

General product safety regulation

OVERVIEW

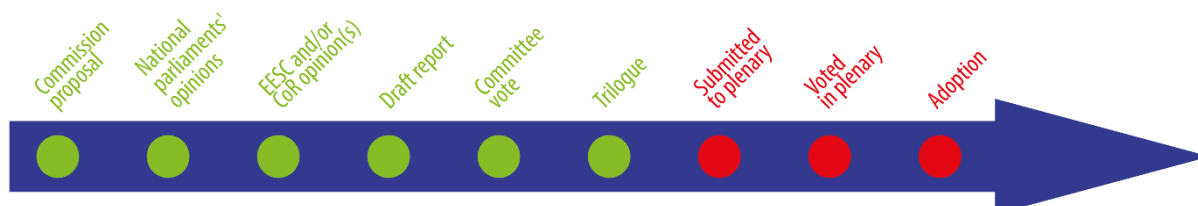
On 28 November 2022, the European Parliament and the Council reached a political agreement on the proposal for a general product safety regulation. The co-legislators are now expected to adopt the agreed text formally, to allow the new regulation to come into force.

The proposed regulation would replace the current General Product Safety Directive. It seeks to address the product safety challenges of emerging technologies, including use of artificial intelligence (AI) and connected devices, and to establish clear obligations for online marketplaces, which consumers increasingly use for their online purchases. The proposal would create a single set of market surveillance rules for both harmonised and non-harmonised products, including by aligning the provisions with the Market Surveillance Regulation, and would improve the effectiveness of product recalls.

Three trilogue meetings were held between 15 September and 28 November 2022. The text agreed simplifies the EU's legal framework for product safety, in particular by including references to key EU regulations, such as Regulation 2019/1020 and the Digital Services Act. The text also extends consumer protection to the new digital technologies, and reinforces consumer rights with several provisions, including the extension of the possible remedies to be offered in the event of a recall.

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

<i>Committee responsible:</i>	Internal Market and Consumer Protection (IMCO)	COM(2021) 346
<i>Rapporteur:</i>	Dita Charanzová (Renew, Czechia)	30.6.2021
<i>Shadow rapporteurs:</i>	Marion Walsmann (EPP, Germany) René Repasi (S&D, Germany) Kim Van Sparrentak (Greens/EFA, the Netherlands) Alessandra Basso (ID, Italy) Beata Mazurek (ECR, Poland) Anne-Sophie Pelletier (The Left, France)	2021/0170(COD) Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
<i>Next steps expected:</i>	Final first-reading vote in plenary	



Introduction

On 30 June 2021, the European Commission adopted a [proposal](#) for a regulation on general product safety, with a view to improving the safety of non-food consumer products on the internal market. Announced in the new consumer agenda [strategy](#), the proposal aims to replace the current General Product Safety Directive (GPSD), as part of the regulatory [fitness check](#) programme (REFIT).

The exact proportion of unsafe products on the EU market is unknown, mainly because market surveillance authorities in the Member States do not inspect every single product placed on the market, but base their activities on the assessment of risk. The data provided by the national market surveillance authorities for a Commission [study](#) showed that, in 2018 and 2019, depending on the Member State, between 1 % and 16 % of inspected products were found to be dangerous, with a median share of around 4 % of all products inspected.¹ Shares of unsafe products can also vary widely between specific product categories; for instance, coordinated activities on the safety of products (CASP) found 97 % of [baby nests, bedside sleepers and sleep bags](#) tested and 38 % of [toasters](#) tested to be dangerous, while 14 % of toys tested exceeded the limit values for [nitrosamines](#). On the other hand, most consumers seem to be satisfied with product safety in the EU. According to the Commission's 2021 consumer conditions [survey](#), 72 % of consumers think most consumer non-food products are safe.² Nevertheless, 4 % said they had experienced product-related accidents, injuries and health problems in the previous two years, and 8 % said that a product they owned had been recalled.³ The Commission estimates consumer detriment due to unsafe products at €11.5 billion per year. This includes preventable detriment caused by non-fatal product related injuries and the cost of premature death.⁴

