

Brussels, 3 December 2021

Orgalim position on the proposal for a General Product Safety Regulation

Executive summary

Orgalim supports the revision of the existing General Product Safety Directive (GPSD) and the decision to transform it into a Regulation (GPSR), which will improve uniform application across the European Union. We recognise the importance of ensuring the safety of all products, regardless of whether or not they fall under harmonised legislation. However, we are concerned by certain aspects of the new proposal which may create legal uncertainty and unnecessary burdens, with no or limited benefits to consumers.

Main messages:

- Health and safety requirements for products should be proportionate to the risk of a product. We call on policymakers to refrain from introducing the precautionary principle in the GPSR. The application of the precautionary principle to non-harmonised products which present no to low risk for the health and safety of consumers might lead to disproportionate burdens for companies, with no concrete impact on the actual safety of consumers
- The broadening of the definition of 'product' in Article 3 does not allow for a line to be drawn between consumer and professional products, thus increasing uncertainty. Moreover, it should be clarified in the text that stand-alone software is not covered by this Regulation
- The current draft creates inconsistencies with other legislation that is currently being revised, reviewed, or newly proposed. Such inconsistencies exist in definitions (e.g. 'substantial modification') but also in requirements going beyond those set out in harmonised legislation. This will increase legal uncertainty and complexity and create the risk of diverging requirements for the same product
- Cybersecurity products or cybersecurity aspects of products should not be regulated in the GPSR, but through the introduction of a horizontal legislation on cybersecurity for networkable products following NLF principles
- With regard to the standardisation system, we encourage a close consultation with industry, the European Standardisation Organizations (ESOs) and other relevant stakeholders throughout the process and we stress the need to solve the well-known existing problems affecting the European standardisation system
- Formal and administrative requirements (e.g. technical documentation, risk analysis, operating instructions, etc.) are excessive and should not be applied in case of no or low risk products
- Penalties should be designed in such a way as to strike the right balance between effective deterrence and proportionality, as defined in Regulation 2019/1020
- The envisaged 6 month transition period is too short and should be increased to at least 24 months

1. General considerations

Orgalim supports the revision of the existing General Product Safety Directive (GPSD) and the decision to transform it into a Regulation (GPSR), which will improve uniform application across the EU. We recognise the need to update the rules for product safety in the Single Market and appreciate the Commission's willingness to align the GPSR proposal with the New Legislative Framework for products (NLF), and most notably with the new rules on market surveillance which recently entered into force.

We recognise the importance of ensuring the safety of all products, regardless of whether or not they fall under harmonised legislation. However, the GPSR should remain a 'safety net' and should therefore apply whenever a consumer product or a safety aspect of a consumer product is not covered by harmonised legislation.

In light of these considerations, we are concerned that the proposed text may widen the scope of the Regulation and create unnecessary burdens that will not contribute to the increased safety of consumers while jeopardising the competitiveness of European industries. On a broader level, we also see growing inconsistency and lack of coherence between the GPSR and NLF requirements, as well as other legislation that is currently being revised, reviewed, or newly proposed. Moreover, as the GPSR aims to align with Regulation 2019/1020 on Market Surveillance, it should not include deviations from such rules.

Below, we outline the aspects we consider most problematic. We remain available to support EU policymakers in designing a balanced and effective GPSR.

1.1. Application of the precautionary principle (Article 2(5))

While we recognise the role of the precautionary principle in the context of EU law, we recall that its application is for use by the legislator only in the face of scientific uncertainty as clearly stated in the Commission Communication on the precautionary principle¹. Local authorities have neither the means (financial, staff, etc...), nor the legitimacy to devise – instead of the legislator – the acceptable level of protection for safety or other public policy objectives. If the precautionary principle were to be introduced in the GPSR, it would open the way for arbitrary bans and marketing restrictions from local inspectors. We are concerned that the application of this principle to non-harmonised products which present no to low risk for the health and safety of consumers will lead to disproportionate burdens for companies, with no concrete impact on the actual safety of consumers. For this reason, **Orgalim calls on policymakers to refrain from introducing the precautionary principle in the GPSR.**

1.2. Definition of product (Article 3)

Compared to the definition of 'product' included in the GPSD, the new definition poses two issues of concern.

