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POSITION PAPER

21 December 2021

General Product Safety Regulation (GPSR)

KEY MESSAGES

- **We support the goal to align with the New Legislative Framework (NLF) for products and the EU Regulation on market surveillance 2019/1020. However, the GPSR should seek alignment and not expand beyond the current legal framework for the harmonised sector.**

- **Several new concepts and definitions introduced in the GPSR are too vague and inconsistent with the EU legal framework on product safety, which may result in unnecessary overlaps and arbitrary implementation.**

- **Risks from new technologies should be addressed through harmonisation legislation on the product specific risk assessment basis, as this allows for more tailored solutions and prevents unnecessary overlaps.**

- **Chapter III places greater and disproportionate obligations on economic operators for non-harmonised products than exists for the harmonised sector under the NLF – which wrongly infers that non-harmonised products present a greater risk to consumers (e.g., Art. 17 traceability requirements).**

- **We should tap into the potential of digital technologies for a more effective application of the GPSR, without being overtly prescriptive to ensure that dynamic solutions can be developed.**

- **The obligation to appoint a responsible person in the EU for low-risk imports risks causing disproportionate bureaucracy and trade tensions and should therefore be based on a risk-assessment.**

- **We support due diligence obligations for online marketplaces that are consistent with the Digital Services Act and recommend upholding the limited liability scheme throughout the GPSR.**

- **Only products presenting a serious risk should be notified in the Safety Gate.**

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CONTEXT

The General Product Safety Directive 2001/95/EC (GPSD) covers the safety of non-harmonised products and of non-harmonised aspects of harmonised products. It thus functions as a *lex generalis* to the areas where no (sector-)specific EU product safety legislation applies. In addition, it includes provisions on the 'Safety Gate' where market surveillance authorities exchange information about dangerous products (both harmonised and non-harmonised) that circulate in the internal market. On 30 June 2021, the Commission presented a proposal updating the General Product Safety Directive, in order to 1) respond to issues related to new technologies and online sales, 2) ensure better enforcement and more efficient market surveillance, 3) simplify the standardisation process and 4) improve the recall of dangerous products in the hands of consumers.

BusinessEurope welcomes the conversion of the Directive into a Regulation, which will facilitate uniform application across all European Union Member States and therefore enhance the free movement of goods. As a general principle, the GPSR must remain a "*safety net*" that ensures a basic level of product safety for consumer products that are not covered by sector-specific harmonised legislation. We also welcome the alignment with the New Legislative Framework for products (NLF) as well as the EU Regulation 2019/1020 on Market Surveillance.

As a key societal stakeholder and European social partner, BusinessEurope outlines its reaction to the Commission's proposal for the GPSR, below.

COMMENTS

Chapter I: General Provisions

Scope (Article 2)

BusinessEurope is concerned by the extended scope and stringent obligations for consumer products that pose no or inherently low risks, without any distinction between product types and without any assessment linked to the nature of a product and its ordinary use, which risks undermining the competitiveness of certain sectors. The GPSR should remain a general "safety net" and not be used to introduce further bureaucratic and economic burdens on all categories of products. For products covered both by the GPSR and sector-specific legislation, we recommend the development of guidance to ensure legal certainty.

Article 2(3) extends the scope of the Regulation to products that are repaired, refurbished, or recycled. BusinessEurope welcomes the usage of second-hand products for environmental reasons and a considerate handling of limited resources. If the repair or reconditioning of a product entail putting in the effort to update it to the latest state of the art so it will be considered safe under Article 6, economic operators may in fact be deterred from placing second-hand products on the market. Therefore, for used, repaired, or reconditioned products, clarification is needed that such products, when made available on the market, must comply with the state of the art that was applicable when the product was placed on the market for the first time (before first use).

With regards to the application of the precautionary principle under article 2(5), we stress that this principle is for use by the legislator only in the face of scientific uncertainty. Local authorities have neither the means, nor the legitimacy to devise – instead of the legislator – the acceptable level of protection for safety or other public policy objectives.[1] Otherwise, it would open the ground for arbitrary bans and market restrictions from local inspectors.

