of respondents expressed that current EU safety rules for non-food consumer products covered by the GPSD could be improved in specific areas to be more adequate to protect consumers (71%). Nearly one in four respondents held that the current rules were fully adequate, whereas only a small minority considered them not to be adequate at all (6%), see the following figure.



Total no. of respondents: 214, Single-choice question

Q2 Are you aware of any problems related to the implementation of EU safety rules for consumer products covered by the GPSD?

When asked about problems related to the implementation of safety rules for products covered by the GPSD, respondents most commonly expressed that rules were not adapted to online trade (39%) and that the rules were not appropriately enforced (39%). More than a third also considered the rules not to be adapted to new technologies (36%) and perceived legal definitions as not sufficiently clear or outdated (35%). Slightly less than a third of respondents (30%) reported that roles and obligations of different economic operators were not appropriately defined and that there were difficulties for consumers to report unsafe products. Lastly, approximately a fifth of respondents regarded as problematic that there were no specific requirements for product recalls (22%) or listed other issues (23%) (see the following figure).



Total no. of respondents: 205, Multiple-choice question

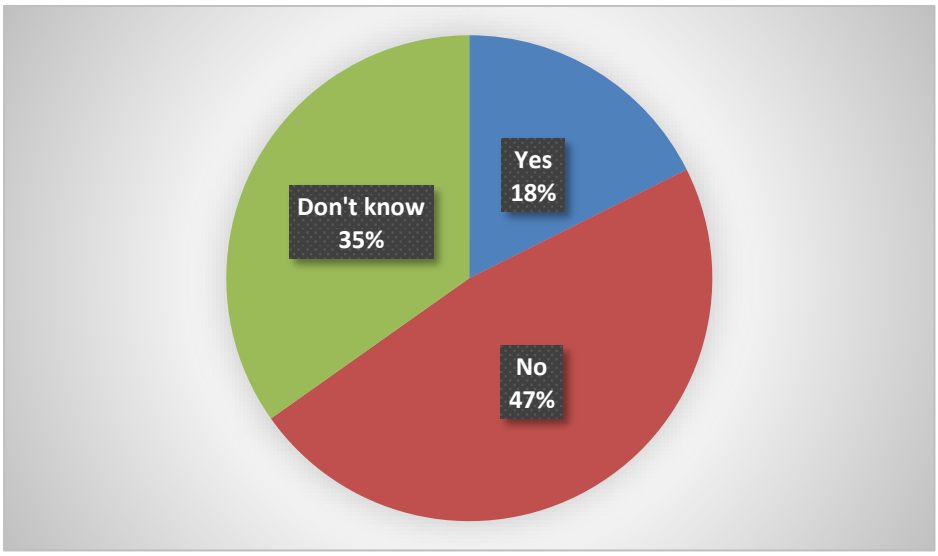
In their comments, respondents detailed their views regarding problems with the implementation of the GPSD. In line with 'online trade' being a major concern to the safety of products, many respondents referred to problems in this area, often specifically referring to online trade with third countries. In this context, the "current lack of responsibility and acknowledgment of online marketplaces' role in the supply chain" was mentioned by a large number of respondents. A related issue that was frequently indicated concerned customs controls of consignments from non-EU countries to consumers. Often, comments were framed as suggestions for improvement, i.e. it was suggested to ensure better customs controls of these consignments.

Many stakeholders considered that the GPSD was not properly enforced or implemented effectively, with a typical example being a statement that the "current framework is not implemented effectively (over 500 MSAs in Europe with no minimum standard for recall or takedown notices)". Respondents referred to differences in risk assessment, and considered resources of market surveillance authorities to be insufficient, including regarding testing. Finally, a number of respondents raised specific issues, such as:

- The lack of data on injuries and accidents, and the need that accident and incident alert systems must be adjusted to work in practice;
- Limitations in scope of the directive, such as the lack of services covered (including financial services and online gambling services with a high addictive potential), and counterfeiting;
- Limitations of the concept of "safe product", which was considered to not always meaning that the product is safe for specific vulnerable groups;
- The absence of specific rules on the safety of child appealing products;
- Lack of adaptation to new technologies, including the lack of coverage of software as "product" (see also next question).

Q3 Do you think that the safety of products involving new technologies is adequately regulated?

Almost half the respondents considered the safety of products involving new technologies to be not adequately regulated (47%), with only 18 % stating the opposite. The other 35% did not know (see the following figure).

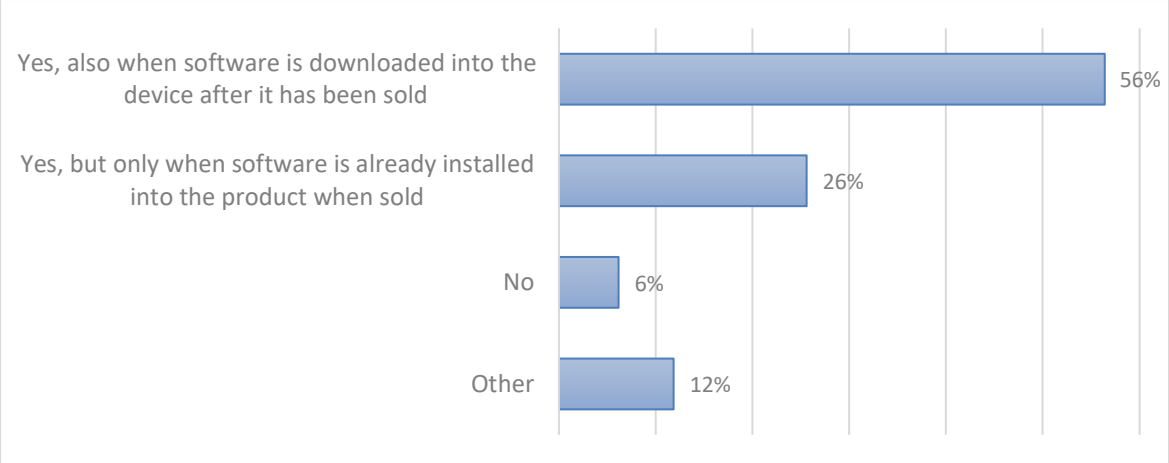


Total no. of respondents: 227, Single-choice question

Q4 When incorporated into a physical product, software can malfunction and cause a safety issue. When considering whether a product is safe, should the definition of a product in the GPSD specifically encompass also the software incorporated into it?

When asked whether the definition of a product in the GPSD should specifically encompass software incorporated into the product, the majority of respondents agreed, even in case the software is downloaded after the product has been sold (56%).

About a quarter of respondents considered that only software already installed into the product when sold should be included. Only a small minority answered that the definition should not encompass software (6%) or preferred an “other” option (12%), see figure below.



Total no. of respondents: 211

Respondents could provide comments, and again explained their positions. Those that argued that all software should be covered (even if downloaded after the purchase of a product) typically provided one or more of the following arguments:

- Safe software is as essential as safe hardware. One cannot function without the other;
- Software can change the properties and hence the safety of a device. The GPSD must have a safety net function here;
- Modern goods are made from software and hardware, and both of them can cause safety issue. It is important that both are covered;
- Encompassing software into the product definition would eliminate ambiguities.

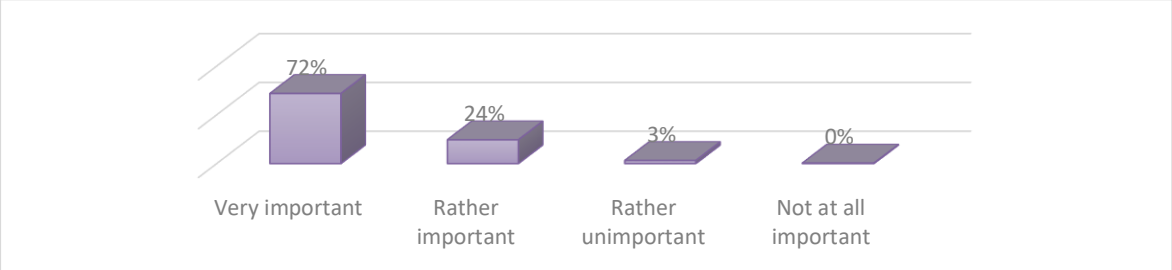
In contrast, there were also several respondents that did not see any need for changes to the GPSD in this respect, arguing:

- Physical product can cause harm and should be designed to be safe, not software;
- The definition of products currently used in the GPSD is up to date and broad and flexible enough to reflect new developments and challenges;
- A risk-based approach should be taken with new technologies. If there are gaps, targeted legislation is the most effective way to address risks.

Finally, comments considered how responsibility should be allocated in case software would cause a product to be unsafe. There was no consensus in this respect. Rather, the answers reflected the different perspectives of the respondents: Those that saw a strong role of the manufacturer argued that the safety of the product must take into account software designed to operate the product, even if the software is installed afterwards, and that a product should have safety functions that minimise the risk of malfunction of added software. In contrast, others suggested that the duties of the manufacturer of a device should not cover safety risks posed by a standalone software installed later, over which the manufacturer has no control. Some respondents also argued that if users installed software, manufacturers or distributors should not be responsible for its safety unless they had instructed or authorised this.

Q5 How important do you think it is that products that could be modified via software updates/downloads or machine learning are required to remain safe throughout their lifetime?

