Poland comments on three main issues to be solved on SMEI Omnibuses

According to the Presidency Flash (WK 14649/2023) there are three main issues to be solved on SMEI Omnibuses:

1. **Scope:**

   Poland maintains the Council position and its previously communicated position regarding exclusion from the scope of the SMEI Omnibus two directives:

   - Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles

   and

   - Directive 2014/28/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market and supervision of explosives for civil uses.

   That is "red line" for us. Poland believes it is unjustified to apply emergency/derogatory procedures in the field of conformity assessment to products covered by these two directives. Both directives relate to specific products that are particularly important due to the safety of their use. They could present a risk to the health or safety of persons if they do not be assessed by notified bodies.

   In the case of the explosives for civil uses Directive 2014/28/EU, a full assessment of compliance with the essential requirements is necessary. This is also important because notified bodies not only test the explosives for civil uses but also constantly supervise their production. Therefore, any form of derogation from the conformity assessment procedures requiring mandatory involvement of a notified body (any form of simplified or accelerated conformity assessment), which results in limiting the scope of accredited laboratory tests of explosives, does not ensure that the explosives for civil uses placing on the market will meet the essential requirements. Moreover, in practice, a reliable conformity assessment can only be conducted by notified bodies, because only they have the appropriate knowledge, experience and specialized equipment. There is no presumption of conformity in the case of the explosives for civil uses. These products must be compliant with the essential requirements, what must be confirmed by the appropriate conformity assessment procedure. In extreme cases, using an explosive for civil uses with an alleged degree of compliance, but not meeting the essential requirements, may pose a threat to people, property and the environment.

   We do not agree to broaden the scope of the SMEI Omnibus and that is why we do not support to add the General Product Safety Regulation to the scope of the SMEI Omnibus. The Regulation (EU) 2023/988 lays down only general safety requirements of consumer products and it does not specify any conformity assessment procedures, what means that derogation procedures for the time of crisis, which are the objective and subject of the SMEI Omnibus, will not apply. Moreover, it is the economic operator that chooses the method of safety assessment and this regulation does not require mandatory involvement of notified bodies in the conformity assessment procedures.

2. **Free movement of crisis relevant products:**

   Poland prefers the Council mandate.

3. **Standards:**

   Poland prefers the Council mandate.

As far as the first compromise text on Article 1 of the proposal for the SMEI Omnibus Regulation (**WK 14598/2023**) please find our comments (also enclosed).

- We prefer SMEI not IMERA and Single Market not internal market. The term „Single Market" is more common used than "Internal Market, especially by the European Commission. We have SMET, SDG, SMOT, Single Market Scoreboard, 30th anniversary of the single market, Single notification window, Single Market Programme (SMP) etc.
- We prefer to add "disproportionate" before "the additional costs" as we agreed in the Council text (Art. 1 par.1.point (2), row 45).
- In the Article 1.1. point (2) (rows 70a-70e) relating to presumption of conformity based on standards and common specifications we prefer the text of the Council mandate.

Council of the European Union
General Secretariat

Interinstitutional files:
2022/0279 (COD)

Brussels, 16 November 2023

WK 15151/2023 INIT

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NOTE

From:	BG, CZ, DK, EE, FI, LT, LU, LV, PL Delegation
To:	Working Party on Technical Harmonisation (SMEI Omnibus)
N° prev. doc.:	WK 14598/23
Subject:	SMEI omnibus Regulation and Directive: written comments to the compromise text by BG, CZ, DK, EE, FI, LT, LU, LV, PL

EE comments on SMEI Omnibus (15.11)

We appreciate the Presidency's efforts with SMEI omnibus text, nevertheless we believe that Council's mandate is better at addressing various issues, including free movement of crisis-relevant goods and standards for the derogation procedure. Below are our detailed comments.

1. Scope

Regarding the scope, we have the same comments as before: all construction-related products should not be subject to a simplified conformity assessment procedure.

The simplified conformity assessment procedure should apply only to products falling within the scope of directives **2000/14/EU** and **2014/28/EU** (in the first case, it is the noise requirements of equipment used in outdoor conditions, and in the second case, the requirements for explosive materials).

In addition, transportable pressure equipment (**2010/35/EU**) should be subject to the same requirements as simple pressure vessels, because transportable pressure vessels are also cylinders that are installed indoors.

2. SMEI and GPSR

When do not really need SMEI derogation for conformity assessment procedure for non-harmonised products. The principle of mutual recognition automatically guarantees the free movement of products within the EU in a non-harmonized area if the product is already legally marketed in an EU member state.

3. Hierarchical Approach to Standards (70e)

In line 70a, we see that the hierarchical approach to standards has been abandoned, i.e. if there is an international standard, the conformity assessment should be based on it first. We believe this is the preferred solution as it provides legal certainty and ensures the free movement of goods.

The current compromise wording leaves open the possibility of using common specifications even where international standards already exist. Establishing common specifications in a crisis situation when standards exist does not seem rational to us.

MINISTRY OF INDUSTRY, BUSINESS AND FINANCIAL AFFAIRS

MINISTER FOR INDUSTRY, BUSINESS AND FINANCIAL AFFAIRS

MINISTRY OF INDUSTRY, BUSINESS AND FINANCIAL AFFAIRS
Slotsholmsgade 10-12
DK-1216 Copenhagen K

Tlf. +45 33 92 33 50
Fax +45 33 12 37 78
CVR-nr. 10 09 24 85
EAN nr. 5798000026001
em@em.dk
www.em.dk

Denmark - written comments to the Presidency's compromise text to the SMEI Omnibus proposals

General

- Denmark welcomes the Presidency's compromise text on the SMEI Omnibus-proposals, which includes much of the Council mandated text.
- However, we would encourage that the questions raised in the Presidency's flash are discussed at the Council Working Party.
- In general, we don't find it sufficient or good practice to prepare trilogues in writing only.

Scope

- Denmark doesn't find that the EP's position on adding the General Product Safety Regulation to the scope of the SMEI Omnibus proposals to be neither necessary nor proportionate,
- Furthermore, we find that only relevant harmonized legislation should fall under the scope of the Omnibus proposals, and that the proposals already include many legislative acts.
- In general, we find the EP's proposed widening of the scope to not be clearly defined or reasoned, and don't see the added value of including the GPSR to the already long list of legislative acts.

Free movement of crisis relevant products

- On EP's original position, we continue to state the importance of maintaining the necessary security and safety of products developed during an emergency procedure.
- We find that the Council mandate strikes a proportionate balance in maintaining free movement throughout the

Union, whilst ensuring that it does not compromise on consumer protection and safety.

Standards

- Denmark strongly encourages the Presidency to follow the Council's general approach on article 43e paragraph 1a listing different standards in a prioritized order.
- This approach will allow for the implementing acts to prioritize and ensure that the most relevant instruments are used when available.
- Also, by making clear the prioritization of standards the legal text will give companies the most certainty of what standards to use and strive for presumption of conformity.
- The prioritization i.e., international, European, common specifications, national standards reflect the general approach to standardisation i.e., the international first principle, and prioritizes the standards with the broadest possible uptake and application.

BG written comments on SMEI-Omnibus (recitals and art. 1)

WK 14598/2023 INIT

1. Bulgaria **does not support** the proposal of the European parliament (EP) to **include Regulation (EU) 2023/988 (GPSR) in the scope** of the Omnibus.

The EP's proposal to include GPSR in the scope of the Omnibus is not supported by reasons and arguments; therefore, it is not clear what necessitates the inclusion of GPSR. Furthermore, no impact assessment has been presented identifying certain issues that will be overcome if the proposed proposal is supported. Additionally, it should be noted that the GPSR does not address any legal matter related to the conformity assessment of products.

It should also be borne in mind that the GPSR contains requirements and regulation on cases where certain products pose some serious risk. In this regard, Bulgaria does not consider it necessary to provide additional restrictions/obligations with another legislative act for cases of serious risk related to a certain product.

2. Article 43e – Bulgaria maintains the position expressed so far that after non-harmonized European standards are added, a hierarchy should be introduced for their use – in the first place the European ones, in the second place the international ones and in the third place the national standards. In this regard, Bulgaria **does not support the EP's proposal not to introduce a hierarchy of standards**, as this would create legal uncertainty and confusion regarding the applicable standards for individual cases.

3. Regarding the other provisions, Bulgaria **supports the proposals (mandate) of the Council, incl. the acts covered by the Omnibus**.

Bulgaria has repeatedly expressed a position to exclude certain acts from the Omnibus scope, namely Regulation (EU) 2016/424 (cableways), Regulation (EU) № 305/2011 (construction products), Regulation (EU) 2023/1230 (machinery) and Directives 2010/35/EU (transportable pressure equipment), 2014/28/EU (civil explosives), 2014/29/EU (simple pressure vessels), 2006/42/EC (machinery) and 2014/33/EU (lifts).