Definitions (Article 3)

BusinessEurope welcomes the Commission's ambition to align the General Product Safety Regulation with the New Legislative Framework (NLF) for Products, in particular the definitions of economic operators. However, further alignment is needed to ensure consistency between the horizontal NLF acts and complementary legislations (e.g., Artificial Intelligence Act; Digital Services Act). For example, we recommend aligning and clarifying the interplay between the newly introduced definition of "*online marketplace*" with the definitions of "*information service providers*", "*fulfilment service providers*" and "*online platforms"* contained in the EU Regulation 2019/1020 on market surveillance and the Digital Services Act, respectively. It would help clarify the obligations of different operators and avoid overlaps or inconsistencies. For example, as currently drafted, the definition of "*economic operators"* would oblige all economic operators to fulfil several obligations set in this Regulation, regardless of their respective role in the value chain – which risks creating legal uncertainty and disproportionate burdens on certain economic operators

We also welcome the definition of "*serious risk*". This will prevent easy classification of products as presenting a "*serious risk*", notably under the Safety Gate. Further legal certainty regarding the classification of "*serious risk*" would be helpful.

We are concerned that the newly proposed definition of "*safe product*" introduces that a product must be safe in case of "*reasonably foreseeable conditions of misuse*". While it

[1] Communication from the Commission on the Precautionary Principle, 2000

is appropriate to require manufacturers to provide safety warnings and usage instructions to guide usage and prevent accidents resulting from misuse, misuse is primarily driven by user behaviour, which manufacturers cannot control. Virtually all products can cause harm if misused, but that is not a valid reason to qualify a product as "*dangerous*" as the safety risk is attributable to the user not due to a lack of safety inherent to the product. Furthermore, the reference to "*minimum risks*" in the definition of "*safe product*" will cause legal uncertainty and interpretation divergences amongst market surveillance Authorities. In the same vein, we also recommend clarifying the definition of "*dangerous products".* We fear that the vague concepts introduced risk creating a regulatory framework that is difficult to apply, with unnecessarily heavy burdens, and subject to diverging interpretations.

The proposed definition of a "*product*" is too broad and needs to be clarified. For example, the definition refers to items that are "*interconnected or not to other items"*. We recommend clarifying this concept, to ensure legal certainty and to avoid overlaps with products already covered under the Radio Equipment Directive 2014/53/EU. In all cases, software or data should not be defined as a 'product'. Similarly, with view to keeping the GPSR focused on consumer products, we recommend reverting to the definition of the existing GPSD with regards to the 'likelihood' of a product being used by a consumer. Concretely, we recommend replacing the wording as follows: "(…) which *is intended for consumers or ~~can~~* ***is likely to****, under reasonably foreseeable conditions, be used by consumers*". In our view, this slight change is important to maintain the proportionality of the proposal.

Under the old GPSD, the definition of "*recall"* in Article 3(2)(3) was limited to the return of **dangerous products** that have already been made available to the consumers, whereas under the draft proposal, the reference to "dangerous" is removed. This change broadens the scope and is inconsistent with a risk-based approach.

<u>Presumption of safety (Article 6)</u>

As currently phrased, Article 6 (1) (b) makes it possible for products that are not covered by a European standard to achieve "*presumption of safety*" if they comply with national requirements set by a Member State. BusinessEurope is concerned that such possibility could be in violation of the principle of mutual recognition. It is therefore important to clarify that such possibility would not be used as a barrier by national authorities to prevent the free movement of goods. Mutual recognition must therefore prevail, and it should be explicitly stated in this article or in the respective recitals.

According to Article 6(2), the Commission is enabled to adopt implementing acts determining the specific safety requirements to satisfy the general safety requirement laid down in Article 5. The aim to facilitate standardisation under the GPSR is welcome, but it should not circumvent stakeholders/the co-legislators from the process for

determining specific safety requirements. The well-established practices under the harmonised sector of separation of the essential requirements laid down in product legislation, on one hand, and description of their technical realization according to the state of the art in product-specific voluntary standards on the other should however not be undermined.