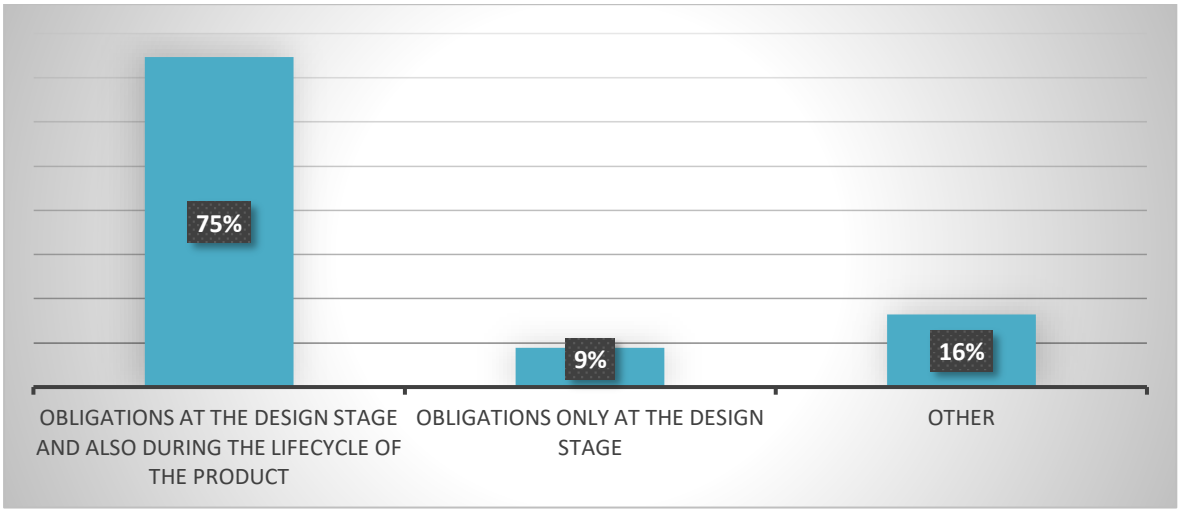
Almost all respondents considered a requirement for products that could be modified via software updates/download or machine learning to remain safe to be very important (72%) or rather important (24%). A mere 3% regarded the requirement as rather unimportant, while none of the respondents considered it not to be important at all (see the following figure).



Total no. of respondents: 217, Single-choice question

Q6 Products incorporating AI applications can evolve via machine learning and other techniques, even after they have been acquired by consumers, potentially posing safety risks. In your opinion, at which moment of the lifecycle of the product should manufacturers have safety obligations?

A clear majority of respondents favoured safety obligations for manufacturers of products incorporating AI applications at the design stage and also during the lifecycle of the product (75%), whereas only 9% of respondents expressed that the obligations should be limited to the design stage. 16% preferred an "other" solution (see the following figure).

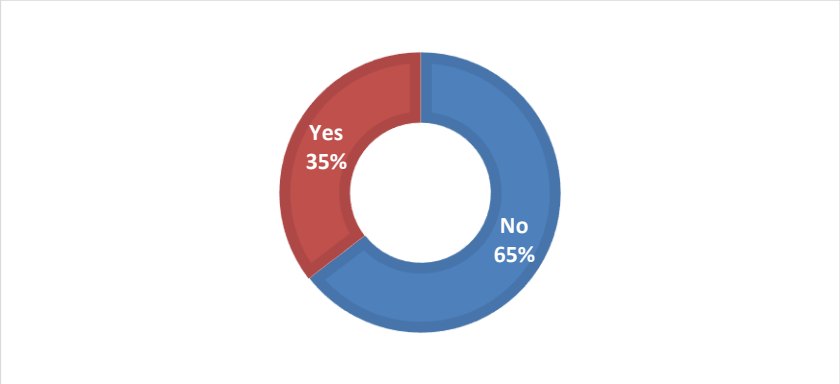


Total no. of respondents: 213, Single-choice question

In their comments, respondents mostly reiterated their views without providing additional details. Some respondents that agreed to safety obligations of manufacturers during the lifecycle of the product, elaborated on limitations to this principle. According to their view the level of safety during the lifecycle should be compared to the level of risk with human control (not "zero risk"), should exclude "substantial modifications" or be limited to the "foreseeable period of use of the product". Finally, there were also respondents that saw a need for regulating AI horizontally, and not in the GPSD.

Q7 Have you experienced any product safety incident within the last 5 years?

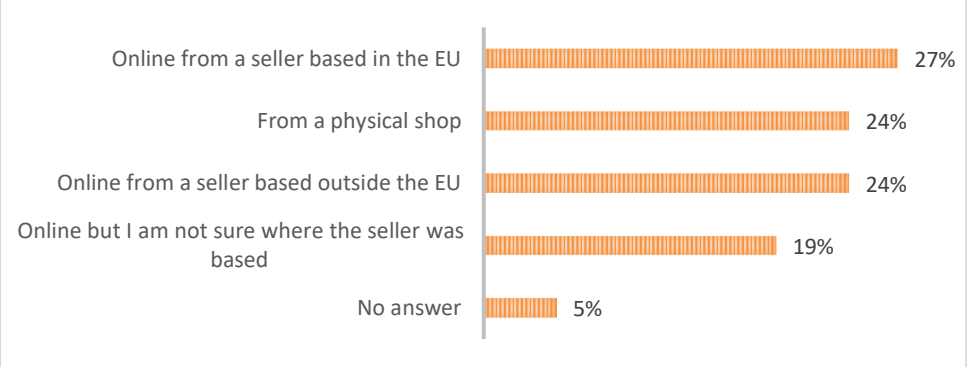
A clear majority of respondents did not experience any product safety incident within the last 5 years (65%), with the share of affirmative answers being 35%, see the following figure).



Total no. of respondents: 175, Single-choice question

If yes, how did you buy the product?

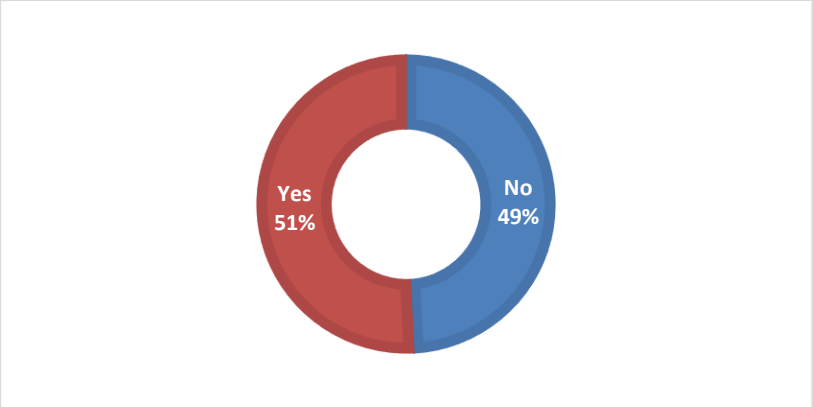
Among the 62 respondents that answered yes to Q7 the largest group had bought the product online from a seller based in the EU (27%), followed by each 24% of respondents that had acquired the product from a physical shop or online from a seller based outside the EU. About one fifth of respondents stated that they had obtained the product online but were unsure where the seller was based and 5% gave no answer (see the following figure).



Multiple-choice question

Q8 Have you experienced any lack of information linked to safety when buying products online?

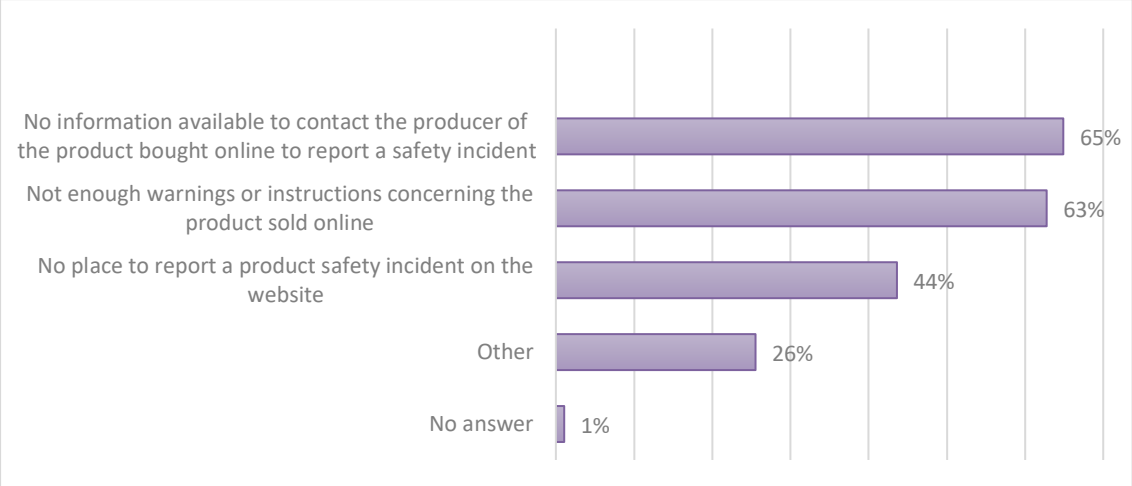
A small majority of the respondents reported that they had experienced a lack of information linked to safety when buying products online (51%), while the other half did not share this experience (49%), see the figure below.



Total no. of respondents: 185, Single-choice question

If yes, what was this lack of information linked to?

Of those 94 respondents that answered yes to Q8 a clear majority considered the lack of information to be linked to missing contact of the producer of a product bought online to report a safety incident to (65%) and/or to not receiving enough warnings or instructions concerning the product sold online (63%). Slightly less than half of the respondents perceived that there was no place to report a product safety incident on the website as problematic in this respect (44%), while a quarter of the respondents considered other factors to be relevant. Another 1% gave no answer (see the following figure).

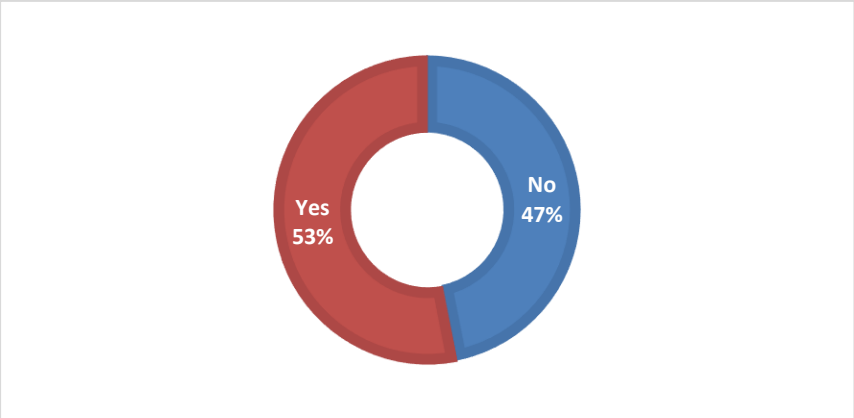


Multiple-choice question

Q9 Online marketplaces enable companies to sell to EU consumers but, according to EU rules, they do not have direct legal obligations for the safety of products hosted

on their platform by sellers. Are you aware of any problems this regime would bring about?