SMEI omnibus Regulation and Directive

CZ comments on WK 14598/2023

In general, the Czech Republic can support the compromise text proposed by the PRES underlying the following:

Scope

The Czech Republic cannot agree with inclusion of the Regulation (EU) 2023/988 on general product safety (GPSR) into the SMEI omnibus regulation and considers it as a redline. GPSR covers all non-harmonised products as well as products that are harmonised in some parameters but are not specifically regulated by NLF harmonisation legislation. By inclusion of GPSR the scope of SMEI omnibus regulation would cover all products within the internal market, which we do not consider desirable. The example presented by EP (textile masks) is not the most suitable one, because when the purpose of the mask would be to protect the person that is wearing it, PPE regulation should be applicable. On the other hand, we can point out that including GPSR to the SMEI omnibus regulation scope also e.g., books, furniture or products with unregulated chemical substances would be covered and regulated, which we again do not consider effective and desirable. The Czech Republic understand the SMEI omnibus regulation/directive as an effective tool, which will make all necessary processes, which must be undertaken before placing specific categories of products on the on internal market, functioning even during crises and emergency situation – e.g., compulsory conformity assessment and market surveillance.

Free movement of crisis relevant products

From the point of view of the Czech Republic, the most important aspect of SMEI omnibuses proposals is ensuring the free movement even of crisis relevant products assessed by emergency procedures throughout the EU while ensuring the product safety. This objective will be achieved both through the mutual recognition of the products themselves placed on the market suggested by the European Parliament and through the EC implementing acts extending the validity of marketing authorisation for such goods to the entire EU as proposed in the Council mandate. To avoid unnecessary delays during the emergency situation, the process itself should be as simple as possible, therefore the Czech Republic can be flexible towards the proposal of the European Parliament. However, we are only a bit reticent about the idea of compulsory risk assessment that has to be carried out by competent national authority – see row 48 below.

Standards

The Czech Republic supports the Council mandate in this regards, e.g. merging of Articles 43d and 43e and the draft compromise text proposed by PRES in row 70a. Original EC proposal, nor EP mandate do not take into consideration the situation, when most effective solution during the crisis would be harmonize using already existing international or national standards instead of preparing brand new common specification, which shall be mentioned in the text.

Other issues

- *Row 43*

The Czech Republic considers the impact of the introduced obligation to prioritise the conformity assessment of crisis-relevant goods on the contractual obligations of notified bodies to be unclear in relation to the possible impact/sanctions resulting from the breach of their contractual obligations and supports any clarification of the text in this sense. The Czech Republic supports the Council mandate, the EP proposal can be also acceptable provided that Council mandate is maintained.

- *Row 45*

The Czech Republic considers it important to define that the setting of the price for the priority conformity assessment of crisis relevant products should not abuse the situation of insufficient supply of these goods on the market and strongly supports the clarification of the text in this respect proposed in the Council mandate. The proposal of the EP can be acceptable. However, drafted PRES compromise text does not take into account the effort to stress out the aspect of disproportionality of possible increased costs.

- *Row 46*

The Czech Republic does not consider it appropriate to impose an obligation on notified bodies to make maximum efforts to increase their personnel or material capacities (equipment, premises, etc.) in connection with priority conformity assessment or verification of product characteristics during an emergency situation. Such a requirement would not be feasible in the context of the expected duration of the emergency regime and would entail additional costs and burdens for these entities. Therefore, the Czech Republic strongly supports the Council mandate in this regard.

- *Row 48*

The Czech Republic prefers the Council mandate as it seems to be inappropriate to impose on the national authority the obligation to carry out a risk assessment before issuing the authorization to place the crisis relevant goods assessed by emergency procedures on the market. Each Member State should set out its own procedures, which can also cover some kind of risk assessment or any other steps that would ensure the same level of security as the risk assessment. We consider it ineffective and burdensome to introduce compulsory risk assessment without any instructions or explanation how national authority should provide it. On the other hand, also EP proposal is acceptable, especially if it would be crystal clear what has to be covered by risk assessment provided by competent national authorities.

- *Row 54*

The Czech Republic supports the Council mandate. The EP proposal is not clear as regards the addition of "unless otherwise specified" and can lead to the misinterpretation of the text.

- *Row 56a*

The Czech Republic supports the introduction of the obligation of special marking of crisis-relevant goods assessed according to emergency procedures. However, the Czech Republic considers the introduction of an obligation to place a radio frequency identifier on such products to be an unnecessary requirement, even though it would facilitate the tracking and identification of products on the market, but which would increase costs for manufacturers and could affect the speed of placing such goods on the market in times of crisis. Therefore, the Czech Republic supports the Council mandate.

- *Row 57*

The Czech Republic strongly supports the Council mandate. There is no need to amend the conditions and requirements in the authorization after the deactivation or expiry of the emergency situation.

- *Row 59*

The Czech Republic supports the Council mandate as this provision deals with the administrative procedures set out by market surveillance authorities that are already used and applicable in such Member State. In this regard the addition of the text suggested by EP is redundant.

- *Row 61a*

The Czech Republic would prefer the Council mandate and does not consider the possibility of assessing crisis-relevant goods using emergency procedures and placing such goods on the market even after the end of the emergency situation as the best solution.
However, we are flexible to EP position.

- *Row 81*

The Czech Republic can support the draft compromise text proposed by PRES merging the EP and Council mandates and aimed at clarifying the text.

LU written comments on SMEI-Omnibus

Thank you for the flash and the 4-column document on the SMEI Omnibus provisions.

However, we would like to insist on a WP meeting to discuss the questions raised in the Flash and allow Member States to raise any other issues. Preparing trilogues only in writing is not sufficient and not transparent. It is also unclear how the SMEI Omnibus texts are linked with the main SMEI Regulation.

In the meantime, please find below some red lines.

1. **Scope: the EP wants the scope to be as large as possible. In addition, they have added the General Product Safety Regulation to the scope, in order to cover some of the non-harmonised products, like textile masks, which should be able to circulate freely and safely between Member States in times of crisis.**

   First, we need to understand the rationale behind the EP's proposal: **Precisely, which non-harmonised products do they target to fall under the GPSR?** Because products such as masks already fall under medical devices or personal protective equipment legislation, which are already regulated under their respective procedures.

   Furthermore, we strongly believe that the **focus of the SMEI omnibus should remain on harmonised products.** These products usually carry higher risks and hence are subject to more stringent safety measures. That's why we have harmonised EU procedures in place and foresee derogations in the SMEI Omnibus to speed up the market availability of crisis-relevant products and to ensure their free movement across the EU. That's the goal of having the SMEI Omnibus based on Article 114 TFEU (=Single Market legal basis).

   We don't understand why the SMEI derogations should apply to **non-harmonised products** (such as those under the GPSR, e.g. pencils, buttons, rulers) since they **already benefit from a simpler and well-established procedure to put products on the market - through the Mutual Recognition Regulation (2015/515)**. Under this regulation, once a national authority authorises a product for its market, the principle of mutual recognition automatically applies and the product can be commercialised in other EU Member States (without having to wait for an EU implementing act as foreseen in the SMEI Omnibus). The EP's approach would actually complicate the free movement of non-harmonised products in times of crisis which is not in line with the objectives of the SMEI Omnibus and contrary to the legal basis Article 114 TFEU.

   Therefore, we **question the necessity and legality of including non-harmonised products in the SMEI framework**, as it could lead to operational and legal complications in times of crises, diminish the effectiveness of the existing, more straightforward processes, and create a dangerous precedent in that it is rolling back the Single Market in times of crises.

2. **Free movement of crisis relevant products: the EP's original position was to allow free movement throughout the Union of all products which are authorised following the emergency conformity assessment procedure. The Presidency explained the Council's concerns of security and safety of products if the EP's solution was chosen.**

   We suggest to have a discussion at WP level in order to express our views. The EP's position remains close to the Commission's initial proposal which had fragmentation as a result – this is therefore not acceptable as it is contrary to the objectives of the SMEI to improve the functioning of the Single Market.

3. **Standards: the Parliament did not introduce the hierarchy of standards like the Council did. The aim of the Parliament's text is that the standards be created very quickly for crisis-relevant products and that the Commission be given powers to adopt standards or common specifications quickly.**

We are supportive of a hierarchical approach to standards as enshrined in the Council General Approach, thereby helping free movement and providing legal certainty. The EP's proposal does not seem to be in line with the objectives of the SMEI to improve the functioning of the Single Market in times of crises. We are open to hear the explanations provided by the EP to better understand their approach.

LV redlines and comments on SMEI Omnibus Directive and Regulation - compromise proposal - WK 14598/2023

1. Comments on enlarged scope of Omnibus proposals regarding added General Product Safety Regulation EU 2023/988 (point 2):

For Latvia, the scope of the General approach text was already too wide, including too many high risk products, where in our view full conformity assessment procedures should be kept. This especially relates to the products that will be incorporated into a building or structure, like construction products, cableways, pressure equipment and lifts, or high-risk products like explosives – these should be excluded from the scope. For this reason, further widening of the scope and the inclusion of the General Product Safety Regulation is not supported by Latvia. We believe that this addition would create a lot of uncertainty, as non-harmonised products under the GPSR that normally do not have conformity assessment will need to obtain an authorization. We fail to understand how it would support the free flow of crisis products.