Chapter II: Safety Requirements

Aspects for assessing the safety of products (Article 7)

Recital 12 seems to expand the notion of safety or "*health*" to immaterial damage. BusinessEurope strongly recommends that only physical damage should continue to be covered under EU product safety framework.

Considering the significant increase in connected devices throughout Europe, ensuring a risk-based level of cybersecurity for both hard and software is of paramount importance to maintain Europe's cyber-resilience. At the same time, coherent legal provisions on cybersecurity for products are crucial to preserve the international competitiveness of European industry. Therefore, we oppose any insertion of cybersecurity requirements into the GPSR. Rather, and as rightly indicated in recital 22, we recommend addressing cybersecurity separately, for example in the framework of the announced EU Cyber Resilience Act, based on the principles of the New Legislative Framework for products. This is also applicable for products embedding AI, which is dealt by the Artificial Intelligence Act. Furthermore, it is important to ensure legal certainty for businesses and to balance strict responsibilities for damages linked to poor cyber-hygiene practices by consumers.

Articles 7(1)(b) and (c) of the proposal make it explicit that the safety assessment of products which are meant to be used in combination with others needs to take into consideration the interconnection of products among them and the effect that other products might have on the product to be assessed. A manufacturer can only execute his risk assessment toward other, third-party products to the extent that he is aware of intended combined used, their nature and composition. Manufacturers cannot assess the co-use of products not manufactured by them as there is not sufficient information on all possible products and the possible permutations are of course endless. Therefore, it needs to be clear that this co-assessment needs to be limited to facts that are obvious and straightforward. This is also valid for other safety criteria listed under Article 7.

Chapter III: Obligations of economic operators

BusinessEurope welcomes the ambition to ensure consistency between this Regulation and sector-specific Union harmonisation legislation regarding specific obligations of

economic operators. However, obligations should be targeted to cases where it is proportionate to the aim. We are concerned that Chapter III places disproportionate obligations on economic operators, especially for products that pose no or are inherently low risk, without any assessment linked to the nature of a product and its ordinary use; which risks undermining the competitiveness of certain sectors. We are particularly concerned that Chapter III places greater obligations and requirements on economic operators for non-harmonised products than exists for harmonised products under Union harmonisation legislation – which wrongly infers that non-harmonised products present a greater risk. We therefore strongly recommend reassessing the obligations to ensure a proportionate risk-based balance.

Obligations of manufacturers (Article 8)

Under Article 8, the proposed obligations on manufacturers no longer refer to the risks related to each product, nor to commensurate measures, and may therefore have disproportionate effects, especially for SMEs and other companies that tend to put smaller quantities on the market or outsource their manufacturing activities. While we welcome the aim to ensure consistency between the legislation for harmonised and non-harmonised products, the requirements placed on manufacturers go beyond the specifications for harmonised product areas such as those provided by the Decision 768/2008/EC and are not proportionate to the risks presented by these products.

Technical documentation

Article 8 (5) obliges manufacturers to "*draw up technical documentation of the product*", that they should keep for a period of ten years after the product has been placed on the market and make available to the market surveillance authorities upon request. BusinessEurope finds it essential to distinguish the technical documentation of harmonised products, as stated in the current EU Regulation 2019/1020 on market surveillance, from documentation associated with non-harmonised products, in order to avoid confusion and extensive documentation for products that inherently present no or negligible risk, including those that have a simple and safe production line. Moreover, the contents of technical documentation, which can be shared with different economic operators in the value chain, may constitute confidential business information, notably for innovative products integrating new technologies.

Identification of the product

Article 8(7) obliges manufacturers to indicate their "*postal **and** electronic address*" on the product. Such requirement is inconsistent with the New Legislative Framework for products, under which manufacturers are only required to indicate "the address at which they can be contacted". As such, we recommend leaving the choice to manufacturers to indicate either the postal address or the electronic address on the product. Furthermore,

and as an alternative to providing information exclusively on labels or paper, manufacturers should also be enabled to comply by displaying a matrix barcode on the product – or, where that is not possible, on its packaging – which shall provide access to the required information (e.g., contact address, instructions). Electronic labelling can significantly reduce costs and administrative burden for economic operators, has a positive impact on the environment, and meets the expectations of many consumers.