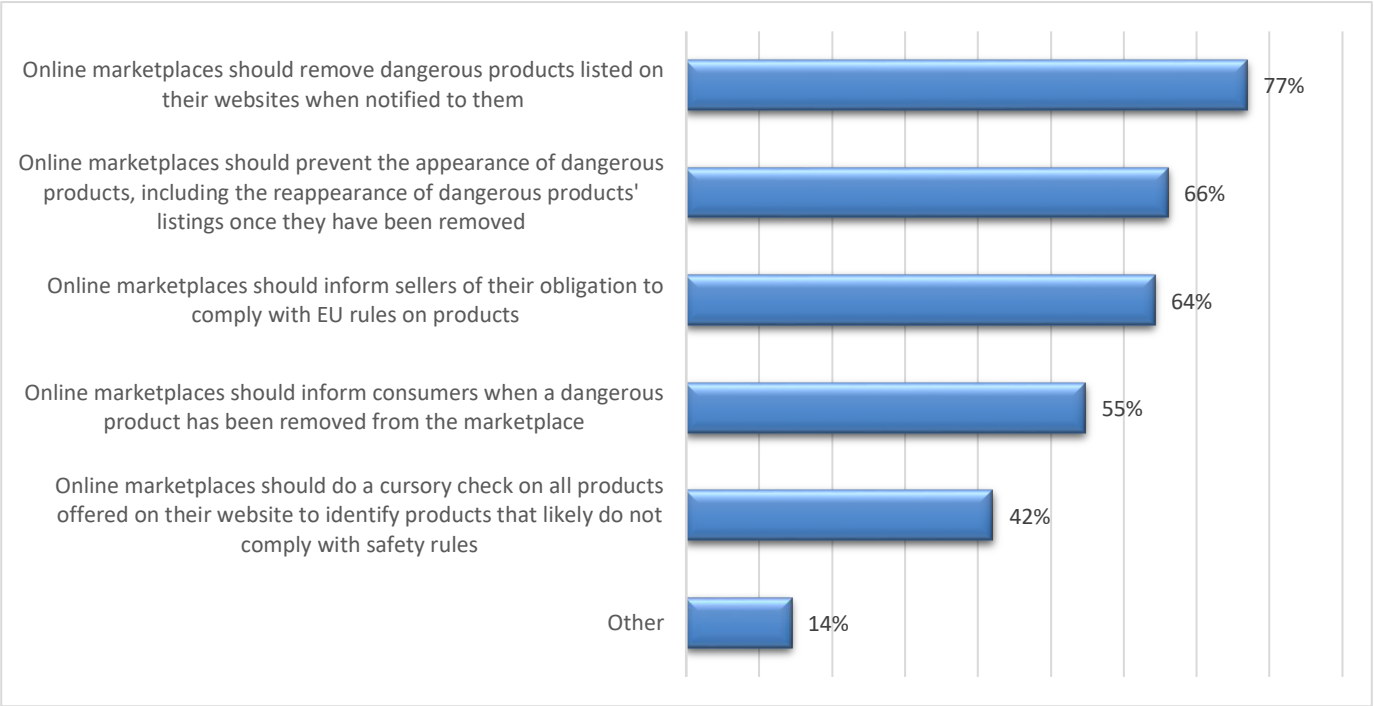
The majority of respondents expressed that they were aware of problems associated with online marketplaces having no direct legal obligations for the safety of products hosted on their platform by sellers (53%). However, almost half of the respondents indicated the opposite (47%) (see the following figure).



Total no. of respondents: 209, Single-choice question

Q10 What should be the role of online marketplaces as regards the safety of products offered on their website?

When asked about the role that online marketplaces should play regarding the safety of products offered on their websites, the most commonly supported notions were that they should remove dangerous products listed on their website when notified (77%), that online marketplaces should prevent the appearance of dangerous products, including their reappearance once they have been removed (66%) and that they should inform sellers of their obligation to comply with EU rules on products (64%). More than half of the respondents agreed that online marketplaces should inform consumers when a dangerous product has been removed from the marketplace (55%). A slightly lower number of respondents thought that online marketplaces should do a cursory check on all products offered on their website to identify products that likely do not comply with safety rules (42%). Several respondents also indicated the option “other” (14%), see the figure below.



Total no. of respondents: 221, Multiple-choice question

Nearly all detailed comments provided by respondents concerned suggestions for additional obligations for online marketplaces. In many cases, respondents considered that due to the active role of the marketplaces in facilitating transactions, platforms should have the same responsibilities as other importers/distributors/traders (selling online or in brick-and-mortar shops). Respondents suggested a large variety of possible additional obligations for online marketplaces, including:

- Taking reasonable efforts/work more proactively to prevent appearance of dangerous products;
- Using technology (such as AI) to swiftly identify and delist unsafe products;
- Checking all products offered in order to identify non-compliant/recalled products;
- Verifying the presence of the CE mark and the absence of obvious safety concerns;
- Implementing testing requirements, especially for products falling under the WEEE, Battery and Packaging Directives;
- Keeping a notification form available for suspected cases of unsafe products;
- Informing market surveillance authorities immediately of unsafe products identified;
- Cooperating with enforcement authorities;
- Informing consumers who have previously bought a product that was later taken down following a valid request for takedown;

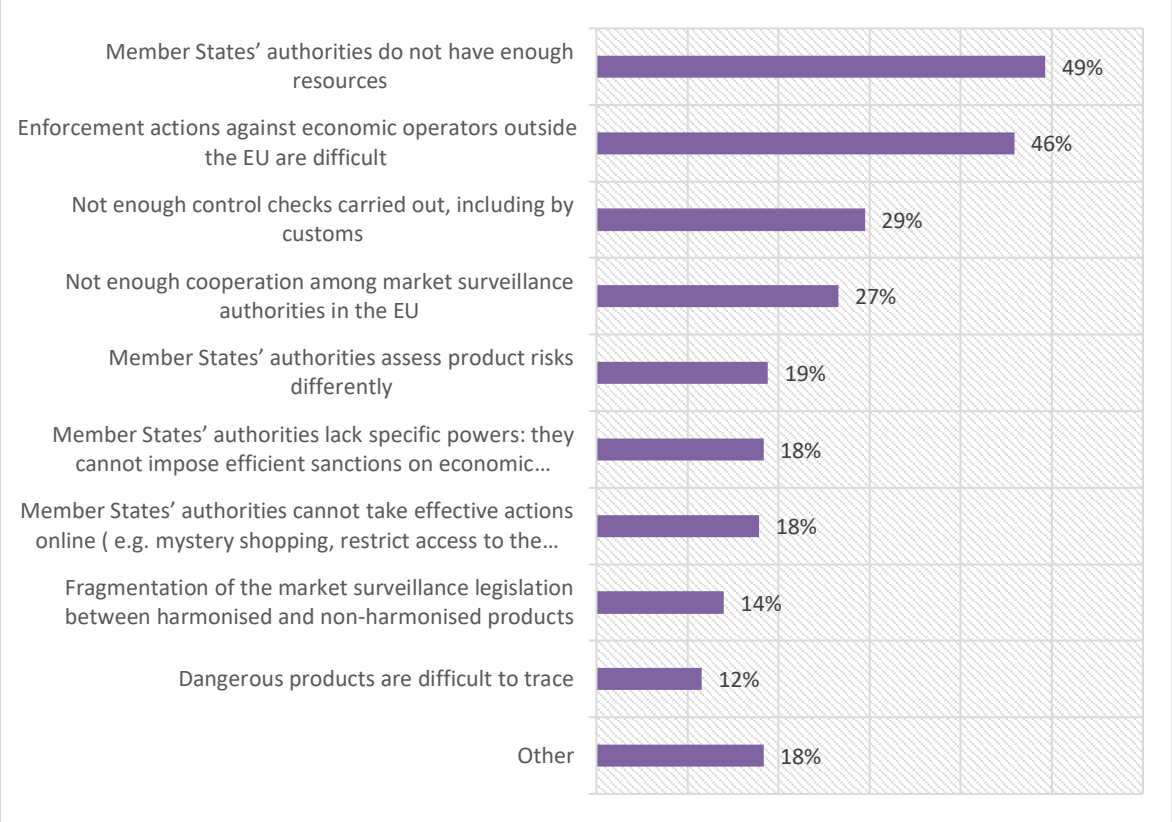
- Not sending unsafe products to consumers when they have already been ordered but are not sent yet;
- Recalling unsafe products from consumers and destroying the stored products;
- Identifying repeat offenders which would prevent them to re-list dangerous products on the marketplace;
- Being liable for products they sell.

A minority of respondents suggested, however, that responsibilities and obligations imposed on online marketplaces should be proportionate (or effective and feasible) and take into account the size and scope of the provider in question. They also considered that obligations should not handicap SMEs competing against bigger and more established companies who are better placed to overcome related regulatory burdens.

Finally, several respondents suggested that the scope of checks to be conducted by marketplaces should include not only unsafe products, but also counterfeit products in general, and life animals/pets sold on platforms, to safeguard that only registered animals are offered by traceable sellers (with a specific reference to illegal puppy trade).

Q11 What are the main challenges for enforcement?

When asked about the main challenges for enforcement half of the respondents considered as problematic that Member States' authorities did not have enough resources (49%), followed by the difficulty of taking enforcement actions against economic operators outside the EU (46%). Other challenges included that not enough control checks are carried out, including by customs (29%), that there is not enough cooperation between market surveillance authorities in the EU (27%), and that these authorities assess product risk differently (19%). All other answer items were indicated by 18% or less of respondents.