2. Free movement of crisis relevant products:

Latvia has indicated previously that free movement of crisis goods should have been the biggest achievement of this proposal. In our view, the general approach achieved in the Council missed out on this opportunity to ensure free movement in crisis situations. In the context of this position, Latvia does not share the concerns mentioned in the Presidency Flash, and still is of the opinion that the General approach text will be too complicated and costly to implement in crisis situations. In this regard, Latvia can support these changes proposed by the EP that stimulate free movement of crisis relevant products:

- In point 58, the EP has replaced words “leave the territory of the Member State which has issued the” to “bear the CE marking”, therefore authorized products can leave the territory of the Member State that issued the authorization and can circulate in other EU member states.
- Also, in point 61a, EP has added text about 6-month period after the end of the crisis, in which there may still be crisis products on the market.

3. Comments on standards and their hierarchy:

Considering this EP proposal we need to keep in mind that it establishes a precedent for other legal acts as well. Regarding standards and common specifications, in all cases the version of the Machinery Regulation should be adhered to, with approach that there is one standardisation system in all legal acts.

Moreover, the idea of standards is to promote free movement of goods and services, any parallel system will only fragment the EU internal market. Therefore, giving the Commission a delegation of power in this area should be viewed with considerable caution.

For the reasons stated above, Latvia would strongly prefer sticking to the General approach text when it comes to standardization.

Council of the European Union
General Secretariat

Interinstitutional files:
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Brussels, 10 November 2023

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NOTE

From:	Presidency
To:	Working Party on Technical Harmonisation (SMEI Omnibus)
Subject:	SMEI Omnibus: 4-column table with draft compromise text

PL COMMENTS

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency (Text with EEA relevance)

2022/0279(COD)

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
Formula				
1	2022/0279 (COD)	2022/0279 (COD)	2022/0279 (COD)	
Proposal Title				
2	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency (Text with EEA relevance)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009***, (EU) 2023/988, (EU) 2023/1230*** and (EU) No 305/2011 as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to ~~*a Single*~~***an internal*** market emergency (Text with EEA relevance)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) ~~2019/1009 and (EU) No 305/2011~~**No 305/2011 and (EU) 2023/1230** as regards emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency (Text with EEA relevance)	*To be revisited after a final decision on the scope has been taken*

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
Formula				
3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	**Green**
Citation 1				
4	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	**Green**
Citation 2				
5	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	**Green**
Citation 3				
6	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	**Green**
Citation 4				
7	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	Having regard to the opinion of the European Economic and Social Committee[1], _____ 1. OJ C , , p. .	**Green**

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
Citation 5				
8	Acting in accordance with the ordinary legislative procedure[1], _____ 1. Position of the European Parliament of xxx (not yet published in the Official Journal) and Decision of the Council of xxx.	Acting in accordance with the ordinary legislative procedure[1], _____ 1. Position of the European Parliament of xxx (not yet published in the Official Journal) and Decision of the Council of xxx.	Acting in accordance with the ordinary legislative procedure[1], _____ 1. Position of the European Parliament of xxx (not yet published in the Official Journal) and Decision of the Council of xxx.	**Green**
Formula				
9	Whereas:	Whereas:	Whereas:	**Green**
Recital 1				
10	(1) [insert reference to SMEI Regulation] aims to ensure the normal functioning of the Single Market, including the free movement of goods, services and persons and guarantee the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis.	(1) [insert reference to ~~*SMEI*~~***IMERA*** Regulation] aims to ensure the normal functioning of the ~~*Single*~~***internal*** market, including the free movement of goods, services and persons and ~~*guarantee*~~***ensure*** the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis.	(1) [insert reference to SMEI Regulation] aims to ensure the normal functioning of the Single Market, including the free movement of goods, services and persons and guarantee the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis.	(1) [insert reference to SMEI/IMERA Regulation] aims to ensure the normal functioning of the [Single/Internal] Market, including the free movement of goods, services and persons and ensure the availability of crisis-relevant goods and services and goods and services of strategic importance to citizens, businesses and public authorities during a crisis.
Recital 2				
11	(2) The framework established by [insert reference to SMEI Regulation] lays down	(2) The framework established by [insert reference to ~~*SMEI*~~***IMERA*** Regulation] lays down measures,	(2) The framework established by [insert reference to SMEI Regulation] lays down measures,	*To be revisited after final decisions on the name of the SMEI/IMERA Regulation, on the reference to Single/Internal and on the*

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
	measures, which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact on the functioning of the Single Market that a crisis may cause.	which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact ***a crisis may cause*** on the functioning of the ~~*Single*~~***internal*** market ~~*that a crisis may cause*~~.	which should be deployed in a coherent, transparent, efficient, proportionate and timely manner, so as to prevent, mitigate and minimise the impact on the functioning of the Single Market that a crisis may cause.	*definitions in the SMEI/IMERA Regulation have been taken*
Recital 3				
12	(3) [insert reference to SMEI Regulation] lays down a multi-layered mechanism consisting of contingency planning, vigilance mode and Single Market emergency mode.	(3) [insert reference to ~~*SMEI*~~***IMERA*** Regulation] lays down a multi-layered mechanism consisting of contingency planning, ~~*vigilance mode and Single*~~***and internal*** market ***vigilance and*** emergency ~~*mode*~~***modes***.	(3) [insert reference to SMEI Regulation] lays down a multi-layered mechanism consisting of contingency planning, vigilance mode and Single Market emergency mode.	*To be revisited after final decisions on the name of the SMEI/IMERA Regulation and on the reference to Single/Internal have been taken*
Recital 4				
13	(4) [insert reference to SMEI Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the Single Market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to SMEI Regulation] applies to both goods and services.	(4) [insert reference to ~~*SMEI*~~***IMERA*** Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the ~~*Single*~~***internal*** market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to ~~*SMEI*~~***IMERA*** Regulation] applies to both goods and services.	(4) [insert reference to SMEI Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the Single Market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to SMEI Regulation] applies to both goods and services.	*To be revisited after final decisions on the name of the SMEI/IMERA Regulation and on the reference to Single/Internal have been taken*

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
Recital 5				
14	(5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that referred to in [insert reference to SMEI Regulation] may be swiftly placed on the Union market in order to contribute to addressing and mitigating the disruptions.	(5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that ***crisis-relevant goods*** referred to in [insert reference to ~~*SMEI*~~***IMERA*** Regulation] may be swiftly placed on the ~~*Union*~~***internal*** market in order to contribute to addressing and mitigating the disruptions.	(5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that referred to in [insert reference to SMEI Regulation] may be swiftly placed on the Union market in order to contribute to addressing and mitigating the disruptions.	(5) In order to complement, ensure consistency and to further enhance the effectiveness of such measures, it is appropriate to ensure that crisis-relevant goods referred to in [insert reference to SMEI/IMERA Regulation] may be swiftly placed on the Union market in order to contribute to addressing and mitigating the disruptions.
Recital 6				
15	(6) A number of Union sectoral legal acts lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of certain products. Such legal acts include Regulations (EU) 2016/424[1], (EU) 2016/425[2], (EU) 2016/426[3], (EU) 2019/1009[4] and (EU) No 305/2011[5] of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2019/1009 are also aligned to the reference	(6) A number of Union sectoral legal acts lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of certain products. Such legal acts include Regulations (EU) 2016/424[1], (EU) 2016/425[2], (EU) 2016/426[3], (EU) 2019/1009[4]***, (EU) 2023/1230***[4a] and (EU) No 305/2011[5] of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426***, (EU) 2019/1009, (EU) 20[illegible]88***[5a] ***and (EU) 2023/1230*** ~~*and (EU) 2019/1009*~~ are also aligned to the	(6) A number of Union sectoral legal acts lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of certain products. Such legal acts include Regulations (EU) 2016/424[1], (EU) 2016/425[2], (EU) 2016/426[3],[4] **(EU) No 305/2011**[5] **and (EU) No 2023/1230**[6] ~~(EU) 2019/1009[4] and (EU) No 305/2011[5]~~ of the European Parliament and of the Council. Those legal acts are based on the principles of the new approach to technical harmonisation. Moreover, Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) ~~2019/1009~~**No 2023/1230** are also aligned to the reference provisions	*To be revisited after a final decision on the scope has been taken*