The Commission proposal for a new regulation comes at the time when the EU is redefining its rules on e-commerce, which has seen rapid growth in the decades since the EU rules were adopted. Consumers increasingly shop online; according to the consumer conditions survey, 71 % of them made an online purchase in 2020 – an increase from 50 % in 2014 – and 21 % ordered something from outside the EU (8 % in 2014). At the same time, according to Safety Gate's 2020 annual [report](#), 26 % of the notifications of dangerous products made by the national market surveillance authorities in 2020 concerned products sold online, while at least 62 % concerned products originating outside the EU and the European Economic Area. Testing by the European consumer organisation [BEUC](#), which included 250 products bought from online marketplaces, showed that two thirds failed EU safety requirements.

Existing situation

Ensuring the safety of non-food consumer products on the internal market consists of two different regimes:

- **Harmonised products** (whose technical or other characteristics are covered by EU harmonisation legislation) fall under Annex I of [Regulation](#) (EU) 2019/1020 on market surveillance and compliance products and product-specific legislation (for instance the Toy Directive), with some provisions of the GPSD also applying (these cover aspects of product safety that are covered by the GPSD, but that are not covered by the Market Surveillance and Compliance Regulation or the harmonising legislation). These products make up around two-third of non-food products on the EU market;
- **Non-harmonised products** fall under the full scope of the GPSD, with the Market Surveillance and Compliance Regulation applying to customs control for imported products. These products represent one third of non-food products on the EU market and are among the most popular products sold online, according to [Eurostat](#) (especially clothes and shoes, followed by furniture and home accessories).

Figure 1 – General overview of the EU product safety framework

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

Source: European Commission, [Impact assessment accompanying the proposal for regulation on general product safety](#), p. 5.

The Commission attempted to modernise and reform this system as early as 2013, by proposing a product safety and market surveillance [package](#). However, the Member States were repeatedly unable to reach an agreement in the Council, and in 2020, the Commission decided to withdraw the package. The urgent issues regarding market surveillance of harmonised products have in the meantime been tackled with the Market Surveillance and Compliance Regulation, which was adopted in 2019, and took effect in July 2021. This, however, left the regime for market surveillance for non-harmonised products unchanged.

General Product Safety Directive

The GPSD requires that all non-food consumer products placed on the internal market are safe and functions as a 'safety net'. It applies fully to non-harmonised products, as well as to those aspects of product safety of harmonised products that are not covered by the Market Surveillance and Compliance Regulation or the harmonising legislation. A product is considered safe if, under normal or reasonable, foreseeable conditions of use, it 'does not present any risk or only the minimum risk compatible with the product's use'. The directive also lays down general rules as to how European standards should be drawn up.

The directive lays down requirements for **producers, importers and distributors**. Producers and importers are required to place only safe products on the market. Distributors are required to act with due care to not supply products that they know, or should have known, do not comply with the requirements. Producers, importers and distributors are required to withdraw products placed on the market if they turn out to be dangerous, or, as a last resort, recall them from the consumers who have already bought them.

The directive lays down **rules for market surveillance** of non-harmonised products (market surveillance of harmonised products being regulated by the Market Surveillance and Compliance Regulation). Each Member State has to appoint an authority to monitor product compliance. While the Member States define the tasks, powers, and organisation of these competent authorities and the penalties for infringements, the directive defines the minimum powers allocated to the national authorities. The directive requires the competent national authorities to take due account of the [precautionary principle](#) in cases where products are or could be dangerous.

The GPSD promotes collaboration between the national competent authorities and the Commission in a **European network of the enforcement authorities**, of Member States, competent for product safety. It also lays down rules for the **Community rapid exchange of information system (RAPEX)**, through which national competent authorities can alert their counterparts in other Member States of dangerous products on the market that present a serious risk to consumers.