Alerting consumers and authorities

Art 8 (11) obliges manufacturers to "*immediately alert consumers of the risk to their health and safety presented by a product they manufacture and immediately inform the market surveillance authorities of the Member States in which the product has been made available to that effect*".*"* Most non-serious risks do not require the involvement of the authorities and have very modest impact on consumers. This requirement would generate an enormous traffic of information/workload to be managed by all stakeholders including the authorities, which is not consistent with the risk-based approach and not proportionate. We recommend reviewing the current approach and aligning with a case-by-case risk assessment, instead of a default immediate notification to consumers **and** authorities. Exacerbating the requirement for speed and absolute transparency would not, in practice, increase consumer safety; instead, it would likely be very counterproductive. Stakeholder involvement in the development of guidelines for the Business Safety Gate will be key.

Obligations of Importers (Article 10)

Article 10(9) obliges importers to keep technical documentation for a period of 10 years. Such obligation is inconsistent with existing practices under the New Legislative Framework for products, under which importers are only required to make technical documentation available to the relevant authorities upon request. Moreover, the content of technical documentation can be overarching and constitute trade secret, which is why such requirement must be carefully weighed against the need to protect confidential information.

Obligations of distributors (Article 11)

We believe that obligations for distributors to "***verify*** *that the manufacturers and importers have complied with their requirements"* under Article 11 are disproportionate given the limited role of distributors. Indeed, we question the effectiveness and proportionality of this requirement for certain products and their feasability with respect to micro and small businesses. Distributors have previously been subject to a standard of "*due care*" and "*within the limits of their respective activities*" under the old General Product Safety Directive. We consider that it would be reasonable to again include

reference to distributors acting with "*due care*" given their specific limited role in the value chain.

Cases in which obligations of manufacturers apply to other economic operators (Article 12)

BusinessEurope welcomes the introduction of the concept of "*substantial modification*" that is referred to in Article 12, in which case responsibility for the safety of the product, or part of a product, shifts to the person making the modification. We recommend aligning the definition of "*substantial modification" with* other proposals (e, g. Machinery Regulation, Artificial Intelligence Act) to ensure a consistent legal framework and to avoid discretionary implementation.

Internal processes for product safety (Article 13)

Article 13 obliges economic operators to put in place internal processes for product safety, that can be controlled by market surveillance authorities as per Article 21 (4). Such obligation is inconsistent with Regulation (EU) 2019/1020 on Market Surveillance and would create confusion with certain economic operators as well as lead to discretionary implementation. Therefore, we oppose the obligation for internal product safety processes. Any procedures for controlling internal company processes should instead be promoted and developed nationally on a purely voluntary basis.

Cooperation of economic operators with market surveillance authorities (Article 14)

Requirements for market surveillance should be implemented on a risk-based approach and not extend beyond the current legal framework for the harmonised sector. To this end, we recommend aligning with existing rules and not introducing new provisions under the GPSR that would cause further fragmentation between the harmonised and non-harmonised sector. For instance, the new possibility for market surveillance authorities to request economic operators to submit regular progress reports is burdensome and would require dedicated resources that SMEs do not have.

Responsible person for products placed on the Union market (Article 15)

BusinessEurope supports the regulatory objective to facilitate the work of market surveillance and customs authorities, and measures that can improve enforcement and that help preserving a level playing field. This should be achieved through the creation of a consistent legal framework. Therefore, the obligation to appoint a responsible person in the EU should be consistent with other obligations set in this Regulation as well as obligations under Article 4 (3) of EU Regulation 2019/1020 on market surveillance. For example, Article 15 (2) obliges economic operators to carry out sample testing of randomly chosen products made available on the market. Such obligation to perform

sample testing should be aligned with existing provisions under Union harmonisation legislation, under which manufacturers and importers are required to carry out sample testing **when deemed appropriate with regard to the risks presented by the product**

Furthermore, Article 15 extends the obligation set out in Article 4(1), (2) and (3) of the EU Regulation 2019/1020 on market surveillance to the non-harmonised sector. We stress that Article 4 of the EU Regulation 2019/1020 on market surveillance started applying as of 16 July 2021 and introduces the requirement for a responsible person for **higher risk product categories**. Currently, we (including market surveillance authorities, the Commission, and businesses) still do not have a clear perspective on the effectiveness of this obligation. This approach should not be seen as the main solution to the product safety challenges. Therefore, we believe that it is premature to use this experience in the GPSR expanding it to all products. Instead, the obligation of a responsible person in the EU should be imposed based on a risk assessment and be limited to products for which information from the market provides evidence of real risk.