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	provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council [6]. _____ 1. OJ L 81, 31.3.2016, p. 1. 2. OJ L 81, 31.3.2016, p. 51. 3. OJ L 81, 31.3.2016, p. 99. 4. OJ L 170, 25.6.2019, p. 1. 5. OJ L 88, 4.4.2011, p. 5. 6. OJ L 218, 13.8.2008, p. 82.	reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council [6]. ***In addition, Regulation (EU) 2023/988 lays down essential rules on the safety of consumer products placed or made available on the market.*** _____ 1. OJ L 81, 31.3.2016, p. 1. 2. OJ L 81, 31.3.2016, p. 51. 3. OJ L 81, 31.3.2016, p. 99. 4. OJ L 170, 25.6.2019, p. 1. ***4a. OJ L 165, 29.6.2023, p. 1*** 5. OJ L 88, 4.4.2011, p. 5. ***5a. OJ L 135, 23.5.2023, p. 1.*** 6. OJ L 218, 13.8.2008, p. 82.	laid down by Decision No 768/2008/EC of the European Parliament and of the Council**[7].** ~~[6].~~ _____ 1. OJ L 81, 31.3.2016, p. 1. 2. OJ L 81, 31.3.2016, p. 51. 3. OJ L 81, 31.3.2016, p. 99. 4. OJ L 170, 25.6.2019, p. 1. 5. OJ L 88, 4.4.2011, p. 5. 6. OJ L ~~218, 13.8.2008, p. 82~~**165, 29.6.2023, p 1**. **7. OJ L 218, 13.8.2008, p. 82.**	
Recital 7				
16	(7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral nionU harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Regulations, aimed at preparing and responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Regulations.	(7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral ~~nionU~~***Union*** harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Regulations, aimed at preparing and responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Regulations.	(7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral ~~nionU~~**Union** harmonisation legislation provide for procedures designed to apply in crisis. It is appropriate to introduce targeted adjustments to those Regulations, aimed at preparing and responding to impacts of crises affecting products that have been designated as crisis-relevant goods and covered by those Regulations.	**Green**

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Recital 8				
17	(8) Experience from the recent crises that have affected the Single Market has shown that the procedures laid down in the sectoral legislation are not designed to cater for the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [insert reference to SMEI Regulation].	(8) Experience from the recent crises that have affected the ~~*Single*~~***internal*** market has shown that the procedures laid down in the sectoral legislation are not designed to cater for the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [insert reference to ~~*SMEI*~~***IMERA*** Regulation].	(8) Experience from the recent crises that have affected the Single Market has shown that the procedures laid down in the sectoral legislation are not designed to cater for the needs of crisis-response scenarios and do not offer the necessary regulatory flexibility. It is therefore appropriate to provide for a legal basis for such crisis-response procedures as a complement to the measures adopted under [***insert reference to SMEI Regulation***~~insert reference to SMEI Regulation~~].	*To be revisited after final decisions on name of the SMEI/IMERA Regulation and on the reference to Single/Internal have been taken*
Recital 9				
18	(9) In order to overcome the potential effects of disruptions on the Single Market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant.	(9) In order to overcome the potential effects of disruptions ~~*on the Single*~~***to the internal*** market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products~~,~~ which have not been designated as crisis-relevant.	(9) In order to overcome the potential effects of disruptions on the Single Market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant. **In the context of such prioritisation, any potential additional costs charged by the**	(9) In order to overcome the potential effects of disruptions on the [Single/Internal] Market and in order to ensure that crisis-relevant goods are placed on the market swiftly, it is appropriate to provide for a requirement for the conformity assessment bodies to prioritise the conformity assessment applications of such products over any pending applications concerning products, which have not been designated as crisis-relevant. In the context of such prioritisation, no additional

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			conformity assessment body to the manufacturer should be proportionate to the direct costs incurred by the conformity assessment bodies in order to put in place the said prioritisation. The notified bodies are encouraged to increase their testing capacities for such products designated as crisis-relevant goods in respect to which they have been notified.	costs may be charged by the conformity assessment body to the manufacturer. Furthermore, the notified bodies are encouraged to increase their testing capacities for such products designated as crisis-relevant goods in respect to which they have been notified.
Recital 10				
19	(10) To that end, emergency procedures should be laid down in Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011. Those procedures should be available only following the activation of the Single Market emergency mode in accordance with [insert reference to SMEI Regulation].	(10) To that end, emergency procedures should be laid down in Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009***, (EU) 2023/988, (EU) 2023/1230*** and (EU) No 305/2011. Those procedures should be available only following the activation of the ~~*Single*~~***internal*** market emergency mode in accordance with [insert reference to ~~*SMEI*~~***IMERA*** Regulation].	(10) To that end, emergency procedures should be laid down in Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) ~~2019/1009 and (EU) No 305/2011~~**No 305/2011 and (EU) 2023/1230**. Those procedures should be available only following the activation of the Single Market emergency mode in accordance with [***insert reference to SMEI Regulation***~~insert reference to SMEI Regulation~~].	*To be revisited after final decisions on the scope, the name of the SMEI/IMERA Regulation and on the reference to Single/Internal have been taken*
Recital 11				
20	(11) Furthermore, in cases where the disruptions might affect the conformity assessment bodies or in cases	(11) Furthermore, in cases where the disruptions might affect the conformity assessment bodies or in cases where the testing capacities	(11) Furthermore, in cases**, for example,** where the disruptions might affect the conformity assessment bodies or in cases	(11) Furthermore, in cases, for example, where the disruptions might affect the conformity assessment bodies or in cases

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	where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective EU sectoral legislation.	for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective ~~*EU*~~*Union* sectoral legislation. ***The authorisation for products granted exceptionally and temporarily should remain valid for six months after deactivation or expiration of the internal market emergency mode, where it does not does not affect in any way the health, safety and security of consumers. After this period, products should only be made available on the market after receiving an authorisation under the normal authorisation procedure provided for under the applicable rules. Products already granted authorisation exceptionally and temporarily may be re-authorised under the normal authorisation procedure. Nevertheless, products or components already purchased for use, or which are already in use, may continue to be used without new authorisation.***	where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective EU sectoral legislation.	where the testing capacities for such crisis-relevant products would not be sufficient, it is appropriate to provide for the possibility for the national competent authorities to exceptionally and temporarily authorise the placing on the market of products, which have not undergone the usual conformity assessment procedures required by the respective Union sectoral legislation.

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Recital 12				
21	(12) As regards products falling within the scope of those Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing Single Market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, in those cases where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they comply with all the applicable essential safety requirements. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures, which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority.	(12) As regards products falling within the scope of those Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing ~~*Single*~~***internal*** market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, ~~*in those cases*~~ where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they comply with all the applicable essential safety requirements ***and that the safety of consumers and end-users is fully assured***. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures, which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority. ***The principle of mutual recognition should apply to goods***	(12) As regards products falling within the scope of those Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing Single Market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, in those cases where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they **ensure the conformity** ~~comply~~ with all the applicable essential safety requirements. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures, which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority.	(12) As regards products falling within the scope of those Regulations that have been designated as crisis-relevant goods, the national competent authorities should be able, in the context of an ongoing [Single/Internal] Market emergency, to derogate from the obligation to carry out those conformity assessment procedures laid down in those Regulations, where the involvement of a notified body is mandatory and should be able to issue authorisations for those products, provided that they ensure the conformity with all the applicable essential safety requirements. Compliance with those substantive requirements may be demonstrated by various means, which may include testing performed by the national authorities of samples provided by the manufacturer having applied for an authorisation. The specific procedures, which were followed to demonstrate the compliance and their results should be clearly described in the authorisation issued by the national competent authority.

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		placed on the market under that derogation. The competent national authority should keep relevant technical documentation to ensure compliance with applicable rules. Products manufactured during the internal market emergency mode, where derogation from the conformity assessment procedures was authorised, should also be subject to the relevant obligations of traceability provided for in Regulation (EU) 2023/988, in particular those set out in Article 15(5) thereof.		
Recital 12a				
21a			**(12a) Since the essential safety requirements harmonised by the existing Regulations remain applicable and the authorisation issued by a national competent authority without the CE marking may occur exceptionally, temporarily and additionally to the conformity assessment procedures laid down in those Regulations, this amending Regulation continues to improve the conditions for the functioning of the internal market. Therefore, this amending Regulation takes into account both the context**	(12a) Since the essential safety requirements harmonised by the existing Regulations remain applicable and the authorisation issued by a national competent authority without the CE marking may occur exceptionally, temporarily and additionally to the conformity assessment procedures laid down in those Regulations, this amending Regulation continues to improve the conditions for the functioning of the internal market. Therefore, this amending Regulation takes into account both the context constituted by the fully harmonised

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			constituted by the fully harmonised rules stemming from the existing Regulations and the complementary rules stemming from amendments that would be made to them which would not only allow national authorities to recognise authorisations issued in other Member States but would also require the Commission to extend the validity of such national authorisations from the territory of a single Member State to the territory of the Union by means of implementing acts unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in these Regulations. Such a parallel national authorisation scheme in exceptional times of crisis, in addition to the Union conformity assessment procedure, is justified and proportionate for the achievement of the legitimate objective of protecting health, life and safety. By not providing for an automatic mutual recognition of each national authorisation which is granted on a derogatory basis in times of crisis, this amending Regulation aims to avoid any circumvention or undermining of the CE marking procedure and thereby to	rules stemming from the existing Regulations and the complementary rules stemming from amendments that would be made to them which would not only allow national authorities to recognise authorisations issued in other Member States but would also require the Commission to extend the validity of such national authorisations from the territory of a single Member State to the territory of the Union by means of implementing acts unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in these Regulations. Such a parallel national authorisation scheme in exceptional times of crisis, in addition to the Union conformity assessment procedure, is justified and proportionate for the achievement of the legitimate objective of protecting health, life and safety. By not providing for an automatic mutual recognition of each national authorisation which is granted on a derogatory basis in times of crisis, this amending Regulation aims to avoid any circumvention or undermining of the CE marking procedure and thereby to maintain consumer confidence in the safety of products bearing the CE marking