Firstly, the replacement of the sentence "intended for consumers or likely, [...], to be used by consumers" with the text "intended for consumers or can, [...], be used by consumers" shows an intention to broaden the range of products affected by the GPSR to also include products that are not intended for consumers, but that could still be accessible to consumers without any probability parameters. Orgalim believes that this definition makes it more difficult to draw a line between consumer and professional products and creates further uncertainty. We therefore ask policymakers to replace the word "can" with the word "likely", thus keeping the wording currently in use in the GPSD.

Secondly, we are concerned that a broad interpretation of the text of Article 3 could consider stand-alone software as a product itself. We strongly oppose such an interpretation, as stand-alone software is unlikely to cause personal injuries or

¹ See the Commission Communication on the precautionary principle ([COM/2000/0001 final](#))

property damage, which are the types of damage covered by the Product Liability Directive. **We urge policymakers to amend the text to clarify that stand-alone software is not in the scope of the GPSR.**

1.3. Presumption of safety and the role of standardisation (Article 6)

The GPSR proposal introduces the concept of “presumption of safety” to mirror the concept of “presumption of conformity” included in the NLF. **We argue that the change of terminology from presumption of conformity to presumption of safety is not necessary** and only adds complexity to the understanding of the working of the Single Market for products. The text of Article 6 clearly states: presumption of safety means that a product is “presumed to be *in conformity with* the general safety requirements [...]”. Therefore, in the case of the GPSR, safety requirements correspond to the NLF mandatory health and safety essential requirements.

In addition, **Article 6(1)(b) states that a product can fulfil the general safety requirements** applicable to the placing or making available of a product in the EU market (as outlined in Article 5) **by complying with national requirements set by a Member State**. Orgalim is concerned that this provision could undermine the principle of mutual recognition. **We call on policymakers to clarify, either in the article or in recitals, that this is without prejudice to the mutual recognition principle.**

When it comes to **standardisation** for General Product Safety, we understand the attempt made by the Commission to streamline the process and align it to the one in place for harmonised products. In this context, we encourage a close consultation with industry, the European Standardisation Organizations (ESOs) and other relevant stakeholders throughout the process and **we stress the need to solve the well-known existing problems affecting the European standardisation system**, including the development of too rigid standardisation requests and the lengthy approval procedures.

1.4. Safety requirements linked to artificial intelligence and cybersecurity (Article 7)

If presumption of safety cannot be ensured through Article 6, Article 7 provides a number of aspects to be taken into consideration to assess the safety of a product. These aspects include cybersecurity (point h) and artificial intelligence (point i) features. While we recognise that more and more consumer products include AI and cybersecurity features and we understand the intention of protecting consumers from possible threats caused by them, we are also concerned that the current provisions may have serious unintended consequences for the coherence of product safety legislation at EU level. Such aspects should only be dealt with in horizontal harmonised legislation, and not be included in the GPSR and other sectorial legislation.

In the case of AI, for example, the GPSR leads to inconsistencies as it tries to define AI in a different way from the draft Artificial Intelligence Regulation (AI Act). The AI Act defines “artificial intelligence systems” as software developed using techniques and approaches outlined in Annex I of the Regulation. The GPSR, on the other hand, looks at “evolving, learning and predictive functionalities” with no alignment to the techniques and approaches identified in Annex I of the AI Act. **This type of discrepancy increases legal uncertainty and complexity and creates the risk of diverging requirements for the same product. For this reason, we call on policymakers to remove AI and cybersecurity requirements from the GPSR.**

In the case of cybersecurity, this issue is even more acute, considering that there is currently no horizontal legislation on cybersecurity and different solutions are being included in several legislative proposals without a thorough assessment of the potential interplay between these legislative acts. Cybersecurity requirements are currently included in the proposals for the GPSR, the Machinery Product Regulation, the AI Act and the delegated act under the Radio Equipment Directive. However, these requirements vary from one to the other. In some cases, the product in question must be able to “withstand [...] intended and unintended external influences, including malicious attempts from third parties to

create a hazardous situation”², in others the cybersecurity features are defined as protection “against external influence”³ or resilience towards “attempts by unauthorised third parties to alter their use or performance”⁴. **We believe cybersecurity products or cybersecurity aspects of products should be regulated through the introduction of a horizontal legislation on cybersecurity for networkable products which would follow the NLF principles.** This would ensure a coherent regulatory framework.