Total no. of respondents: 207, Multiple-choice question with maximum 3 choices

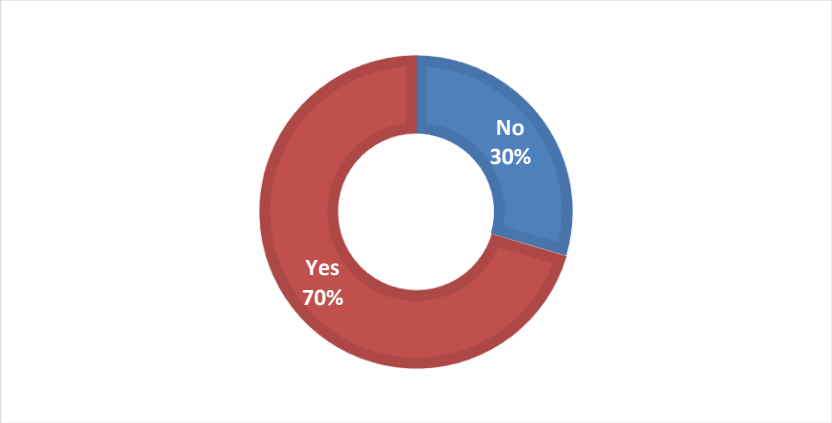
In their comments, respondents referred to the above listed challenges in detail. It was suggested that the listed enforcement issues would need to be addressed through GPSD reform and through making available more resources at national level for enforcement and better controls, including customs controls. Several stakeholders referred to Regulation (EU) 2019/1020 on market surveillance (which is applicable in the harmonised product sectors), indicating that it provided relevant means of enforcement. Other suggestions included that:

- National authorities needed more resources or information on products coming from outside the EU to ensure effective checks;
- The GPSD should be converted into a regulation in order to rule out national differences in implementation;
- Powers should be specified and harmonised, and enforcement be improved through joint action by several Member States.

Q12 Do you think that products covered by the GPSD should only be placed on the EU market if there is an economic operator established in the EU who is responsible for product safety purposes?

A large majority of respondents considered that products covered by the GPSD should only be placed on the EU market if there is an economic operator established in the EU

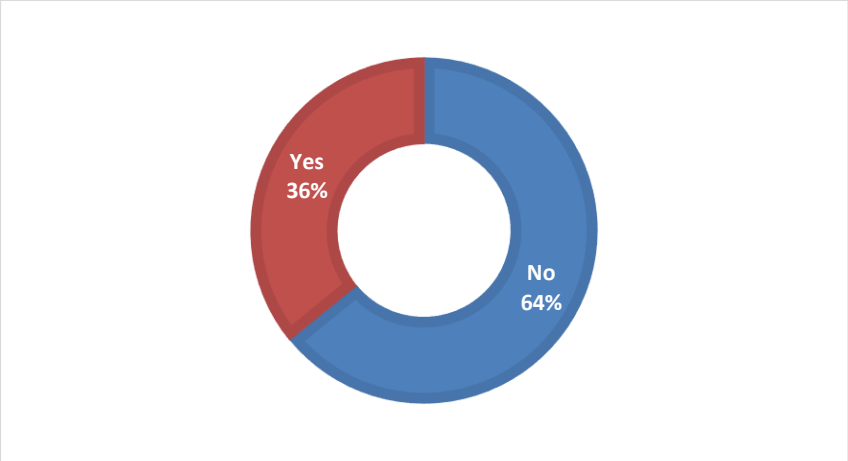
responsible for product safety purposes (70%), with the other 30% expressed the opposite view (see the following figure).



Total no. of respondents: 186, Single-choice question

Q13 Are you aware of any issue where additional competences of the European Commission for the enforcement of product safety rules could improve the safety of consumers?

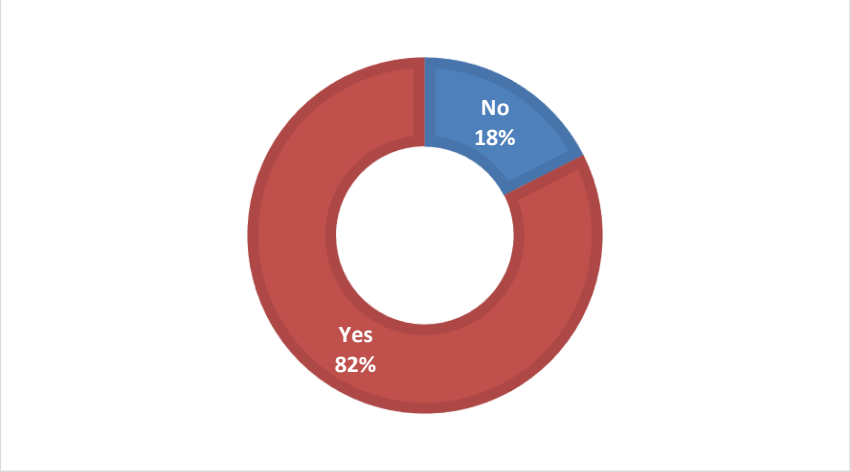
Close to two thirds of respondents indicated that they were not aware of issues where additional enforcement competences of the European Commission could improve the safety of consumers (64%). However, more than a third of the respondents suggested the opposite (36%), see the figure below.



Total no. of respondents: 170, Single-choice question

Q14 Should the system of product traceability be reinforced in the GPSD so that products can be better traced if there is a safety issue?

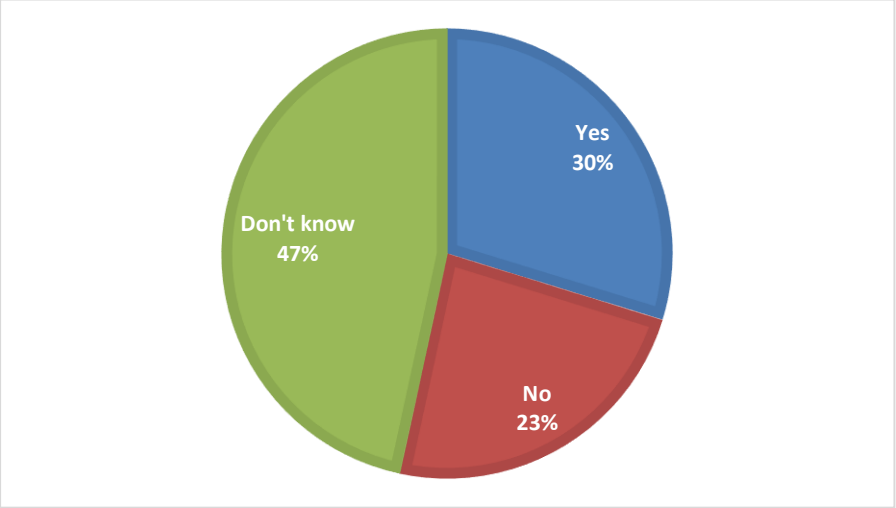
A large majority of respondents agreed that the system of product traceability should be reinforced in the GPSD (82%), while only 18% of respondents did not regard this as necessary (see the following figure).



Total no. of respondents: 171, Single-choice question

Q15 Do you experience problems with the divergence of rules between harmonised and non-harmonised products?

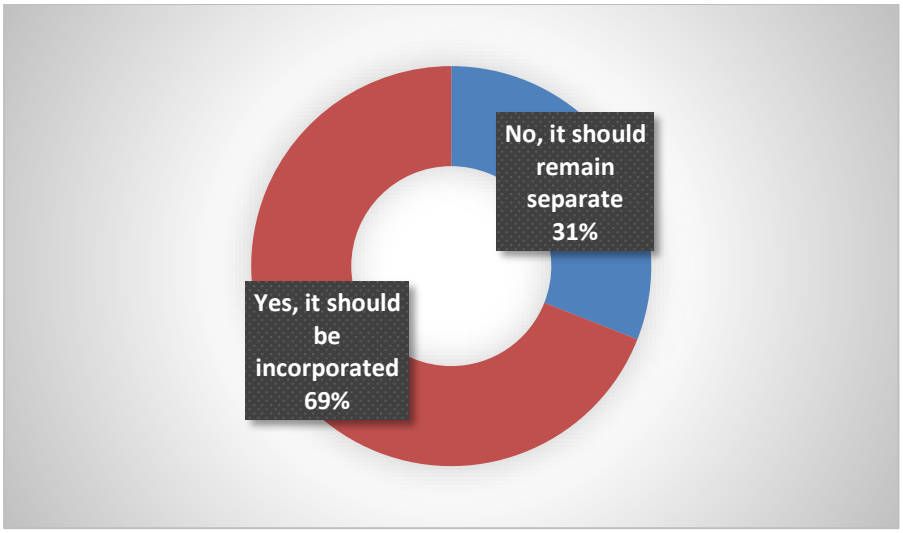
Almost one in three respondents reported having experienced problems with the divergence of rules between harmonised and non-harmonised products (30%), while 23% stated the opposite. Almost half of the respondents expressed that they did not know (47%) (see the following figure).



Total no. of respondents: 178, Single-choice question

Q16 Products which resemble foodstuff, while not being such, have a separate regime (Council Directive 87/357/EEC). This has given rise to different interpretations on whether such products are dangerous in itself or not. Should these products keep having a separated regime or be incorporated into the general product safety legal instrument?

A large majority of respondents expressed that products which resemble foodstuff should be incorporated into the general product safety legal instrument (69%), whereas the other 31% felt that the regime should remain separate.