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			maintain consumer confidence in the safety of products bearing the CE marking in the Union market. Therefore these new derogatory rules, insofar as they prohibit the CE marking on the products which have been approved only at national level, should not affect the harmonised product legislation and consumer confidence in the CE marking which can only be affixed where all the harmonised substantive and procedural rules have been respected.	in the Union market. Therefore, these new derogatory rules, insofar as they prohibit the CE marking on the products which have been approved only at national level, should not affect the harmonised product legislation and consumer confidence in the CE marking which can only be affixed where all the harmonised substantive and procedural rules have been respected.
Recital 12b				
21b			**(12aa) Where the Commission has extended the validity of an authorisation issued by a Member State by means of an implementing act, the conditions for the placing on the market of the concerned goods set out therein should apply only to those goods placed on the market after the date of entry into force of the said implementing act. All pre-existing authorisations adopted by Member States prior to the entry into force of the Commission implementing act should cease to provide a legal basis for the placing of the goods on the market after the entry**	(12aa) Where the Commission has extended the validity of an authorisation issued by a Member State by means of an implementing act, the conditions for the placing on the market of the concerned goods set out therein should apply only to those goods placed on the market after the date of entry into force of the said implementing act. All pre-existing authorisations adopted by Member States prior to the entry into force of the Commission implementing act should cease to provide a legal basis for the placing of the goods on the market after the entry into force of the Commission

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			into force of the Commission implementing act concerning the same goods and Member States should take the necessary actions to that effect. Goods already placed on the market on the basis of an authorisation adopted by a Member State prior to the adoption of the Commission implementing act are not to be withdrawn or recalled unless specific safety concerns have been identified with respect to such goods which result in corrective or restrictive actions to be taken by the Commission by means of another implementing act.	implementing act concerning the same goods and Member States should take the necessary actions to that effect. Goods already placed on the market on the basis of an authorisation adopted by a Member State prior to the adoption of the Commission implementing act are not to be withdrawn or recalled unless specific safety concerns have been identified with respect to such goods which result in corrective or restrictive actions to be taken by the Commission by means of another implementing act.
Recital 12c				
21c			**(12b) The validity of all authorisations for the placing on the market of goods designated as crisis-relevant in the context of an active Single Market emergency mode, as referred to in [the SMEI Regulation], should automatically expire on the date of expiry or deactivation of the Single Market emergency mode. However, it should also be possible to issue authorisations with a shorter validity. Once the authorisation has expired, no further placing of crisis-relevant**	(12b) The validity of all authorisations for the placing on the market of goods designated as crisis-relevant in the context of an active Single Market emergency mode, as referred to in [the SMEI Regulation], should automatically expire on the date of expiry or deactivation of the Single Market emergency mode. However, it should also be possible to issue authorisations with a shorter validity. Once the authorisation has expired, no further placing of crisis-relevant goods on the market

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			goods on the market should occur on the basis of that authorisation. However, the expiry of an authorisation should not automatically trigger an obligation to withdraw or recall goods which have already been placed on the market on the basis of that authorisation. In cases where the placing on the market has occurred in breach of the conditions laid down in the authorisation or where there are sufficient reasons to believe that the goods covered by such authorisation present a risk to the health or safety of persons, the national market surveillance authorities should be entitled to take all the corrective and restrictive measures at their disposal in accordance with the provisions of Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230 and Regulation (EU) 2019/1020. In order to ensure uniform conditions for the implementation of the sectorial emergency procedures, the Commission should be empowered to lay down rules regarding the follow-up actions to be taken and the procedures to be followed with respect to the goods placed on the market in	should occur on the basis of that authorisation. However, the expiry of an authorisation should not automatically trigger an obligation to withdraw or recall goods which have already been placed on the market on the basis of that authorisation. In cases where the placing on the market has occurred in breach of the conditions laid down in the authorisation or where there are sufficient reasons to believe that the goods covered by such authorisation present a risk to the health or safety of persons, the national market surveillance authorities should be entitled to take all the corrective and restrictive measures at their disposal in accordance with the provisions of [Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230 and Regulation (EU) 2019/1020]. In order to ensure uniform conditions for the implementation of the sectorial emergency procedures, the Commission should be empowered to lay down rules regarding the follow-up actions to be taken and the procedures to be followed with respect to the goods placed on the market in accordance with the relevant sectorial emergency procedures.

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			accordance with the relevant sectorial emergency procedures.	*to be revisited after a final decision on the scope has been taken*
Recital 12d				
21d			**(12c) In order to ensure timely sharing of information and to allow all Member States to react, it should be ensured that the Commission and the other Member States are immediately informed of any decisions at national level to authorise crisis-relevant goods. The Information and Communication System for Market Surveillance (ICSMS) already provides the necessary functions to allow quick notification of administrative decisions and therefore can be used by Member States for this purpose. Moreover, information on all corrective or restrictive measures should also be shared. Pursuant to Regulation (EU) 2019/1020 such information is to be accessible in ICSMS irrespectively whether those measures have to be notified or not in Safety Gate [formerly known as RAPEX] due to the products presenting a serious risk. Double entry will be avoided by means of the data interface between Safety Gate [formerly known as RAPEX] and**	(12c) In order to ensure timely sharing of information and to allow all Member States to react, it should be ensured that the Commission and the other Member States are immediately informed of any decisions at national level to authorise crisis-relevant goods. The Information and Communication System for Market Surveillance (ICSMS) already provides the necessary functions to allow quick notification of administrative decisions and therefore can be used by Member States for this purpose. Moreover, information on all corrective or restrictive measures should also be shared. Pursuant to Regulation (EU) 2019/1020 such information is to be accessible in ICSMS irrespectively whether those measures have to be notified or not in Safety Gate due to the products presenting a serious risk. Double entry will be avoided by means of the data interface between Safety Gate and ICSMS maintained by the Commission in accordance with article 20(5) of Regulation (EU) 2019/1020.

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			ICSMS maintained by the Commission in accordance with article 20(5) of Regulation (EU) 2019/1020.	
Recital 13				
22	(13) Where a Single Market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods, which comply with the applicable essential health and safety requirements.	(13) Where ~~*a Single*~~***an internal*** market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods~~,~~ which comply with the applicable essential health and safety requirements.	(13) Where a Single Market emergency entails an exponential increase in the demand for certain products and in order to support the efforts of economic operators to meet such demand, it is appropriate to provide technical references, which may be used by the manufacturers to design and produce crisis-relevant goods, which comply with the applicable essential health and safety requirements.	*to be revisited after a final decision on the Single/Internal has been taken.*
Recital 14				
23	(14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by	(14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. ***Furthermore, the general product safety framework laid down in Regulation (EU) 2023/988 provides for the possibility for a***	(14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by	(14) A number of sectoral Union harmonisation legislation provide for the possibility for a manufacturer to benefit from a presumption of conformity if their product complies with a harmonised European standard. However, in cases where such standards do not exist or the compliance with them might be rendered excessively difficult by the disruptions caused by the crisis,

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	the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms.	***product to benefit from a presumption of conformity with the general product safety requirement if that product conforms with the European standard or parts thereof as far as the risks and risk categories covered by that standard are concerned, the references of which have been published in the Official Journal of the European Union.*** However, in cases where such standards do not exist or the compliance with ~~*them*~~***such standards*** might be rendered excessively difficult ~~*by*~~***as a result of*** the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms.	the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms.	it is appropriate to provide for alternative mechanisms. *to be revisited after a final decision on the scope has been taken.*
Recital 15				
24	(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and, (EU) 2019/1009, the competent national authorities should be able to presume that products manufactured in accordance with national or international standards within the meaning of Regulation (EU) No 1025/2012[1] ensuring an equivalent level of protection to that offered by the harmonised European standards comply	(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426***, (EU) 2019/1009*** ~~*and*~~, (EU) ~~*2019/1009*~~***2023/988, and (EU) 2023/1230***, the competent national authorities should be able to presume that products manufactured in accordance with national or international standards within the meaning of Regulation (EU) No 1025/2012[1] ensuring an equivalent level of protection to that offered by the harmonised European	(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and~~, (EU) 2019/1009,~~ **(EU) 2023/1230** the competent national authorities should be able to presume that products manufactured in accordance with ~~national or international~~**international, European or national** standards within the meaning of Regulation (EU) No 1025/2012[1] **identified by the Commission as suitable to reach conformity and** ensuring an	(15) With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 [and, (EU) 2019/1009], (EU) 2023/1230 and [(EU) 2023/988] the competent national authorities should be able to presume that products manufactured in accordance with international, European or national standards of the Member States within the meaning of Regulation (EU) No 1025/2012[1] identified by the Commission as suitable to reach conformity and ensuring an