Food Imitating Products Directive

The Food Imitating Products [Directive](#) (FIPD) was adopted in 1987, before the adoption of the GPSD. It requires Member States to take measures to prohibit the marketing, import, manufacture and export of products (such as cosmetics or household cleaning products), which are not food, but can be confused with food by consumers because of their shape, colour, appearance, packaging, labelling or size. Such products are especially dangerous for children, who could be tempted to put them in their mouth or eat them.

Parliament's starting position

In its [resolution](#) of 25 November 2020, on addressing product safety in the single market, Parliament urged the Commission to update and establish aligned market surveillance rules for both harmonised and non-harmonised products placed on the market, offline or online, and to make them fit for the digital age. It called for updated product safety rules that would tackle the challenges of emerging technologies such as AI, connected products, robotics and 3D printing. In this context, it also pointed out the need to redefine the term 'product' and 'safe product' in the GPSD, so that for products embedded with AI, internet of things (IoT) and robotics, standalone software and software updates leading to substantial modifications would clearly be covered. It presented a number of possible measures for improving product safety, including harmonising risk-assessment methodology, especially for high-risk products; setting minimum sampling rates; regular sector-specific 'mystery shopping' on online marketplaces; improving cybersecurity; increasing the resources and expertise of market surveillance authorities in the Member States and enhancing cooperation among them; supporting the creation of harmonised standards to ensure the safe use of new and interoperable digital technologies on a uniform basis throughout the EU; and to improve recalls of unsafe products. Parliament also called on the Commission to explore the option of requiring non-EU economic operators to designate an economic operator in the EU for non-harmonised products that EU market surveillance authorities could contact in case of product safety issues.

In its [resolution](#) of 12 February 2020, on 'automated decision-making processes: ensuring consumer protection and free movement of goods and services', Parliament urged the Commission to update the General Product Safety Directive and the sector-specific harmonising legislation, to ensure that users and consumers are protected from harm caused by products with automated decision-making capabilities.

Preparation of the proposal

As part of the preparations, the European Commission conducted an external evaluation of the General Product Safety Directive that focused on the 2004-2020 period. It was supported by a GPSD [study](#) prepared by Civic Consulting in March 2020.

From June to September 2020, the Commission organised a [public consultation](#) on the combined [inception impact assessment and roadmap](#) for the revision of the GPSD. The public consultation sought feedback on several consumer files. The part on the revision of the GPSD, which was optional, received 257 replies, with the same proportion coming from business associations and individual EU citizens (26 %), followed by companies (15 %), public authorities (11 %) and consumer organisations (8 %). More than three quarters of participants said that the rules on product safety could be improved, entirely, or in specific areas, with most respondents mentioning that the rules

are not adapted to online trade and are not properly enforced or adapted to new technologies. The Commission also organised an open public consultation and stakeholder workshop, collected ad hoc contributions and ran targeted consultations with Member States and other stakeholders.

These consultations and their evaluation fed into the Commission [impact assessment](#) (IA) (with [executive summary](#)). According to this document, too many unsafe products still reach consumers or remain in their hands. The IA identified several main issues to be addressed:

- **product safety challenges linked to new technologies, including digital technologies.** It is not clear to what extent the GPSD is applicable to new technologies, such as AI and connected devices, or to software updates and standalone software, and whether the cybersecurity risks are included in the definition of safety. The GPSD study also identified an issue with products involving machine learning and AI, as these can evolve over time, potentially increasing the risk of a product that may originally have been safe;
- **product safety challenges in the online sales channels.** The impact assessment concluded that the GPSD does not establish clear obligations for the new online business models, such as online marketplaces, as they do not fall under the current definition of either producers, importers or distributors. Nor does it provide adequate powers to the market surveillance authorities (e.g. to block websites offering dangerous products). A major issue is market surveillance of products ordered by individual consumers directly from companies established outside the EU;
- **ineffective product recalls.** While the GPSD requires recall of dangerous products as a last resort, it does not lay down specific rules as to how this should be done. The rate of return of products remains low, partly due to the fact that many consumers are not aware of recalls, and partly because recall notices often downplay the risk by using terms such as 'voluntary/precautionary recall', 'potential concern/problem', or 'in rare cases/in specific conditions';
- **complex market surveillance rules.** Market surveillance authorities have different powers and have to follow different rules when it comes to harmonised and non-harmonised products, and since the adoption of the 2019 Market Surveillance and Compliance Regulation, the difference between the two regimes has increased. For instance, the regulation introduced an operator in the EU responsible for products entering the EU market for some high-risk harmonised products, which does not apply to non-harmonised products. The evaluation found that non-harmonised products are more difficult to trace throughout the supply chain, that there are differences in the implementation of the GPSD between the Member States, and that the sanctions and penalties for product safety infringements remain low;
- **inconsistent application of product safety rules for food-imitating products.** While some Member States base their measures regarding these products on a risk assessment in line with the GPSD, others maintain a ban on them, in line with the FIPD.
- **legal form.** The fact that the GPSD is a directive has led to uneven transposition and implementation. For instance, Member States have transposed the provisions on traceability differently.

The impact assessment looked at several policy options: option 1 would rely on enhanced enforcement of the current legislation; option 2 would include a targeted revision of the GPSD with new risks included in its scope, but not software; option 3 would lead to a full revision of the GPSD, recast it as a regulation, bring software within its scope and include additional requirements; option 4 would integrate the GPSD market surveillance provisions and the Market Surveillance and Compliance Regulation in a single market surveillance legal instrument. The preferred option was option 3.

An EPRS [implementation appraisal](#) concluded that the GPSD needed to be revised, but that the Commission would have to find a balance between ensuring unhindered trade and guaranteeing

the safety of all products on the internal market. EPRS has also published an [appraisal](#) of the Commission's impact assessment.

The changes the proposal would bring

On 30 June 2021, the Commission adopted a proposal for a general product safety regulation, which would repeal current General Product Safety Directive and the Food-Like Products Directive and amend the [Standardisation Directive](#).

Under the political agreement, the proposal contains the following elements:

- **scope:** the definition of a 'product' would be extended to cover 'items' (currently 'products'), 'interconnected or not to other items' (article 3(1)). This is meant to address emerging safety risks introduced by new digital technologies;
- **new digital technologies:** aspects for assessing the safety of products would include cybersecurity (article 7(h)) and evolving, learning and predictive functionalities of a product (article 7(i));
- **traceability:** manufacturers, authorised representatives, importers, distributors and responsible persons would be required to place their contact details on product packaging or their website (article 15.3). Currently, Member States **can** require producers to place an indication of their identity on the packaging, but contact details are not required. In addition, in cases where products present a serious risk, the Commission would have the possibility to adopt delegated acts that would introduce a more stringent traceability system. Market surveillance authorities, consumers, economic operators and other relevant actors would have to have free access to such data (article 17);
- **person responsible for products placed on the market:** the requirement that a product can be placed on the market only if there is a manufacturer, importer, authorised representative or a fulfilment service provider established in the Union, would be extended to non-harmonised consumer products (article 15). This responsibility would include regular safety checks of products after their placing on the market. Currently this is only required for some groups of harmonised products, under Article 4 of the Market Surveillance and Compliance Regulation;
- **substantial modification:** any natural or legal person that modifies a product substantially, including through digital means, would be considered a manufacturer, with all the associated obligations. The proposal lists the criteria for a modification to be deemed substantial (article 12);
- **new obligations for distance sales:** the information available to consumers online would be brought in line with information in the offline world. Online offers, for both harmonised and non-harmonised products, would have to indicate the name, trademark, postal and electronic address of the manufacturer or person responsible; and warnings or safety information would have to be affixed to the packaging or an accompanying document (article 18);
- **obligations on providers of online marketplaces:** the regulation would impose specific obligations on providers of online marketplaces, in line with the general principles laid down in the Digital Services Act, in particular its Article 9(2). Online marketplaces would be required to establish a single point of contact for market surveillance authorities and apply voluntary measures on the basis of notifications in the Safety Gate. Market surveillance authorities would be able to order that an online marketplace remove specific illegal content referring to a dangerous product, to disable access to it, or display an explicit warning without undue delay, within two working days. More broadly, the providers of online marketplaces will have to ensure that they have internal processes for product safety in place in order to comply with the regulation, without undue delay. (article 20);