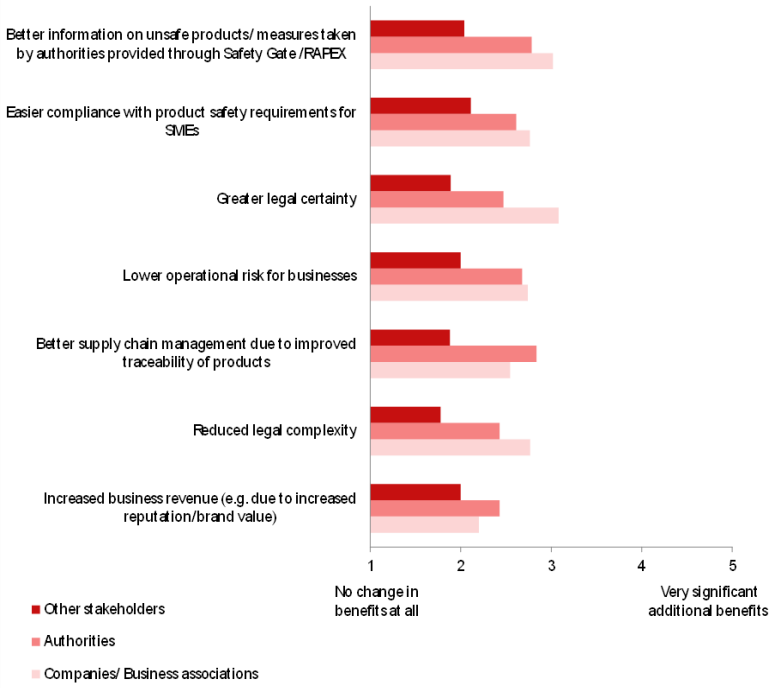


Total no. of respondents: 155, Single-choice question

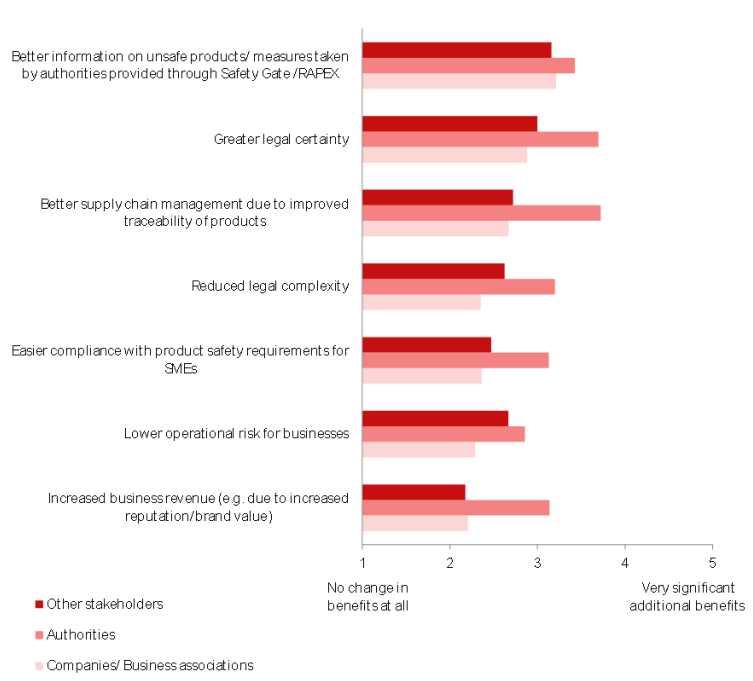
Annex 12: Stakeholders opinions on the benefits of the different options

The survey conducted in the context of the GPSD Study shows the following stakeholders' views on the additional benefits for businesses resulting from the different options:

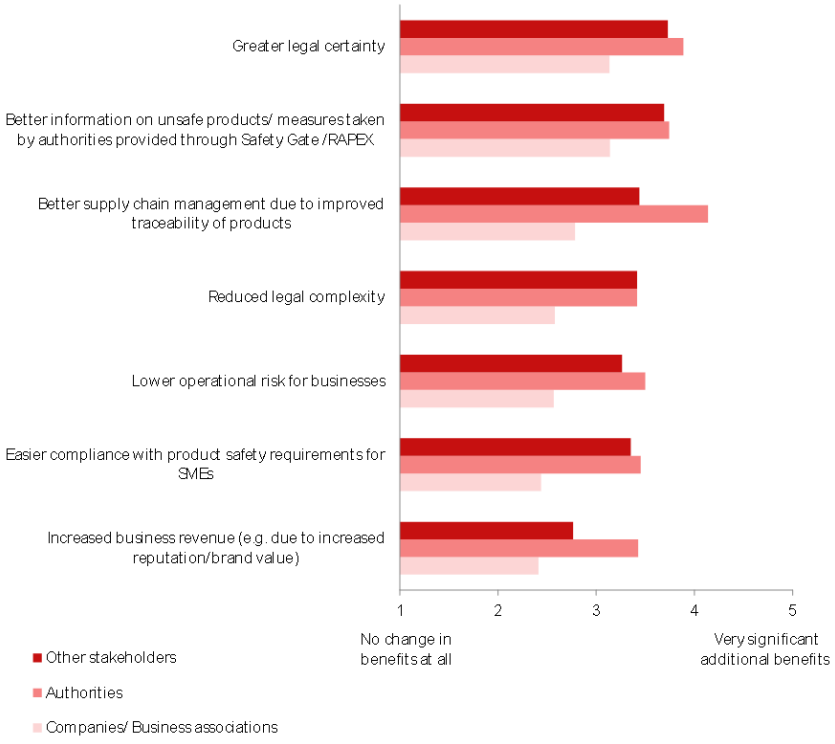
Additional benefits for businesses resulting from the implementation of Option 1



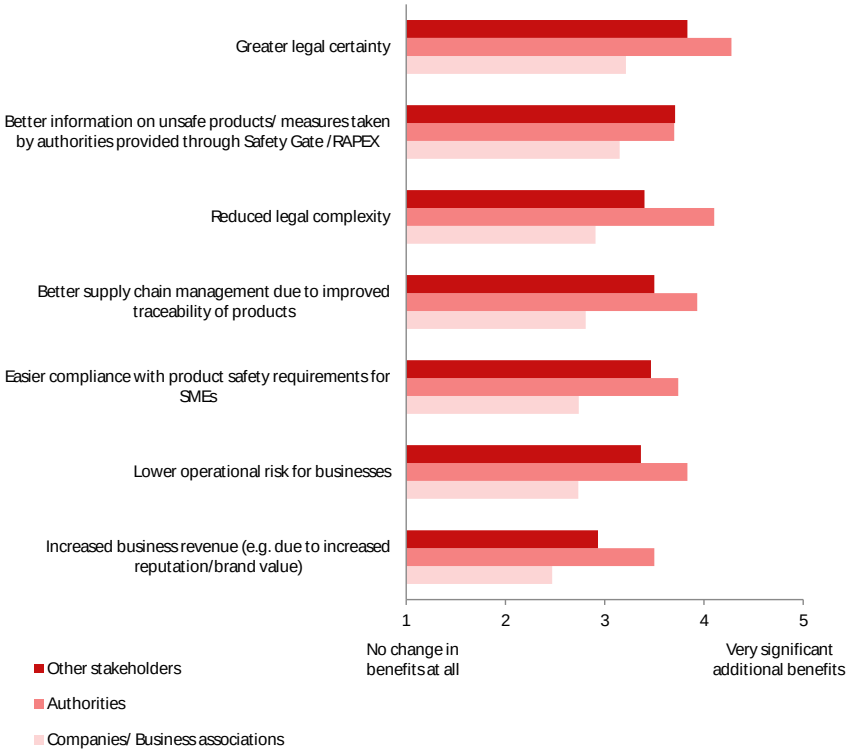
Additional benefits for businesses resulting from the implementation of Option 2



Additional benefits for businesses resulting from the implementation of Option 3



Additional benefits for businesses resulting from the implementation of Option 4


Greater legal certainty
Better information on unsafe products/ measures taken by authorities provided through Safety Gate / RAPEX
Reduced legal complexity
Better supply chain management due to improved traceability of products
Easier compliance with product safety requirements for SMEs
Lower operational risk for businesses
Increased business revenue (e.g. due to increased reputation/brand value)
1
2
3
4
5
No change in benefits at all
Very significant additional benefits
Other stakeholders
Authorities
Companies/ Business associations

Annex 13: Minutes from the EU workshops addressing the sale of illegal goods online

The workshops were co-organised by DG CNECT and DG JUST, 8, 10, 13 and 17 July 2020, as part of a broader engagement with stakeholders and evidence collection strategy for the Digital Services Act package as well as the revision of the General Product Safety Directive.

The objective of the workshops was to gather up-to-date information on the state of play concerning the main challenges in addressing the sale of illegal goods online. It focused in particular at measures and good practices from marketplaces and the cooperation with authorities and responsible third parties. Panellists and participants – which included online marketplaces, retail associations, consumer organisations, national market surveillance authorities as well as representatives from the European Commission - were invited to share their experiences and engage in a discussion on potential new policy and regulatory measures.

The event was made of four separate online sessions:

Session 1: Sellers and products identification mechanisms, 8 July 2020 - The first session was focused on the information online marketplaces are currently gathering on their sellers. Online marketplaces started with a short overview of practices in identifying their business sellers and product listings on their platforms. Most online marketplaces specified that business sellers are required to submit background information (e.g. company name, VAT number, address, etc.) before being admitted to sell.

Overall, all participants agreed on the importance of having transparency as regard business traders. Some participants highlighted that more should be done in this context, especially when it comes to sellers established outside the EU and therefore not always covered by EU rules. Some stakeholders considered that more cooperation with authorities in Member States could also help identifying rogue sellers.

Session 2: How to tackle dangerous goods and product safety issues online: notice and action procedures and the role of the Safety Gate/RAPEX - The first part of this session concerned best practices on notice and action procedures to tackle dangerous goods, including notices from authorities, consumer associations, consumers and other actors. Generally, all participants agreed that a harmonised notice and action procedure would facilitate the fight against dangerous products online. Some participants highlighted that often notices are not accurate enough and online marketplaces have difficulties in identifying the dangerous products notified. In this regard, many participants called for a minimum information requirement for notices. Online marketplaces also stated that filters are not entirely reliable and that such tools should always be accompanied by human review and notice and action mechanisms.

The second part of the session concerned Safety Gate/RAPEX. In this regard, a number of investigations carried out by consumer organisations, retail associations and market surveillance authorities were also presented, with results on the number of dangerous products available online raising clear concerns. Marketplaces are taking some action, such as periodically checking Safety Gate/RAPEX (as they have committed in the Product Safety Pledge). Some participants pointed out, the information in the Safety Gate

only shows only part of the issue and more needs to be done in this regard. Some remedies were proposed by national authorities, such as establishing an obligation to cooperation with market surveillance and custom authorities. Some participants also suggested to have an API interface to Safety Gate/RAPEX which would then be linked to online marketplaces and allow them and consumers to have real-time information on product safety.