In these actions we need to ensure a careful balance between control and unnecessary barriers to trade. This obligation could lead to additional supply chain bottlenecks and rise in costs. A general 'responsible person' requirement for all products, including those typically considered as very low risk (books, etc.), will be too costly and present very few benefits, especially when balancing the perspectives of enforcement capacity, resources available to smaller economic actors, the need for high product safety standards and evaluated risk

Traceability of products (Article 17)

The traceability system envisaged here for products susceptible of posing a serious risk appears to be difficult to implement from the industry's point of view. Moreover, it goes significantly beyond the requirements of the New Legislative Framework as well as the EU Regulation 2019/1020 on market surveillance. Requirements for market surveillance, traceability and requirements for economic operators **should be implemented on a risk-based approach and not extend beyond the current legal framework for the harmonised sector.** Under existing legislation, economic operators have the information of their respective customers and suppliers, but not that of the entire supply chain. These can only ever be determined along the supply chain. Information on every supplier in the supply chain can hardly be collected given the mass of components of each individual product and would represent an enormous additional bureaucratic effort for the manufacturers.

It is also unclear how the system of electronic traceability provided for in Article 17(2) is to be implemented, in particular regarding the requirement to affix a data carrier to the product, the accompanying documents or the packaging. This does not seem possible

for traceability down to each individual component in view of the international supply chains. It appears problematic if components, for example from the EU, which are subsequently supplied to third countries and back again within the framework of supply chains, have to be equipped with such systems. In addition to the possibly unintended transfer of data from the EU to third countries, such requirements could conflict with laws in third countries for the purpose of cross-border data transfer. **Therefore, we recommend the deletion of Article 17.**

Obligations in case of distance sales (Article 18)

Article 18 obliges economic operators, both in the harmonised and non-harmonised sectors, to display all safety information online that is also required to be provided in "*brick-and-mortar*" stores. Online sales should not bear disproportionate burden in providing information to consumer compared to what offline sales offer. We suggest limiting this obligation to certain information potentially relevant to consumers' purchasing decisions andnarrowing the scope of the provisions especially concerning batch/serial number. Building the necessary databases for such level of information will take significant time and resources.

Obligations of economic operators in case of accidents or safety issues related to products (Article 19)

As previously addressed, the obligation to notify accidents or safety issues related to products should be consistent with a risk-based approach. Under the old General Product Safety Directive, the obligation to notify accidents did not concern "*isolated circumstances"* or products for which the notification was not relevant. Moreover, the concept of *'accident'* is not defined and could therefore be subject to misinterpretation. We recommend linking the obligations to notify accidents or safety issues to the concept of *'dangerous product'* in order to exclude reporting of incidents that are irrelevant to the assessment of the safety of a product.

Furthermore, the obligation to notify accidents under two working days is far too rigid and short. BusinessEurope recommends reviewing the notification framework to ensure sufficient flexibility and to ensure their easy adoption by SMEs and small-scale providers. Indeed, as currently drafted, the obligation does not consider any special features of the individual case, nor does it give companies in general an appropriate period for consideration and for establishing a clear causal link between the product and the accident.

Chapter IV: Online marketplaces

Specific obligations of online marketplaces related to product safety (Article 20)

BusinessEurope agrees that the application of the General Product Safety Regulation regardless of the channel of sale or the location of the economic operator is key to ensure product safety and the level-playing field. However, there should be **unambiguous separation of responsibilities among various types of economic operators and alignment with the proposed Digital Services Act (DSA)** that addresses responsibilities of the online platforms specifically, or with other existing harmonisation legislation.