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	with the relevant essential health and safety requirements. _____ 1. OJ L 316, 14.11.2012, p. 12.	standards comply with the relevant essential health and safety requirements. _____ 1. OJ L 316, 14.11.2012, p. 12.	equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements. _____ 1. OJ L 316, 14.11.2012, p. 12.	equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements. *to be revisited after a final decision on the scope has been taken.*
Recital 16				
25	(16) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency.	(16) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009***, (EU) 2023/988, (EU) 2023/1230*** and (EU) No 305/2011, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the ~~Single~~***internal*** market emergency.	(16) Furthermore, **if no such international or European standards are available,** with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) ~~2019/1009 and (EU) No 305/2011~~**No 305/2011 and (EU) 2023/1230**, the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency.	(16) Furthermore, with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, [(EU) 2019/1009], [(EU) 2023/988, (EU) 2023/1230 and [(EU) No 305/2011], the Commission should have the possibility to adopt by means of implementing acts common specifications, on which the manufacturers may rely in order to benefit from a presumption of conformity with the applicable essential requirements. The implementing act laying down such common specifications should remain applicable for the duration of the Single market emergency. *to be revisited after a final decision on the scope has been taken.*
Recital 17				
26	(17) With respect to Regulations (EU) 2016/424,	*deleted*	*deleted*	*deleted*

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	(EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011, in exceptional and duly justified circumstances, notably in order to ensure the interoperability among products or systems, the Commission should be able to adopt by means of implementing acts common specifications laying down mandatory technical specifications, with which the manufacturers will be required to comply. The implementing act laying down such common specifications should remain applicable for the duration of the Single Market emergency.			
Recital 18				
27	*(18)* In order to ensure that the level of safety provided by the harmonised products is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant and including by enabling closer cooperation and mutual support among the market surveillance authorities.	(18) In order to ensure that the level of safety provided by the harmonised products ***or by products under the general safety framework*** is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant and including by enabling closer cooperation and mutual support among the market surveillance authorities.	(18) In order to ensure that the level of safety provided by the harmonised products is not compromised, it is necessary to provide for rules for enhanced market surveillance, in particular with respect to goods designated as crisis-relevant and including by enabling closer cooperation and mutual support among the market surveillance authorities.	*to be revisited after a final decision on the scope has been taken.*
Recital 18a				

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27a			**(18a) In accordance with the relevant provisions of Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230, Member States should lay down rules on penalties applicable to infringements by economic operators and conformity assessment bodies of the provisions of those Regulations including the new provisions introduced by this amending Regulation and ensure that those rules are enforced by the competent national authorities, including the respective notifying authority.**	(18a) In accordance with the relevant provisions of Regulations [(EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) No 305/2011 and (EU) 2023/1230], Member States should lay down rules on penalties applicable to infringements by economic operators and conformity assessment bodies of the provisions of those Regulations including the new provisions introduced by this amending Regulation and ensure that those rules are enforced by the competent national authorities, including the respective notifying authority. *to be revisited after a final decision on the scope has been taken*
Recital 19				
28	(19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications.	(19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications.	(19) In accordance with its established practice, the Commission would systematically consult the relevant sectoral experts in the context of the early preparation of all draft implementing acts laying down common specifications.	**Green**
Recital 20				
29				*to be revisited after a final decision on the scope has been taken.*

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	(20) Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009 and (EU) No 305/2011 should therefore be amended accordingly,	(20) Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009***, (EU) 2023/988, (EU) 2023/1230*** and (EU) No 305/2011 should therefore be amended accordingly,	(20) Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) ~~2019/1009 and (EU) No 305/2011~~**No 305/2011 and (EU) 2023/1230** should therefore be amended accordingly~~,~~**.**	
Recital 21				
30	(21) In order for this Regulation to apply from the same date as [SMEI Regulation], its application should be deferred,	(21) In order for this Regulation to apply from the same date as [~~*SMEI*~~***IMERA*** Regulation], its application should be deferred,	(21) In order for this Regulation to apply from the same date as [SMEI Regulation], its application should be deferred,	*to be revisited after a final decision on the name of the SMEI/IMERA Regulation has been taken.*
Formula				
31	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	**Green**
Article 1				
32	Article 1 Amendments to Regulation (EU) 2016/424	Article 1 Amendments to Regulation (EU) 2016/424	Article 1 Amendments to Regulation (EU) 2016/424	**Green**
Article 1, first paragraph				
33	In Regulation (EU) 2016/424, the following Chapter VIa is inserted:	In Regulation (EU) 2016/424, the following Chapter VIa is inserted:	~~In~~ Regulation (EU) 2016/424~~, the following Chapter VIa is inserted~~ **is amended as follows**:	Regulation (EU) 2016/424 is amended as follows:
Article 1, first paragraph, point (1)				

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33a			**(1) In Article 3 the following points are added:**	(1) In Article 3 the following points are added:
Article 1, first paragraph, point (1), amending provision, first paragraph				
33b			" **(28) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [SMEI Regulation];**	**"** **(28) 'crisis-relevant goods' means 'crisis-relevant goods' within the meaning of Article 3, point (6) of Regulation (EU) …/…. [SMEI/IMERA Regulation];**
Article 1, first paragraph, point (1), amending provision, second paragraph				
33c			**(29) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [SMEI Regulation].;** "	(29) 'Single Market Emergency' means 'Single Market Emergency' within the meaning of Article 3, point (3) of Regulation (EU) …/… [SMEI/IMERA Regulation].;
Article 1, first paragraph, point (2)				
33d			**(2) The following Chapter Va is inserted after Chapter V:**	(2) The following Chapter Va is inserted after Chapter V:
Article 1, first paragraph, point (2), amending provision, Chapter I				
34	' CHAPTER VIa	' CHAPTER VIa	**Chapter Va** '	**CHAPTER Va** EMERGENCY PROCEDURES

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	EMERGENCY PROCEDURES	EMERGENCY PROCEDURES	~~CHAPTER VIa~~ EMERGENCY PROCEDURES	
Article 1, first paragraph, point (2), amending provision, Article				
35	Article 43a Application of emergency procedures	Article 43a Application of emergency procedures	**Article 43a** ~~Article 43a~~ Application of emergency procedures	**Green**
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1)				
36	1. Articles 43b to 43g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to this Regulation.	1. Articles 43b to 43g ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article ~~*23 of [the SMEI Regulation] activating Article 26 of [the SMEI*~~***14(5) of [the IMERA*** Regulation]~~*with respect to this Regulation*~~.	1. Articles 43b to 43g shall only apply if the Commission has adopted an implementing act pursuant to Article 23 of [the SMEI Regulation] activating Article 26 of [the SMEI Regulation] with respect to **subsystems and safety components covered by** this Regulation.	1. Articles 43b to 43g of this Regulation shall only apply if the Commission has adopted an implementing act pursuant to Article 26 of [the SMEI/IMERA Regulation].
Article 1, first paragraph, point (2), amending provision, numbered paragraph (2)				
37	2. Articles 43b to 43g shall apply exclusively to subsystems and safety components, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.	2. Articles 43b to 43g shall apply exclusively to subsystems and safety components, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.	2. Articles 43b to 43g~~ shall~~ apply exclusively to subsystems and safety components, which have been designated as crisis-relevant goods ~~in the implementing act referred to in paragraph 1 of this Article~~**pursuant to Article 14 of [the SMEI Regulation]**.	2. Articles 43b to 43g shall apply exclusively to subsystems and safety components, which have been designated as crisis-relevant goods pursuant to Article [14(5) of the SMEI/IMERA Regulation].
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3), first subparagraph				

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38	3. Articles 43b to 43g, except as regards provisions concerning the powers of the Commission, shall apply during the Single Market emergency mode.	3. Articles 43b to 43g, except as regards provisions concerning the powers of the Commission, shall apply during the ~~*Single*~~***internal*** market emergency mode.	3. Articles 43b to 43g, except as regards ~~provisions concerning the powers~~ **the power** of the Commission **in Article 43e(5)**, shall apply **only** during the Single Market emergency mode **activated in accordance with Article 14 of [the SMEI Regulation]**.	3. Articles 43b to 43g, except as regards the power of the Commission in Article 43e(5), shall apply only during the Single Market emergency mode activated in accordance with Article 14 of [the SMEI/IMERA Regulation].
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3), second subparagraph				
39	However, Article 43c(2), second subparagraph, and Article 43c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.	*deleted*	However, ~~Article 43c(2), second subparagraph, and~~ Article 43c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.	However, Article 43c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (4)				
40	4. The Commission shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken with respect to subsystems and safety components placed on the market in accordance with Articles 43c to 43f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).	*deleted*	4. The Commission ~~shall be empowered to lay down by means of implementing acts rules regarding the follow-up actions to be taken~~**may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements** with respect to subsystems and safety components placed on the market in accordance with Articles 43c to ~~43f~~**43e**. Those implementing acts	4. The Commission may adopt implementing acts regarding the corrective or restrictive actions to be taken, the procedures to be followed and the specific labelling and traceability requirements with respect to subsystems and safety components placed on the market in accordance with Articles 43c to 43e. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