Session 3: What other measures and challenges for keeping consumers safe from dangerous goods online? – The session focused on other preventive measures that marketplaces can take to ensure that no dangerous product is placed on the market. Three main aspects were mentioned by participants. First, the importance of data, that in many cases is not provided by the seller, making enforcement very difficult. Second, online sales and product safety are global issues, therefore international cooperation is key to address these challenges. Thirdly, many participants mentioned the issue around traceability, and how it needs to be enhanced so dangerous products sold online can be correctly identified and corrective measures can be enforced by both platforms and authorities. The challenge of reappearance of dangerous products already removed was also addressed, although not specific measures or solutions were mentioned by participants.

Session 4: Consumer law and online marketplaces, 17 July 2020 -The main focus of this session was to address content that is illegal because it constitutes a violation of applicable EU consumer law.

The session started with a short presentation held by DG JUST on the relevance of EU consumer law for a) online marketplaces regarding their own activities and content; b) the business users of online marketplaces; and c) online marketplaces in their capacity as hosts of their business users.

The discussion then zoomed in on third-party content and the measures that online marketplaces are taking to prevent activities that violate applicable EU consumer law. Online marketplaces specified that their objective is to create trust on the platform, both for consumers and sellers. They further stated that sellers are in charge of their own compliance, but that they are responsible to give them the means to be able to be compliant with EU law.

Some participants flagged that the main problem with EU consumer law is the lack of resources and enforcement.

Cooperation was also mentioned by many participants as being the key to ensure a coherent enforcement of EU consumer law. According to many participants, all the actors in the supply chain should work together to raise awareness around consumer rules.

Annex 14: Minutes from the EU Workshop on strategies to maximise the effectiveness of product recalls

On 23 October 2019, a workshop has been organised by the European Commission to discuss the strategies to maximise the effectiveness of product recalls. The participants of the workshop included regulators from around the world, representatives of international organisations (OECD, UNCTAD), consumer organisations, industry and academics.

The aim of the workshop was to take stock of existing market practices and regulatory approaches, and identify possible new avenues to maximise recall effectiveness. As a next-step, the most promising ideas could be tested through an EU behavioural study, the results of which should also be of relevance for other stakeholders and jurisdictions.

The workshop was divided into three thematic sessions, focusing on i) Strategies to facilitate direct consumer contact, ii) Strategies to increase consumer response to recalls and iii) Roles and responsibilities in the recall process. The last part of the workshop was limited to regulators in order to discuss possible next steps.

1. Session 1: Strategies to facilitate direct consumer contact

The objective of this session was to:

- get a comparative overview of strengths and weaknesses of various methods of identifying the owners of recalled products, and
- brainstorm on best ways to address the barriers that prevent consumers from sharing their contact details for safety notification purposes.

PRESENTATIONS

UK Electrical Safety First talked about strategies to improve product registration. According to Electrical Safety First research, only 1 in 3 people register electric products, because they 1) fear unwanted marketing communications 2) think it takes too much effort and time 3) do not see the benefit. The charity has launched several awareness-raising campaigns to encourage registration of electrical devices and domestic appliances[346]. Further avenues to encourage product registration include 1) separating marketing from safety notifications, 2) standardising and simplifying registration material, 3) point-of-sale registration and 4) technological solutions (barcodes/QR/RFID, connected devices).

Decathlon explained that the company uses different strategies to communicate recalls to its customers – from general displays in stores and on the website to personalised letters and e-mails. Phone calls and SMS are also used in case of small-scale recalls. The experience shows that direct communication is the most effective strategy.

The main source of consumer data is a voluntary loyalty programme, which varies across different countries, and allows Decathlon to contact affected consumers directly. The

[346] Among others: https://www.electricalsafetyfirst.org.uk/product-recalls/product-registration/, https://www.electricalsafetyfirst.org.uk/what-we-do/campaigns/nan-knows-best/, http://www.whitegoodsafety.com/

company also offers voluntary registration at the moment of purchase, but for the time being this possibility is limited to bicycles, which are the highest-risk product.

The company noted that even if they do not post recall announcements on social media, consumers may do it themselves and even share incomplete and incorrect information. Therefore, the best option is to share recall information directly, or through sports community groups, which additionally encourages word-of-mouth.

The Finnish Safety and Chemicals Agency (Tukes) focused on how economic operators should use loyalty cards data for recalls in the light of the EU personal data protection rules.

They started by recalling an incident of toxic olives causing botulism that occurred in Finland in 2011. In addition to vast media attention, most of the affected consumers were contacted directly due to accessibility to personal data in customer loyalty registers.

Nowadays Tukes's guidance on product recalls explicitly recommends that if a company has a comprehensive customer register available, contacting people directly is the most effective way to notify them about a product recall. Also, according to the European Commission's survey, consumers would prefer direct personal communication regarding recalls.

However, following the entry into force of the EU General Data Protection Regulation (GDPR) in May 2018, economic operators have become much more cautious about using loyalty programmes data to reach out to consumers in case of a recall. In an ideal scenario, recalls should be defined as the initial purpose of personal data processing in customer registers. This way, when consumers sign up for a loyalty scheme or make a purchase online, they would explicitly agree to be contacted in case of safety issues. However, even in the absence of such explicit consent, the use of customers' personal data can be justified. To make sure that companies do not to delay safety measures because of the GDPR concerns, Tukes, the Office of Data Protection Ombudsman, and the Finnish Commerce Federation are currently preparing a memorandum on the issue.

However, some practical questions still remain. This is especially important as GDPR is part of the European legislation, and interpretations need to be harmonised throughout the EU.

The representatives of the Commission mentioned that the Commission is looking into developing a hands-on guidance on how personal data should be handled in the recall process. She confirmed that the recommended default approach, in line with the General Data Protection Regulation, is for businesses to include in their privacy policy the possibility to contact customers to inform them about safety notifications.

GROUP DISCUSSIONS

GROUP 1: Increasing product registration rates

There was a general consensus that the best way to reach out to consumers with recall information is to contact them directly and that increasing product registration rates should therefore be encouraged.

The participants explored major barriers to registration both from a consumer and a business perspective, and suggested possible solutions.

Most consumers simply do not understand the interest of registering their products, and do not make the link between registration and safety. This is especially the case for lower value products (Australian representative mentioned the cut-off threshold of 50 AU$). It is therefore important to clearly communicate about the benefits of product registration.

There is also a widespread lack of trust that the data will not be used for marketing communication. The US product registration card for childcare articles provides a statement that the information will only be used in case of safety alerts and recalls. However, it was mentioned that even that could be further strengthened (e.g. by adding that any other use would be subject to liability).

At the same time, consumers are not a heterogeneous group; they have different risk perceptions and attitudes. The more risk-averse are also more likely to register their products. The challenge is to reach out to the rest. Engaging more vulnerable consumer groups is a particular challenge. Local messengers can be helpful in this regard (for instance churches in New Zealand).

The participants agreed that the registration process should become as seamless as possible. One option to explore is standardising and simplifying registration material to only capture the minimum necessary information. Technological solutions - such as mobile QR code scanning (already very popular in China and Southeast Asia) or even a dedicated product registration app – would also minimise the effort required from the consumer.

The timing of registration matters too. It was noted that the key moment during which consumers can be prompted to register their products is at the point-of-sale. The CPSC evaluation has shown that unless the registration card is filled out (and assisted) immediately after the purchase, there is little chance that it will ever be. While point-of-sale registration may be difficult in physical stores with high customer flow, this is quite straightforward in the case of online purchases. The idea of encouraging registration upon the receipt of the product was also put forward. The UK mentioned their pilot project in cooperation with Whirlpool, testing registration at delivery.

As for the business side, it was noted that economic operators may be reticent to highlight the link between registration and safety so as to not to suggest even the slightest possibility of their product not being safe. It may be therefore more appropriate and effective for the message to come from the government agency.

It was also mentioned that if economic operators were obliged to offer the possibility of product registration to consumers, especially at the point/moment of sale, this would greatly increase registration rates. The role of retailers in the process should be carefully analysed: while they are not the responsible party, they could greatly facilitate communication.

Beyond product registration, it was noted that customers' data is generated also during other touch points of the consumer journey: most products are paid by card; big items are usually delivered and complex items installed. Yet, this data is not being used for safety purposes because of concerns about personal data protection.

Finally, it was mentioned that being able to reach the affected consumers directly does not guarantee that he or she will react. In the case of New Zealand Takata recall, even very intense direct contact (up to 6 letters) did not guarantee a 100% response (despite free repair and very serious risk). New Zealand is therefore shifting from the carrot to

stick approach (“if you fail to respond to the recall, your vehicle will be not pass the compulsory periodic inspection").

GROUP 2: Other methods of identifying affected consumers

To start with, participants were asked about their personal experiences when subscribing to loyalty programs (to which programmes and why they were more likely to subscribe to) and how familiar they were with the concept of "dirty data" (which can be for instance fake contact details or an email address that is not checked by the user).

There was a general agreement that this depends on the trust towards the brand or website. Some said they prefer to create specific email addresses for this very purpose, fearing to be overwhelmed with marketing emails. This is in line with different surveys showing that consumers all over Europe tend to provide “dirty data” for loyalty programme registration: almost a third of people tend to give an email address that they do not regularly check.

The benefits of providing accurate data when signing up to such programmes are not really obvious to consumers (the main motivation being financial), while they see the immediate adverse effects of appearing on more marketing listings and receiving more advertising. This issue is important, as it might undermine the effectiveness of direct safety notifications.

A good practice could be for consumers enrolling in a loyalty programme to have the possibility to provide a specific email address/phone number to receive safety notifications only (similarly to what is suggested for product registration).

The need for the consumer to be “pulled” rather than “pushed” was also stressed when discussing how best to encourage consumers to share their personal data for safety purposes. Most consumers do not see the benefit of giving out their data. Communicating on these issues appears essential. Participants stressed that even though loyalty programmes can be helpful, they should not be the only means of generating customers' data for safety purposes.