- **creating a single market surveillance regime for harmonised and non harmonised products:** Articles 10-11(1) to (7); 12-15; 16(1) to (5); 18; 19; and 21-24 of the Market Surveillance and Compliance [Regulation](#) would also apply to non-harmonised consumer products. These articles cover the designation of market surveillance authorities and single liaison offices; activities and powers of the market surveillance authorities; national market surveillance strategies; market surveillance measures (corrective actions); Union testing facilities; mutual assistance; and requests for enforcement measures (article 21);
- **Creation of the Safety Gate rapid alert system to replace RAPEX:** the Union rapid alert system for dangerous products would be renamed the Safety Gate rapid alert system (article 23). A Safety Business Gateway would be created for economic operators, including the providers of online marketplaces, to provide consumers and market surveillance authorities with information (article 25). Manufacturers would be required to notify accidents caused by their products in this system without undue delay once aware of the accident (article 19). A Safety Gate portal, open to the general public, easily accessible for persons with disabilities, would enable consumers to inform the Commission of dangerous products, (article 32);
- **improved recall rules:** economic operators would be required to inform all the consumers they can identify about a recall. In particular, loyalty programmes and product registration schemes would have to offer consumers the possibility to provide separate contact details that could be used for safety purposes alone, without prejudice to the EU [General Data Protection Regulation](#). The proposal includes detailed rules about how a recall notice should be presented, such as being easily understood by consumers, and it imposes a requirement that expressions that could decrease consumers' perception of risk should be avoided (article 34);
- **consumer remedies:** consumers are entitled to an effective, cost-free and timely remedy. In the event of a recall, they should have the right to at least two of the following possible remedies: repair, replacement or an adequate refund (article 35);
- **penalties:** Member States would have to lay down penalties for infringements (article 40);
- **food-imitating products:** the regulation would not ban such products, however, their characteristics, in particular their appearance, would have to be taken into account when assessing their safety (article 7(f)).

The regulation would apply from 18 months and 20 days after its adoption (article 47).

Advisory committees

The European Economic and Social Committee (EESC) adopted its [opinion](#) on the Commission proposal in October 2021. The EESC raised doubts that consumer protection will be sufficient if the effort to implement it continues to rest primarily on national supervisory authorities rather than on platforms. It expressed regret that the regulation does not place the same requirements on online marketplaces as importers or distributors, depending on their activity and their role in the supply chain. It also said that the work of market surveillance authorities should cover all consumer goods and should be based on shared, coordinated, properly funded and streamlined efforts across Europe. The EESC criticised the lack of obligation for Member States to collect and provide better data on accidents and injuries and called for measures to support small and medium-sized enterprises (SMEs), by providing clear and useful guidelines, advice and adequate training, including a period of financial support.

National parliaments

The deadline for the [national parliaments'](#) submission of reasoned opinions on the grounds of subsidiarity was 22 November 2021. No reasoned opinions were submitted.

Stakeholder views

The European consumer organisation, BEUC, welcomed the proposal. However, it warned against creating loopholes regarding the role and responsibilities of online marketplaces due to interactions between the final versions of the general product safety regulation and the Digital Services Act. It commended the Commission for including cybersecurity requirement for products to be considered safe; creating a single set of rules for market surveillance of both harmonised and non-harmonised products; strengthening the possibilities for international cooperation; and retaining the precautionary principle intact. BEUC voiced hope that the final act would include a pan-EU accident and injuries database to help identify areas where more action is needed.