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			shall be adopted in accordance with the examination procedure referred to in Article 44(3).	
Article 1, first paragraph, point (2), amending provision, Article				
41	Article 43b Prioritisation of the conformity assessment of crisis-relevant subsystems and safety components	Article 43b Prioritisation of the conformity assessment of crisis-relevant subsystems and safety components	**Article 43b** ~~Article 43b~~ Prioritisation of the conformity assessment of crisis-relevant subsystems and safety components	**Green**
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1)				
42	1. This Article shall apply to all subsystems and safety components designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 18 requiring mandatory involvement of a notified body.	1. This Article shall apply to all subsystems and safety components designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 18 requiring mandatory involvement of a notified body.	1. This Article shall apply to all subsystems and safety components designated as crisis-relevant goods, which are subject to conformity assessment procedures in accordance with Article 18 requiring mandatory involvement of a notified body.	**Green**
Article 1, first paragraph, point (2), amending provision, numbered paragraph (2)				
43	2. The notified bodies shall process all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods as a matter of priority.	2. The notified bodies shall ***ensure all reasonable efforts are made to*** process all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods as a matter of priority.	2. The notified bodies shall process all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods as a matter of priority**, irrespective of whether they have been lodged before or after the activation of**	2. The notified bodies shall process all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods as a matter of priority, irrespective of whether they have been lodged before or after the activation of the

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			the emergency procedures pursuant to Article 43a.	emergency procedures pursuant to Article 43a.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3)				
44	3. All pending applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of subsystems and safety components, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.	3. All pending applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of subsystems and safety components, which have not been designated as crisis-relevant goods. This requirement applies with respect to all applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 43a.	*deleted*	*deleted (absorbed in previous paragraph 2)*
Article 1, first paragraph, point (2), amending provision, numbered paragraph (4)				
45	*4.* The prioritisation of applications for conformity assessment of subsystems and safety components pursuant to	4. The prioritisation of applications for conformity assessment of subsystems and safety components pursuant to	4. The prioritisation of applications for conformity assessment of subsystems and safety components pursuant to	4. The prioritisation of applications for conformity assessment of subsystems and safety components pursuant to

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	paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.	paragraph 3 shall not give rise to any ***extraordinary*** additional costs for the manufacturers, who have lodged those applications.	paragraph ~~3~~**2** shall not give rise to ~~any~~ **disproportionate** additional costs for the manufacturers, who have lodged those applications.	paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (5)				
46	5. The notified bodies shall deploy their best efforts to increase their testing capacities for subsystems and safety components designated as crisis-relevant goods in respect of which they have been notified.	5. The notified bodies shall ~~*deploy their best*~~***ensure all reasonable*** efforts ***are made*** to increase their testing capacities for subsystems and safety components designated as crisis-relevant goods in respect of which they have been notified.	*deleted*	*deleted* *(moved to recital 18)*
Article 1, first paragraph, point (2), amending provision, Article				
47	Article 43c Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body	Article 43c Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body	**Article 43c** ~~Article 43c~~ Derogation from the conformity assessment procedures requiring mandatory involvement of a notified body	**Green**
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1)				
48	1. By way of derogation from Article 18, any competent national authority may authorise, on a duly justified request, the placing on the market or the incorporation into a cableway installation within	1. By way of derogation from Article 18, ~~*any*~~***the*** competent national authority***, after carrying out a risk assessment,*** may authorise, on a duly justified request ***from an economic operator established in its Member***	1. By way of derogation from Article 18, any competent national authority may authorise, on a duly justified request, the placing on the market or the incorporation into a cableway installation within the territory of the Member State	1. By way of derogation from Article 18, the competent national authority may authorise, on a duly justified request from an economic operator, the placing on the market or the incorporation into a cableway installation within the

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	the territory of the Member State concerned, of a specific subsystem or safety component which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated.	***State***, the placing on the market or the incorporation into a cableway installation within the territory of ~~*the*~~***that*** Member State ~~*concerned*~~, of a specific subsystem or safety component which has been designated as ***a*** crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated.	concerned, of a specific subsystem or safety component which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated **in accordance with procedures referred to in that authorisation**.	territory of the Member State concerned, of a specific subsystem or safety component which has been designated as crisis-relevant good and for which the conformity assessment procedures requiring the mandatory involvement of a notified body, referred to in Article 18 have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated in accordance with procedures referred to in that authorisation.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1a), first subparagraph				
48a			**1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in Annex II to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance**	1a. The Member State shall immediately inform the Commission and the other Member States of any authorisation granted in accordance with paragraph 1. Unless the requirements set in the authorisation do not ensure the conformity with the essential requirements laid down in Annex II to this Regulation, the Commission shall without delay adopt an implementing act extending for a limited period of time the validity of the authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and

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			with paragraph 1 to the territory of the Union and set the conditions under which the specific subsystem or safety component may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).	set the conditions under which the specific subsystem or safety component may be placed on the market. When preparing the draft implementing act, the Commission may request national market surveillance authorities to provide relevant information or comments regarding the technical assessment that served as the basis for the authorisation referred to in paragraph 1. The implementing act shall be adopted in accordance with the examination procedure referred to in Article 44(3).
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1a), second subparagraph				
48b			**The specific subsystem or safety component subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant,**	The specific subsystem or safety component subject to the extension of validity referred to in the first subparagraph shall bear the information that it is placed on the market as a "crisis-relevant good". The implementing act referred to in the first subparagraph shall specify the modalities of that information. That information, as well as any labelling, shall be clear, understandable and intelligible and, where relevant, in a language which can be easily understood by

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			in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.	consumers and other end-users, as determined by the Member State concerned.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1b)				
48c			**1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).**	1b. On duly justified imperative grounds of urgency relating to the need to preserve the health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1c), first subparagraph				
48d			**1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.**	1c. As long as an implementing act referred to in paragraphs 1a or 1b is not adopted, the authorisation granted by a competent national authority in one Member State shall be valid only on the territory of the issuing Member State, as well as on the territories of any other Member States whose competent national authorities have recognised the validity of that authorisation before the adoption of the said implementing act.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1c), second subparagraph				

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48e			**Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.**	Member States shall inform the Commission and the other Member States of any decision to recognise the validity of that authorisation.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (2), first subparagraph				
49	2. The manufacturer of a subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.	2. The manufacturer of a subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.	2. The manufacturer of a subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the ~~national~~ competent **national** authority.	2. The manufacturer of a subsystem or safety component subject to the authorisation procedure referred to in paragraph 1 shall declare on his sole responsibility that the subsystem or safety component concerned complies with all the applicable essential requirements set out in Annex II and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the competent national authority.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (2), second subparagraph				
50	The manufacturer shall also deploy all reasonable measures to ensure that the subsystem or safety component, which has been granted an authorisation pursuant to paragraph 1, does not leave the territory of the	*deleted*	*deleted*	*deleted*

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	Member State, which issued the authorisation.			
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3)				
51	*3.* Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation, including:	3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation, including ***at least***:	3. Any authorisation issued ~~by a national competent authority~~ pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation~~, including~~**. The authorisations shall at least set out the following**:	3. Any authorisation issued pursuant to paragraph 1 shall set out the conditions and requirements under which the subsystem or safety component may be placed on the market or incorporated into a cableway installation**.** The authorisations shall at least set out the following:
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3), point (a)				
52	(a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;	(a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;	(a) a description of the procedures, by means of which compliance with the applicable essential requirements was successfully demonstrated;	**Green**
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3), point (b)				
53	(b) specific requirements regarding the traceability of the subsystem or safety component concerned;	(b) specific requirements regarding the traceability of the subsystem or safety component concerned;	(b) **any** specific requirements regarding the traceability of the subsystem or safety component concerned;	(b) any specific requirements regarding the traceability of the subsystem or safety component concerned;
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3), point (c)				

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54	(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated;	(c) an end date of validity of the authorisation, ***unless otherwise specified,*** which cannot go beyond the last day of the period for which the ~~*Single*~~***internal*** market emergency mode has been activated;	(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated **activated in accordance with Article 14 of [the SMEI Regulation]**;	(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the Single Market emergency mode has been activated in accordance with Article 14 of [the SMEI/IMERA Regulation];
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3), point (d)				
55	(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;	(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;	(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the subsystem or safety component concerned;	**Green**
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3), point (e)				
56	(e) measures to be taken with respect to the subsystem or safety component concerned upon expiry of the authorisation in order to ensure that the subsystem or safety component concerned is brought back in compliance with all the requirements of this Regulation.	(e) measures to be taken with respect to the subsystem or safety component concerned upon expiry of the authorisation in order to ensure that the subsystem or safety component concerned is brought back in compliance with all the requirements of this Regulation.	(e) measures to be taken with respect to the subsystem or safety component ~~concerned upon expiry of the authorisation in order to ensure that the subsystem or safety component concerned is brought back in compliance with all the requirements of this Regulation~~ **placed on the market upon expiry of the Single Market emergency**.	(e) measures to be taken with respect to the subsystem or safety component placed on the market upon expiry of the Single Market emergency.
Article 1, first paragraph, amending provision, numbered paragraph (3), point (ea)				