We believe that some provisions in Article 20 overlap with the rules on intermediary service providers obligations that are currently being dealt with in the context of the Digital Service Act, notably regarding cooperation with market surveillance authorities, due diligence obligations and the obligations of fulfilment centres and intermediate service providers in the EU Regulation 2019/1020 on market surveillance. To ensure consistency and legal certainty, the GPSR must be fully compatible with the DSA and the EU Regulation 2019/1020 on market surveillance.

Whereas the DSA includes basic due diligence requirements for online platforms to curb the sale of dangerous products more effectively, **the starting point in the GPSR should be that the platforms bear no prior responsibility for checking products covered by the GPSR**. At the same time, it is important to ensure in the GPSR that an obligation is placed on the platforms to cooperate with the authorities in cases where a problem has been identified. In this situation the obligation placed on the online marketplace should be equal to that which follows from the EU Regulation 2019/1020 on market surveillance (Article 4), which is based on a risk-assessment.

We support the application of notice & action mechanisms from Article 14 of the DSA for online marketplaces in the context of this Regulation. This would aid a safer online experience for consumers and business users. While some digital services could feel confident to take decisions in certain instances where the facts presented are obvious, it is by no means that all digital services, for example, online marketplaces permitting thousands of various business users to sell on them, could always be correct. For this reason, we recommend deleting the deadlines for online marketplaces imposed under Article (20), as they are not proportionate in all instances and can quickly overburden SME platforms. Instead, we suggest requiring action “without delay” in order to leave room to take into account all relevant aspects of a specific situation at hand. Indeed, such injunctions are not necessarily within the bounds of a lawful order and often require legal advice, which risks undermining the level playing field for SMEs.

Furthermore, we stress that access to the online interface and possible data scrapping from market surveillance authorities, as foreseen in Article 20 (e), is complex and subject to legal and technical challenges that offline sales channels do not have to dedicate resources to. We welcome further clarity about data search criteria and collaboration.

Chapter V : Market Surveillance and implementation

Market Surveillance (Article 21)

BusinessEurope welcomes the ambition to align market surveillance rules between non-harmonised and harmonised sectors. This will enhance legal certainty and coherence for economic operators in the EU. From a general point of view, the legal framework should have uniform requirements for market surveillance for products under harmonised and non-harmonised legislation. However, market surveillance issues should be regulated exclusively in EU Regulation 2019/1020 on market surveillance and not be duplicated or expanded in the GPSR.

As previously addressed, Article 13 obliges economic operators to have in place internal processes for product safety, that can be controlled by market surveillance authorities as per Article 21 (4). BusinessEurope opposes such an obligation for internal product safety processes, as these go significantly beyond the requirements set down in the current EU Regulation 2019/1020 on market surveillance. Despite this fact, the NLF is based on the personal responsibility of the manufacturers or respective market operators; as such, market authorities may have the right to control product conformity, but it is not to be combined with a general control of the economic operators processes made therefore. Market surveillance authorities should effectively fulfil their task of testing products on the market but should not shift to the control of internal company processes.

Moreover, we have frequently pointed out that the current lack of resources of market surveillance authorities and lack of common methodologies across the EU distort the playing field for compliant manufacturers.[2] In order to ensure effective and efficient surveillance, we advocate for a risk-based approach where authorities focus on products that bring most risk to consumers.

Chapter VI – Safety Gate rapid alert system

Notification through the Safety Gate of products presenting a risk (Article 24)

The EU Safety Gate is a useful tool for businesses – not only they can directly use it to check what product categories and non-compliances are common, but more importantly it allows market surveillance authorities to cooperate better with each other on products **presenting a serious risk to consumers**. We welcome measures to enhance transparency and efficiency for economic operators using the EU Safety Gate.

[2] See https://www.businesseurope.eu/publications/free-movement-goods-priorities-2019-2024 and https://www.businesseurope.eu/publications/businesseurope-comments-commissions-goods-package

Article 24 (8) enables the Commission to adopt implementing acts specifying the criteria to assess the level of risks and the requirements notifications must meet to be reported in the Safety Gate, amongst others. The safety gate must continue to **focus on serious risk and provide clear criteria to justify how and why a serious risk occurs**. Furthermore, Businesses would also welcome further information on the products listed in the Safety Gate, such as the European Article Numbers, to help economic operators link the information to products in their databases.