The organisation that represents consumer interests in the process of standardisation, ANEC, took issue with the GPSD principle that the European standards, on which safety requirements are based, should be developed by private European standardisation organisations, arguing instead that policy-makers should decide on these requirements.

Business organisations highlighted the issue of non-compliant products entering the internal market from third countries, which creates an uneven playing field for European businesses. They were more likely to argue that while a significant revision of the GPSD is necessary, the solution is better enforcement. They also argued that the Market Surveillance and Compliance Regulation should fully enter into force and its implementation be evaluated, before creating any new rules. This view was expressed, for instance, by Business Europe, Digital Europe, the European Automobile Manufacturers' Association (ACEA) and the Alliance for Internet of Things Innovation (AIOTI).

Business Europe added that key definitions in various new legal acts proposed by the Commission should be fully aligned and consistent and that specific aspects of new technologies should be addressed through harmonisation legislation on a product-specific risk assessment basis, where authorities focus on products that bring most risk to consumers.

Digital Europe argued that any safety gaps caused by the use of AI should be addressed within the existing sector-specific regulatory schemes whenever possible, and that the GPSD updates should be targeted only. It noted that Member States' market surveillance authorities are not functioning well, and that this situation should be improved before creating new requirements for businesses.

The Alliance for Internet of Things Innovation (AIOTI) warned that explicit provisions that are technology-specific (AI, robotics, IoT) have no added value and would hinder innovation due to legal uncertainty. The Computer and Communication Industry Association (CCIA) noted that the GPSD is the appropriate EU legal instrument to address the sales of goods through online marketplaces and that the Digital Services Act should remain a cross-sectoral proposal, rather than overlapping or duplicating the provisions of the GPSD. However, it warned that new obligations on online marketplaces should be proportionate and not create barriers to the digitalisation of Europe's economy.

EuroCommerce welcomed the fact that the proposal introduces a person responsible for all products placed on the Union market, but warned that strengthened traceability rules in the proposal need to be further analysed for their practicality, especially for small and medium-sized enterprises (SMEs). It also welcomed the measures aimed at increasing the efficiency of recalls.

Cosmetics Europe noted that the GPSD does not sufficiently address new technologies and online distribution channels; adding that voluntary commitments are not enough and that online intermediaries should have more responsibility for ensuring product compliance.

Legislative process

In the European Parliament, the file was referred to the Committee on the Internal Market and Consumer Protection (IMCO), with Dita Charanzová (Renew, Czechia) as rapporteur. The Committee on Legal Affairs provided an opinion. The rapporteur put forward her draft report on

10 December 2021. The IMCO committee adopted its report on 16 June 2022 and voted to enter into interinstitutional negotiations. The mandate to enter negotiations with the Council, based on the IMCO report, was confirmed, without a vote, in plenary on 4 July 2022.

The report contains the following elements:

- **assessing the safety of products:** when assessing if a product is safe, additional aspects would have to be taken into account, including labelling regarding age suitability for children; different impact on health and safety of different genders; and the impacts on cybersecurity of a possible loss of interconnection in case of connected products (article 5(a));
- **responsible person:** all non-harmonised products would be required to have an economic operator established in the EU responsible for product safety (a manufacturer, an importer, an authorised representative or a fulfilment centre), in line with the proposal. However, only for some products, this 'responsible person' would be required to carry out periodic checks of randomly chosen samples. The European Commission would be required to adopt a list of these products, categories and groups of products at the latest by six months before the date of the application of the new regulation, and would select them taking into account which products are most often notified in the Safety Gate (article 15);
- **obligations of the online marketplaces:** the obligations of online marketplaces would be brought in line with the provisional agreement by the co-legislators on the Digital Services [Act](#) (DSA), with some of the provisions made more specific. In line with article 10a DSA, online marketplaces would be required to use the single points of contact to enable consumers to communicate with them directly and swiftly. The GPSR would lay down concrete deadlines for online marketplaces to comply with market surveillance authorities' orders. Online marketplaces would have one working day to remove listings for dangerous products, disable access, or display an explicit warning, following an order by market surveillance authorities made in line with article 8(2) DSA, provided that the information received is sufficiently precise to enable an immediate identification and location of the illegal listing. If this is not the case, they would still have two working days, as proposed by the Commission. For processing of notices made by other entities or individuals in line with article 14 DSA, they would have three working days (instead of five as proposed by the Commission). In addition, online marketplaces would be required, under certain conditions, to remove all illegal content identical to that which they were required to remove by the national authorities; inform economic operators that their content has been removed; and make reasonable efforts to check randomly whether products offered on their platform have been identified as being dangerous, in particular on the Safety Gate portal (article 20);
- **powers conferred on national market authorities (undercover purchases and sweeps):** market surveillance authorities would be required to conduct inspections on samples of products acquired under a covert identity on a regular basis. This would in particular concern products sold on online marketplaces and products most frequently notified in the Safety Gate (article 21(4a)). They would also be required to regularly conduct simultaneous coordinated control actions ('sweeps') of particular product categories to check compliance with or to detect infringements regarding particular products sold online (article 31);
- **changes to RAPEX:** the Commission would be required to modernise the Safety Gate rapid alert system and develop an interoperable interface that would allow online marketplaces to link their interfaces to the Safety Gate (article 23);
- **consumer complaints:** consumers would have the right not only to file complaints regarding product safety to the national market surveillance authorities and to the Commission, but also to receive a response on the follow up and the decisions made

(articles 31 and 32). Consumers would also be able to file a complaint with the market surveillance authorities if they had not been offered a remedy for unsafe products following a recall (article 35);

- **small and medium-sized enterprises:** the Commission would be required to adopt specific guidelines for economic operators, in particular for SMEs, on how to fulfil the obligations arising from the new regulation (article 16);
- **application date:** the regulation would apply six months later than originally proposed by the Commission.

In the Council, work on the proposal took place within the Working Party on Consumer Protection and Information. Following 22 meetings under the Slovenian, French and Czech presidencies, Member States reached a compromise, and on 20 July 2022, Coreper approved a mandate for negotiations, with the following elements:

- **obligations of online marketplaces:** online marketplaces would be required to have in place internal processes for product safety (article 20(5)(1)(a)). These processes would have to include mechanisms to require traders to commit to offer only products that comply with product safety rules and to supply information on the existence of an economic operator established in the Union or a responsible person for products offered (article 10(5)(a)). Market surveillance authorities would be allowed to require online marketplaces to remove not only specific offers of specific dangerous products from their website, but also all other identical content (article 20(2)(a)). Online marketplaces would be required to suspend for a reasonable period of time and after a warning, traders that frequently offered non-compliant products (article 20(5)(b)). In the event of a product recall, they would be required to notify directly all consumers who had bought the relevant product on their website (article 20(6));
- **responsible economic operator:** the Council suggests that the text should state explicitly that a product can be placed on the market only if there is an economic operator established in the EU responsible for tasks relating to the safety of products. This responsible person would be required to check regularly that the product complied with the description in the technical documentation; that the solutions adopted to eliminate or mitigate risks were still in place and effective; and that the product complied with the rules on traceability, contact information and safety instructions. The responsible person would not be required to test samples regularly as proposed by the Commission (article 15);
- **remedies:** in the event of a recall, economic operators would be required to offer consumers the opportunity to choose between at least two of the following remedies: repair (provided that the safety of the repaired product could be ensured), replacement or refund. The amount of the refund would have to be at least equal to the price paid by the consumer. Consumers could be offered only one remedy if other options were impossible or would cause disproportionate cost to the economic operator (article 35);
- **penalties:** Member States would have 24 months to notify the Commission on rules on penalties, instead of three as proposed by the Commission. A number of provisions proposed by the Commission regarding penalties would be deleted, including the maximum amount of penalties; the indicative criteria for the imposition of penalties; and the requirement for annual reports from the Member States to the Commission on the imposed penalties (article 40);
- **application date:** compared to the Commission's proposal, Member States would get an additional year and a half to start applying the regulation.