The potential role of financial institutions in contacting affected consumers was also discussed. In some cases, it is indeed possible for bank service providers to identify consumers who have purchased a recalled product when the payment has been done with a credit/debit card. Some participants shared experiences with such use of financial institutions in recalls:

- An extra benefit of banks directly communicating recall information to consumers is that consumers tend to have more trust in these messages.
- Handling of personal data is one of consumers' major concerns when third parties are involved in the recall process.
- The emergence of “FinTech” (financial technology companies) should also be considered when looking at ways to facilitate consumer identification, taking into account that customers can have virtual credit cards for purchases online, or can have multiple credit cards per account.

Participants also discussed how online marketplaces can play a facilitating role, taking advantage of the channels and systems they have already put in place to communicate with both consumers and sellers. Two different models exist: some platforms ask the

sellers of recalled products to notify affected consumers, others send the recall message themselves.

The benefits linked to connected products were also stressed. When a connected product itself is subject to a recall, this technology can be used to warn consumers or, if they fail to act, switch off the product or reduce its performance. Connected products may also be able to "monitor" other products. For instance, some smartphones can identify the charger that is plugged to them and could alert consumers in case this charger is recalled. In the food sector, a connected fridge could identify recalled items placed into it.

It was also emphasised that consumers may sometimes not react to a recall alert, even when properly informed. In such situations, different solutions could be explored:

- the role of voice assistants to remind consumers of the need to act;
- the possibility to remotely switch off the unsafe product;
- asking consumers who failed to react to a recall whether they have stopped using the product or have disposed of it (such information could be asked e.g. in recall notifications sent by online marketplaces).

Finally, the issue of products that are no longer in the hands of the initial buyer (e.g. gifts, second-hand products) was discussed. A good practice could for recall notification to include into the instruction "If you have given or sold this product to another person, please forward them this message for their safety".

2. Session 2: Strategies to increase consumers' response to recalls

The aim of this session was to explore how recall communication and procedure can be improved to enhance consumer response.

PRESENTATIONS

UK Office for Product Safety and Standards presented the interim results of the UK government research into consumer attitudes towards product safety. The study revealed that only 17% of consumers consider product safety a priority when purchasing a product, and 23% had registered a product they recently purchased. Overall, the results highlight that consumers assume products are regulated and safe, and are therefore not motivated to register their products. The study has also identified different consumer profiles, indicating that the communication should be adapted to reach each segment: "aware", "busy families", "second-hand shoppers", "less connected", "quick to repair", "buy to last", "latest quality".

Based on the research results and recent Whirlpool tumble dryer recall, some of the most important elements to include in a recall notice include word "safety" in the title, photograph of the product, clear description of the hazard and instructions on what to do as well as highlighting the incentive (e.g. free replacement). Finally, methods for communicating to hard-to-reach consumers should be considered.

In March 2018, the UK government adopted a Guidance on Recalls (PAS 7100), which instructs manufacturers, importers and distributors on how to effectively plan, manage and monitor product recalls. The second part aims at regulators and their role in monitoring incidents and supporting businesses. The guidance will be reviewed and updated, based on learnings from different product recalls.

The Australian Competition and Consumer Commission presented the findings from Australian research into the Takata airbag recall. The Takata recall is the biggest compulsory recall in Australia's history, where 1 in 4 vehicles was affected by defective airbag which had caused 26 deaths worldwide. A communication campaign “A faulty airbag can kill you” was launched to alert consumers of the hazard. The research based on this recall case study focused on identifying the link between recall effectiveness and 1) different communication and engagement strategies, 2) consumers' socio-economic characteristics and 3) behavioural biases. The findings indicate the importance of generating initial recall awareness through mass media, and following up with direct notifications methods (with priority given to two-way channels). It is also crucial to reach out to the local areas where affected consumers live and communicating in the language they speak. Trusted messengers, such as community organisations, are important to get the message across.

The French General directorate for competition, consumer policy and fraud control (DGCCRF) presented the actions taken by the French government to improve recall effectiveness after the 2018 Lactalis infant milk formula crisis. In this particular case, voluntary measures were not enough, so the Minister of Economy and Finance ordered a mandatory recall. The recall faced several effectiveness issues, both on the producer level (failure to correctly identify affected batches, to take effective measure and to withdraw all recalled products from the supply chain) and on retail level (some recalled products still on sale). As a follow-up to the Lactalis crisis, new legal remedies were adopted both in the food law (October 2018) and in the economic law (May 2019): 1) self-test reports showing environmental contamination to be immediately forwarded to authorities 2) increased accountability of producers and retailers during withdrawals and recalls 3) centralised public recalls website. The latter will cover food and feed as well as non-food consumer products (except for pharmaceuticals and medical devices). The website will be linked to a mobile application – “Signal Conso” – that allows consumers to report any concerns (safety as well as economic and commercial).

GROUP DISCUSSIONS

GROUP 1: Content and format of a recall notice

The group reflected on how to improve the content and visual presentation of recall notices to make them more eye-catching and persuasive.

The experts agreed that the message should be short, straight to the point and attention-grabbing. Some argued that terms like 'important safety notice/warning' may actually be preferable to 'recall' in the headline. The risk needs to be communicated in a transparent and understandable way, avoiding "sugar-coating" and jargon. If relevant, the message should be translated into different languages so that it reaches consumers in their own language. Since "a picture is worth a thousand words", product identification information should be accompanied by high-quality visual material. The idea of using a recognisable recall symbol was also mentioned.

It was noted that standardising the content and layout of recall announcements has the potential to make them simpler and more easily recognisable. EBay mentioned their positive experience with recall messages harmonisation. However, there may also be downsides to standardisation: if recall notices become too similar, they may also be less

eye-catching and some products have a very specific target audience). It was agreed that some key elements and ground rules, applicable to all recall notices, should be standardised and compulsory.

Moreover, recall messages could include certain behaviourally-informed 'nudges' and persuasion techniques, such as social proof, loss aversion, reciprocity, personalisation. For instance, appealing to social norms (i.e. highlighting that the majority of people engage in and/or approve of certain behaviour) has proved effective in other policy areas. If using statistics, the numbers need to be real, yet somehow surprising to the public (typically higher than expected). In cases when recall response rates are low, mentioning dynamic statistics ("increasingly many") could be an option. Personalisation (e.g. adding a person's name to the message) has also been shown to encourage action but it is only an option when the consumer can be contacted directly. In addition, opportunity cost (i.e. the costs of not having corrective measures in place) could be highlighted in communication to help enhance consumers trust in the whole product safety system.

There was a broad agreement that setting up a centralised government recall portal can provide a useful single access point for consumers. However, this should not remove the responsibility from businesses to spread the message through all possible channels.

GROUP 2: Communication channels

The group agreed that the most appropriate communication channels to reach out to the affected consumers will depend on a number of factors.

The age of the target audience is of crucial importance. While Facebook and Instagram are key to reach younger consumer groups, traditional media such as TV and radio remain the preferred communication channels for older consumers.

Language, ethnicity and culture were identified as other important aspects when elaborating a recall campaign. In addition, some groups may require very targeted communication approach, e.g. through religious communities. Cultural differences also play a role. As an example, a recall carried out at the same time and with the same communication material in a European country and in an Asian country resulted in very different response times.

In addition, geography and how easy it is for consumers to return a recalled product also needs to be taken into account. An example of a producer sending help to remote communities to repair the product was mentioned. Such approach would also be helpful if the product is too heavy to be brought/sent back. Another solution would be to ask consumers to destroy the product themselves and send only a proof of destruction to receive a remedy.

Regardless of the specificities of the case and characteristics of the target audience, direct communication with individual consumers is always more effective than blanket communication campaigns. According the US CPSC research, direct contact results in an average 50% return rate, compared to 6% in case of generic press releases.

It was also highlighted that the channels should not be separated from the message itself. A recall notice should be formulated in a way that is attractive and understandable for the target audience. Otherwise, it will not motivate action. Consumers should get clear information on the risk at hand and instructions on what to do with the product. If

information is presented in a clear and transparent way, it may actually boost consumers' trust in the recalling company.

Examples of communications to catch consumers' attention and motivate response include using animals or icons as recall ambassadors (e.g. the US campaign with a cat riding a unicorn).

Finally, it was mentioned that the communication capacities will depend on the size of the company and its place in the supply chain. Bigger companies are usually more aware of the importance of recalls and have dedicated departments to deal with them. SMEs and start-ups face more challenges.

GROUP 3: Recall procedure and remedies

The main topic was how to increase consumer response to recalls, focusing on the recall procedure itself. While acknowledging that the "one-size-fits-all" approach is not possible, participants recognised that all steps of the recall process should be as simple as possible and the remedies offered should be sufficient from a consumers' perspective. Often, consumer inaction is due to the procedure to follow being too complex or difficult to understand, while the recall should be as easy as buying the product.

To start with, a recall notice should be attractive and easy to understand for the consumer, providing clear information that a product he/she bought is affected, what steps to take and where to get more information. It is crucial to adopt the consumers' language in the recall communication. For instance, a recent IKEA recall in Sweden was published in Swedish, English and Arabic to reach also immigrant families. Effective communication also means using pictures in addition to text.

Participants emphasised that there is still no means of identification for many recalled products, and suggested that some identification requirements should be mandatory. At the same time, it was noted that multiple model names and codes in the same recall notification may be confusing. The use of online tools would be one solution to allow consumers to easily ascertain if their product is affected by a recall.

The setting up of a hotline to answer to consumers' questions on a recall was also identified as a good practice, even though it might not be possible for SMEs due to the costs involved.

Participants agreed that guidance would be a good idea to help businesses navigate the recall procedure, especially those that do not perform recalls on a regular basis. Having a timeframe for different steps in the recall procedure, following the UK example, would help (even though, again, the need for a case-by-case approach should be stressed); the same goes for standard responses. Overall, economic operators expressed their preference for a coordinated approach to recalls at the EU level.

As for deadlines, the earlier a recall is published the better. However, this does not mean that the information about previous recalls should be removed. To increase recall's speed, IKEA uses "risk communicators", who send targeted messages early in the stage of the recall process. They also keep a communication channel for consumers for any queries.