1.5. Obligations of manufacturers (Article 8)

Overall, the proposal significantly expands the obligations of economic operators and particularly of manufacturers. While we welcome the alignment with the NLF approach, we ask for proportionate requirements and **warn against excessive formal and administrative burdens (e.g. technical documentation, risk analysis, operating instructions, etc.) to be applied regardless of the product’s actual risk potential or hazard.** In many cases the obligations for economic operators are not proportionate to the risk presented by a product and go far beyond requirements within harmonised legislation. This includes the requirement to draw up technical documentation for all products in the non-harmonised sector (Article 8(4)), including requirement to carry out a risk analysis. It further requires manufacturers to provide operating instructions (Article 8(8)) regardless of the risk of the product. Moreover, requirements for contact details go beyond current requirements in the NLF as they include the need to indicate an electronic address *in addition to* a postal address. We recommend opting for a solution in which an electronic address could be used *instead of* a postal address.

The requirement to draw up technical documentation including a “general description [...] and [...] essential properties” of the product, means that the manufacturer may be forced to reveal confidential information about their product to importers, with a consequent threat to the intellectual property of the company. This would be the case particularly in relation to innovative products.

Requirements in this proposal should be consistent with requirements in the NLF, as the regulation aims to enhance consistency with harmonised legislation. The current proposal creates unnecessary burdens and increased costs for businesses and particularly for SMEs. Given the chronic lack of resources of market surveillance authorities, these additional generalised requirements will further distort the level playing field, with a consequent loss of competitiveness for law-abiding companies to the benefit of rogue traders.

1.6. Introduction of concept of substantial modification (Article 12)

The majority of Orgalim members supports the need for a clear definition of what should be considered a substantial modification⁵ and recognises that such a clarification has become more and more urgent in light of the new challenges posed by the digitalisation of the economy and society and the need for a shift to sustainable economic business models. However, given the broad application of this concept, **we believe that such a definition should be provided at a horizontal level within the framework of the NLF, rather than addressed in different ways and forms in various product legislation.** We currently see different provisions related to substantial modification in the proposals for a GPSR, for a Machinery Product Regulation, for an AI Act and for a Battery Regulation. Our concern is that one product could be subject to different definitions of substantial modification, once again increasing legal uncertainty and complexity for all players involved.

² Annex III Section 1.2.1 of the Machinery Product Regulation Proposal

³ Proposal for a General Product Safety Regulation, Article 7(1)(h)

⁴ Proposal for a Regulation on Artificial Intelligence (AI Act), Article 15(4)

⁵ The Orgalim position on substantial modification is not aligned with that of our member association FIM.

1.7. Market surveillance requirements

We are in favour of uniform requirements for market surveillance for products under harmonised and non-harmonised legislation. However, **market surveillance issues should be regulated exclusively in the new Market Surveillance Regulation**. We do not support the fact that the new General Product Safety Regulation creates a possible duplication of requirements, in so far as basic aspects are taken over from the Market Surveillance Regulation and supplemented in some cases (e.g. Article 4). This contradicts the approach of coherent legislation.

Some market surveillance requirements seem to go far beyond requirements in the NLF. For example, Article 13 wrongfully interferes with internal company processes; Article 19 provides for stricter requirements for reporting of accidents and the provisions in Chapter VI related to the Safety Business Gateway risk, defeating the purpose of having a rapid alert system for serious risks, because they extend the notification system to cover all risks.

1.8. Additional comments

The wording of Article 40(4) on penalties is rather obscure, providing for “the *maximum* amount of penalties” to be “at least 4 % of the economic operator’s [...] annual turnover” and should be rephrased. As a general principle, Orgalim believes that **penalties should be designed in such a way as to strike the right balance between effective deterrence and proportionality**. We encourage policymakers to align the wording of Article 40(4) with the provisions in Regulation 2019/1020. In addition, this provision does not seem to differentiate enough between formal non-compliance and substantial breaches, making the sanction regime disproportionately costly for businesses.

Given the extended scope of the new proposal compared to the GPSD and the introduction of several new obligations for economic operators, **we argue that the envisaged 6 month transition period (Article 47) is too short and recommend increasing it to at least 24 months** after the entry into force of the Regulation.

Orgalim represents Europe’s technology industries, comprised of 770,000 innovative companies spanning the mechanical engineering, electrical engineering, electronics, ICT and metal technology branches. Together they represent the EU’s largest manufacturing sector, generating annual turnover of over €2,076 billion, manufacturing one-third of all European exports and providing 11.33 million direct jobs. Orgalim is registered under the European Union Transparency Register – ID number: 20210641335-88.