Parliament and Council started the interinstitutional negotiations with a first trilogue meeting on 15 September 2022. Two further trilogue meetings were held, on 8 November 2022, and on 28 November 2022, when a provisional political agreement was reached.

A number of points included in the Parliament report were retained by the co-legislators. On the **assessment of the safety of products**, article 5 provides for a wide range of mandatory requirements regarding suitability for different users, such as children, and a set of digital safeguards to ensure cybersecurity and cover the evolving, learning and predictive functionalities of a product with an AI element. On the **obligations for providers of online marketplaces**, the Parliament contributed to ensure that orders given by Member States' market surveillance authorities to those online providers comply with the granularity of information prescribed in Article 9(2) of the EU Digital Services Act mentioned above.

The **powers conferred to national market surveillance authorities** were also enhanced, on the basis of the Parliament report. Under article 29, the Commission must organise a regular joint activity whereby market surveillance authorities conduct inspections on products made available online or offline, acquired under a cover identity. This builds on Article 14(4)(d) of [Regulation 2019/1020](#) on market surveillance authorities' powers (which enables them to perform 'unannounced on-site inspections and physical checks of products'). Furthermore, article 31 on simultaneous coordinated control actions of market surveillance authorities ('sweeps') will allow Member States' relevant competent authorities to take joint actions, stressing the transnational dimension of the EU single market.

Furthermore, to incentivise overall compliance, the memoranda of understanding (article 20(a)) will allow economic operators or providers of online marketplaces, as well as organisations representing consumers or economic operators, to undertake voluntary commitments, with the aim of enhancing product safety.

Article 16 pays specific attention to the need to provide appropriate support for **small and medium-sized enterprises** (SMEs), setting out specific guidelines for economic operators, such as SMEs and micro-enterprises, on how to fulfil the obligations laid down in the regulation.

Significant elements of the Council's mandate were also included in the provisional political agreement. For instance, on the **responsible economic operator**, article 15(1) now states explicitly that a product covered by the regulation may be placed on the market only if there is a responsible economic operator established in the Union. These responsible economic operators must carry out regular compliance checks, which should be documented, and communicated to the competent market surveillance authority on request. Parliament's request to give the Commission power to adopt delegated acts to request precise information on implementation of such checks has been included at article 41(1).

The Council position on **remedies** was also retained: rather than offering one possible remedy from repair, replacement or an adequate refund in the event of a recall, article 35 now provides for two remedies (from the same list).

The Council's mandate on **penalties** was also retained in article 40: Member States must lay down the rules on penalties applicable to infringements of the regulation. The list of indicative criteria included in the Commission proposal has been removed.

Lastly, a compromise was reached by the co-legislators regarding the **application date**: article 47 specifies that the regulation will apply as of 18 months following its entry into force.

EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

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ENDNOTES

- ¹ These numbers are not representative of all of the products on the market, as not all products are inspected.
- ² When asked about product safety, 52 % said that a small proportion of products were unsafe, 21 % said that all products were safe, while 20 % thought that a significant number of products were unsafe. For more details, see pp. 39-48.
- ³ While the majority returned the product or disposed of it, 13 % took no action and 8 % continued using it with extra caution.
- ⁴ See European Commission, Impact [assessment](#) accompanying the proposal for regulation on general product safety, p. 11. The Commission estimates that the €11.5 billion per year is about 15 % of the total consumer detriment of €76.6 billion per year from product-related injuries and premature death. The remaining €65.1 billion also involves products, but the injuries and death are not caused by the product being unsafe. The example given is injuries caused by falling from a ladder, where the ladder was not itself unsafe.

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