Typically, businesses face a response peak (highest number of returns) in Month-2 (i.e. after 8 weeks), then they start "re-launching" the recall.

When defining the remedies, it is important to adopt a holistic approach, taking account of both safety and environmental considerations. The type of product and the risk at stake

will also have an impact. Having large numbers of consumers bringing or sending back a product may not always be the most efficient and sustainable solution. It was noted that for large items it may be preferable for the economic operator to pick up the recalled product themselves (even though for SMEs this may be a challenge). For low-value products, providing the information "danger: dispose of it" may be the best approach. In some cases self-repairs by consumers (under instruction) may be feasible, and could also help minimise consumers' fear of losing the product (which is a major barrier to product returns). The question is what burden can be placed on the consumer to return the product and under which circumstances and what type of products can be left in the consumers' hands (for self-repair or disposal).

Another issue is how to take account of reactions other than returns. It would be very helpful to introduce a feedback mechanism, whereby the consumer could indicate what they did in response to a recall (e.g. "I disposed of the product, I repaired it myself, I had it repaired by the manufacturer, I sent//brought it back to the manufacturer/retailer, I no longer own the product").

It was suggested that public authorities should play a more active role in communicating recall information to consumers as "trusted messengers". Official letters by the authorities with a reference to the recalling company can help boost consumers' trust and increase response rates. Authorities should also provide support to businesses in designing the most efficient recall remedies (businesses often go for the least expensive solution). In addition, in case the measures taken by economic operators are not sufficient, the authorities should step in and support businesses in designing a better second recall solution to avoid "recall fatigue". Finally, participants pointed to the need for strengthened cooperation between authorities from different jurisdictions.

Among the challenges on the consumer side, participants mentioned specific socio-demographic characteristics (e.g. consumers with disabilities or living in remote areas) and different risk perceptions. For instance, informed consumers may feel less risk-averse. Some people may also try to repair a dangerous product on their own, the fear of loss being an important barrier to recalls. Therefore, it is important to adopt a flexible approach both to the communication and to the remedies.

It was also highlighted that recalls can be particularly difficult if other people can be harmed by the unsafe product and not necessarily the buyer himself (e.g. cases where the product generates environmental pollution or poses a risk of fire). Incentivising people to take action in such cases may be particularly challenging.

Financial incentives were considered useful, but not appropriate for all products, which again calls for a case-by case approach. The US CPSC recommends a “bounty” (refund of the product's initial price plus a little extra) in well-justified cases. Financial incentives and fines should be used in particularly high-risk cases when the product needs to be removed from homes (e.g. strollers) or when other means do not work. Financial incentives should be used intelligently and not too often so that consumers do not get used to "picking the best offer". The case of a recall where the financial incentive increased during the second wave was brought up; the risk could be that in future recalls, consumers would wait to act until the incentive has increased, which would be counter-productive.

Another way to increase consumers' propensity to reply to a recall is to minimise the effort required from them. This could include product’s collection by the businesses

themselves, repair outside of business hours, or “proposed default dates” for repair/collection.

Hasbro mentioned that in the framework of their programme to return old toys for recycling, consumers have two possibilities, i.e. to print a free-shipping document or leave the toys at a collect point at neighbourhood collection points (retailers). The latter solution, which is similar to systems used to recycle medicines and batteries, has been found to be more effective. It was, however, noted that this solution may not be feasible for products bought online, if the retailer has no physical shop.

3. Session 3: Roles and responsibilities in the recall process

The objective of this session was to discuss the roles and responsibilities of different actors involved in a recall process and how to improve their cooperation to optimise recall effectiveness.

PRESENTATIONS

US Consumer Product and Safety Commission (CPSC) and Health Canada gave a joint presentation on the benefits of regulators' proactive involvement in recall communication and recall coordination across jurisdictions. The CPSC shared their extensive experience of collaborating with the recalling firm on defining the corrective action plan before recall announcement. In particular, the authority and the recalling firm negotiate the language of a joint press release and other recall communications. The CPSC is also closely involved in monitoring the effectiveness of the recall (e.g. on the basis of monthly progress reports from the recalling firm). Moreover, product safety authorities in the US, Canada and Mexico have a long-lasting structured cooperation, which includes coordinating important voluntary recalls across jurisdictions. Around a third of the 250-300 recalls taking place in Canada each year are done jointly with the US. The benefits include increase in consumer participation, leverage from other regulators, information sharing, strengthening cross-border protection of consumers, consistent messaging and reducing the burden on the industry. Health Canada explained their criteria for classifying recalls depending on the level of hazard and corresponding timelines for communicating recall information. Health Canada's Recalls and Safety Alert website provides single access point to all recall information. It also contains guidance for businesses on how to complete an effective voluntary recall.

Goodbaby International explained the company's internal product incident management procedure and its 24/24/24 commitment to product safety. A product recall may be triggered by 1) critical incidents, 2) injury reports and/or 3) test failures. The analysis stage includes full understanding of the risk, possible solutions as well as implications in terms of logistics and project management. Depending on the severity of the case, a decision is made to either continue safety campaign and prepare a product recall or close the campaign and transfer the case to 8D/quality management. The implementation phase consists in determining and developing the most effective overall procedure to "go live" with the recall, The legal authority is also updated at this stage. The activation phase includes recall communication, administering the solution to all products in the market and storage as well as monitoring and reporting on the response rates. In the final stage,

the safety campaign is completed, authorities notified of the outcome and lessons gathered for future incidents.

Amazon described company's product recall programme. In line with the voluntary commitments made in the Product Safety Pledge (June 2018), authorities' recall websites and the EU Safety Gate are monitored on a daily basis and dangerous product listing are removed within 2 working days. The same deadline is applied to responding to authority contacts. Advanced search options are used to identify all affected products (e.g. in case a batch number is missing, image search may be used). Confirmed listings are immediately removed from sale and multilingual key-word based filters are implemented to identify and prevent re-listing. Tailored messages are sent to suppliers and, if required by the recall type and scope, to individual customers. Physical inventory is removed from the supply chain by returning the products to the supplier or destroying them.

SGS Digital Trust Services talked on behalf of the TIC Council about the impact of cybersecurity risks linked to Internet of Things (IoT) devices and the implications for consumers, manufacturers and regulators. IoT vulnerabilities usually affect all Member States (as compared e.g. to food) and may pose a wide range of risks to consumers (including fatal safety risks), businesses and the society as a whole. The vulnerabilities may not be transparent for the manufacturers and the users or there may be technical or other challenges to fixing and patching them. The actions to be taken by consumers and manufacturers were discussed, including the possibility of reducing or switching off the devices capacity to prevent incidents. The implications for the regulation, surveillance and enforcement work were also examined.

GROUP DISCUSSIONS

GROUP 1: Roles and responsibilities of authorities

The Commission announced that a coordinated activity (CASP) on recalls will be organised next year and there are still some places available for EU market surveillance authorities to join.

Different authorities shared their experiences and practices regarding product recalls. From the discussions held, it can be concluded that there is no systematic approach to market surveillance authorities' involvement in the recall process, either before it is launched (e.g. economic operators checking with the authorities whether and how the recall should be carried out) or in monitoring the effectiveness of measures taken by the businesses.

In some jurisdictions, such as the Australia, New Zealand, the UK and the US, specific rules and guidance documents have been issued to support economic operators (particularly smaller ones) in carrying out a successful recall.

The jurisdictions that are more actively engaged in supporting the businesses in the recall process emphasised that this has a positive impact on the timeliness and effectiveness. This is confirmed by the comparative research carried out by the OECD Secretariat.

The role of consumer associations was touched upon as well. Recalls may be triggered by test reports from consumer associations, even though different level of requirements of tests performed by authorities, economic operators or consumer associations may complicate the process. Consumer associations tend to look at levels of safety that go

beyond legal regulations, so the authorities may not be able to use them as a direct basis for corrective measures.

The possibility of joint recalls was also mentioned, based on the example of Canada and the US that have put in place a well-running system of bilateral and even trilateral (with Mexico) recalls. The benefits include greater consistency in the timing of the recall and the remedies offered to consumers. These joint recalls are performed on a voluntary basis: the company performing the recall must agree to this.

The discussion concluded with the suggestion that whenever economic operators are in doubt about how to conduct a recall, they should always contact the authorities.

GROUP 2: Roles and responsibilities of businesses

This Group discussed what businesses could do to make product recalls easier for consumers and increase their effectiveness.

It was noted that bigger manufacturers tend to have more control of their distribution channels and may thus be in a better position to manage recalls on their own. Distributors usually do cooperate (depending on supply chain and market conditions). Several participants agreed that there is a continuous flow of information between manufacturer (technical knowledge) and distributor (local market knowledge) to agree on the best way to perform recalls. It was mentioned that manufacturers may prefer to take over the consumers' mailing list, but distributors may be reluctant to make these available because of data protection concerns and because such lists are an important marketing tool. Participants noted that traceability can be an issue if the supply chain is long and complex.

It was mentioned that authorities may need to step in, in particular in small countries or in case of SMEs that are not able to control their distribution channels. For small companies, a recall can be extremely challenging- not just because of the reputational damage but also because of its financial impact. It was suggested that a possible solution could be to have insurances or emergency funds.

Participants representing online marketplaces noted that they are a different actor than "retailers" or "distributors", as they do not have access to physical products. It was also mentioned that online marketplaces take different approaches to recalls, some companies taking control of the process and approaching the buyers directly and others requesting the sellers to reach out to their customers. An issue is that some sellers are not limiting their sales to one marketplace, and that they have no obligation to report back about recall results.

Regarding communication, participants noted that guidelines would be beneficial for both businesses and consumers. However, such guidelines should remain general because each and every recall is different, and there is a need for flexibility.

The importance of monitoring the effectiveness of each recall action was clearly recognised. IKEA mentioned their internal monitoring system per country (small EU countries tend to be very fast to return while e.g. Japan is very slow). Businesses should create return statistics, as well as Q&A for internal use (not all the information gathered is needed by consumers).