Chapter VII – Commission role and enforcement coordination

It seems that general criteria are provided in this chapter, but the way in which these principles will be applied is not specifically regulated. This could create a risk of putting in place, in the future, unequal treatment both within the various Member States and between the economic operators who will be involved.

Arbitration Mechanism (Article 27)

BusinessEurope welcome the ambition to enhance uniform application across all European Union Member States. Therefore, we support the possibility for the European Commission to intervene in the context of major divergences between Member States. Nevertheless, we recommend including the relevant economic operators in the consultation processes and introducing a strict timeline under which the Commission shall adopt an opinion, to limit costs on businesses.

Chapter VIII – Right to information and remedy

Safety Gate portal (Article 32)

Article 32 (2) enables "*consumers to inform the Commission of products presenting a risk to consumer health and safety through a separate section of the Safety Gate portal*". Such notifications must be subject to accuracy assessment in order not to distract the European Commission and economic operators from focusing on products presenting serious risks. Consumer notifications must be validated by appropriate experts before the information is made public and/or any corrective action is decided.

Recall notice (Article 34)

We welcome the ambition to increase the effectiveness and consistency of product recalls in EU Member States. We welcome in particular the development of a standard recall notice. This will prevent diverging views and methodologies across the single market.

Right to Remedy (Article 35)

The present Commission draft proposes that in the event of a recall, the responsible economic operator should offer the consumer an "*effective, cost-free and timely remedy*". This is based on the warranty law known (among other things) from the sales law. The EU Commission itself recognizes this proximity in that it wants the Regulation to apply "without prejudice to Directive (EU) 2019/771" (EU Sales of Goods Directive). However, it fails to recognize that such a "repressive" liability provision is diametrically opposed to the preventive character of product safety law, which would mean a fundamental break with European legal traditions. Any liability claims of the consumer are comprehensively covered by the national or European harmonized liability regimes. Such Regulations are systematically found in general and special contract law, in fault-based tort law as well as in strict product liability law; also for damage events that can be traced back to product recalls. **Any additional and, above all, non-systematic inclusion of liability claims in product safety law must therefore be strictly rejected**. Such a move would lead to unnecessary duplication and multiple regulation and, as a result, to increased legal uncertainty. We therefore strongly recommend the complete deletion of Article 35.

Chapter IX – International Cooperation

International Cooperation (Article 36)

We welcome measures to reinforce data sharing and international cooperation between market surveillance and customs authorities, to ensure that products imported from third countries are compliant with EU rules.

Chapter XI – Final Provisions

Penalties (Article 40)

We support uniform interpretation and application of the sanction regime throughout the Union, proportional to the respective role of the economic operator in the value chain. As a general principle, penalties must strike the right balance between effectiveness and proportionality and focus on material harm rather than “formal” non-compliance.

Article 40 (4) introduces a level of fine of at least 4% of the annual turnover, including for formal non-compliance (e.g., failure to provide requested information within the required time-limit). In our view, such level of penalty is completely disproportionate. The existing sanctions regime across the EU is efficient and such threat of sanction will only lead to increasing totals costs for businesses.

Amendments to Regulation (EU) No 1025/2012 (Article 44)

We welcome measures that aim at facilitating the standardisation processes for non-harmonised products. Clarifying the requirements that the standards must fulfil can help in this endeavour if they do not become too prescriptive. However, there is also risks of prolonging the compliance process unnecessarily. The requirements should be defined as generally as possible for the individual product. Furthermore, we are concerned that this new process risks adding complexity in the functioning of the single market for products, which risks discouraging stakeholders from participating.

Entry into force and application (Article 47)

In view of the extended scope of the proposal, BusinessEurope recommends extending the transition timeline from 6 months to 24 months after the adoption of the Regulation. This would give sufficient time for economic operators to update compliance schemes and also help Market Surveillance authorities integrate the new requirements.