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56a		***(ea) labelling requirements, including radio frequency identification, indicating that the subsystem or safety component was authorised under the internal market emergency mode.***		*Already included in letter b), line 53 above*
Article 1, first paragraph, point (2), amending provision, numbered paragraph (4)				
57	4. By way of derogation from Article 43a(3), first subparagraph, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph 3also after the deactivation or expiry of the Single Market Emergency mode.	4. By way of derogation from Article 43a(3), ~~*first subparagraph,*~~ where appropriate, the national competent authority may ***also*** amend the conditions ~~*of the authorisation*~~***and requirements*** referred to in paragraph ~~*3also*~~***3 of this Article*** after the deactivation or expiry of the ~~*Single*~~***internal*** market emergency mode.	*deleted*	*deleted*
Article 1, first paragraph, point (2), amending provision, numbered paragraph (5)				
58	*5.* By way of derogation from Articles 7 and 20, subsystems or safety components, for which an authorisation has been granted in accordance with paragraph 1 of this Article, shall not leave the territory of the Member State which has issued the authorisation and shall not bear the CE marking.	*deleted*	5. By way of derogation from Articles 7**, 20 and 21** ~~and 20~~, subsystems or safety components, for which an authorisation has been granted in accordance with paragraph 1 ~~of this Article,~~ shall not ~~leave the territory of the Member State which has issued the authorisation and~~**bear the CE marking and Article 7** shall not ~~bear the CE marking~~**apply**.	5. By way of derogation from Articles 7, 20 and 21, subsystems or safety components, for which an authorisation has been granted in accordance with paragraph 1 shall not bear the CE marking and Article 7 shall not apply.

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
Article 1, first paragraph, point (2), amending provision, numbered paragraph (5a), first subparagraph				
59	6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such subsystems or safety components.	6. The market surveillance authorities of the Member State, whose competent authority has granted an authorisation pursuant to paragraph 1, shall be entitled to take all corrective and restrictive measures at national level provided for under this Regulation with respect to such subsystems or safety components. ***The market surveillance authorities shall keep all records related to products authorised under a derogation for a period of 10 years. They shall make those records available to other market surveillance authorities upon request.***	~~**6**~~**5a**. The market surveillance authorities of ~~the~~ **a** Member State, ~~whose competent authority has granted~~**where** an authorisation pursuant to ~~paragraph 1,~~ **paragraphs 1, 1a and 1c is valid ,** shall be entitled to take all corrective and restrictive ~~measures~~ **actions** at national level provided for **under Regulation (EU) 2019/1020 and** under this Regulation with respect to such subsystems or safety components.	5a. The market surveillance authorities of a Member State, where an authorisation pursuant to paragraphs 1, 1a and 1c is valid , shall be entitled to take all corrective and restrictive actions at national level provided for under Regulation (EU) 2019/1020 and under this Regulation with respect to such subsystems or safety components.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (5a), second subparagraph				
59a			**They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.**	They shall immediately inform the Commission and the market surveillance authorities of other Member States of these actions.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (7)				
60	7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the	7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market ***or***	*deleted*	*deleted*

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
	market of subsystems or safety components in accordance with paragraph 1.	***incorporation into a cableway installation*** of subsystems or safety components in accordance with paragraph 1.		
Article 1, first paragraph, point (2), amending provision, numbered paragraph (8)				
61	*8.* The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraph 1 of this Article does not affect the application of the relevant conformity assessment procedures laid down in Article 18 on the territory of the Member State concerned.	8. The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraph 1 of this Article ~~*does*~~***shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 18 ~~*on the territory of the Member State concerned*~~.	8. The ~~application of Articles 43a to 43g and the~~ use of the authorisation procedure set out in paragraph 1 ~~of this Article~~ **to 1c** does not affect the application of the relevant conformity assessment procedures laid down in Article 18 on the territory of the Member State concerned.	8. The use of the authorisation procedure set out in paragraphs 1 to 1c does not affect the application of the relevant conformity assessment procedures laid down in Article 18 on the territory of the Member State concerned.
Article 1, first paragraph, amending provision, numbered paragraph (8a)				
61a		***8a. Subsystems or safety components subject to derogation under paragraph 1 shall remain valid for six months after deactivation or expiration of the internal market emergency mode. After this period, they shall only be made available on the market after receiving an authorisation under the normal authorisation procedure provided for in this Regulation.***		
Article 1, first paragraph, point (2), amending provision, Article				

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
62	Article 43d Presumption of conformity based on national and international standards	Article 43d Presumption of conformity based on national and international standards	*deleted*	*deleted*
Article 1, first paragraph, point (2), amending provision, Article, first paragraph				
63	Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that subsystems and safety components, which comply with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential requirements set out in Annex II, comply with those essential requirements in either of the following cases:	Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider that subsystems and safety components, which comply with the relevant international standards or any national standards in force in the Member State of manufacture, ensuring the safety level required by the essential requirements set out in Annex II, comply with those essential requirements in either of the following cases:	*deleted*	*deleted*
Article 1, first paragraph, point (2), amending provision, Article, first paragraph, point (a), first subparagraph				
64	*(a)* where no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European Union	(a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;	*deleted*	*deleted*

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
	in accordance with Regulation (EU) No 1025/2012;			
Article 1, first paragraph, point (2), amending provision, Article, first paragraph, point (a), second subparagraph				
65	Where	*deleted*	*deleted*	*deleted*
Article 1, first paragraph, point (2), amending provision, Article, first paragraph, point (b)				
66	*(b)* severe disruptions in the functioning of the Single Market, which were taken into consideration when activating the Single Market emergency mode in accordance with Article 15(4) of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.	(b) ***where*** severe disruptions in the functioning of the ~~*Single*~~***internal*** market, which were taken into consideration when activating the ~~*Single*~~***internal*** market emergency mode in accordance with Article ~~*15(4) of [the SMEI*~~***14 of [the IMERA*** Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.	*deleted*	*deleted*
Article 1, first paragraph, point (2), amending provision, Article				
67	Article 43e Adoption of common specifications conferring a presumption of conformity	Article 43e Adoption of common specifications conferring a presumption of conformity	**Article 43e** ~~Article 43e~~ ~~Adoption of common specifications conferring a~~	Article 43e Presumption of conformity based on standards and common specifications

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			~~presumption of conformity~~**Presumption of conformity based on standards and common specifications**	
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1)				
68	1. Where subsystems and safety components, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases:	1. Where subsystems and safety components, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases:	1. Where subsystems and safety components~~,~~ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts**, listing appropriate standards or** establishing common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases:	1. Where subsystems and safety components~~,~~ have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts**,** listing appropriate standards or establishing common specifications for such subsystems and safety components to cover the essential requirements set out in Annex II in either of the following cases:
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1), point (a)				
69	(a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;	(a) where ~~*no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the Official Journal of the European Union in accordance with*~~ ***the European standardisation deliverables addressing a request pursuant to Article 10(1) of*** Regulation (EU) No 1025/2012 ***were not adopted***;	(a) ~~where~~ no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published in the ***Official Journal of the European Union***~~Official Journal of the European Union~~ in accordance with Regulation (EU) No 1025/2012;	(a) where no reference to harmonised standards covering the relevant essential requirements set out in Annex II is published *in the Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012;
Article 1, first paragraph, amending provision, numbered paragraph (1), point (aa)				

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
69a		***(aa) where a reference to harmonised standards covering the relevant essential requirements set out in Annex II is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012 and such reference is not expected to be published within a reasonable timeframe during the internal market emergency mode;***		
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1), point (b)				
70	(b) where severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 14 of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.	(b) where severe disruptions in the functioning of the ~~*Single*~~***internal*** market, which led to the activation of the ~~*Single*~~***internal*** market emergency mode in accordance with Article 14 of [the ~~*SMEI*~~***IMERA*** Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.	(b) ~~where~~ severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 14 of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II ~~to this Regulation~~ and already published in the ***Official Journal of the European Union*** ~~Official Journal of the European Union~~ in accordance with Regulation (EU) No 1025/2012.	(b) severe disruptions in the functioning of the Single Market, which led to the activation of the Single Market emergency mode in accordance with Article 14 of [the SMEI Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential requirements set out in Annex II and already published in the *Official Journal of the European Union* in accordance with Regulation (EU) No 1025/2012.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1a)				

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70a			**1a. The implementing acts referred to in paragraph 1 may:**	1a. The implementing acts referred to in paragraph 1 shall deploy the most appropriate alternative technical solution for the purposes of providing a presumption of conformity in accordance with paragraph 3. To this end, the implementing act may publish the references to European standards, to relevant applicable international standards or to national standards or may establish common specifications.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1a), point (a)				
70b			**(a) publish the references to relevant applicable international standards that provide presumption of conformity in accordance with paragraph 3;**	
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1a), point (b)				
70c			**(b) if there is no relevant applicable international standards as referred to in point a of this paragraph that cover the essential requirements set out in Annex II [to this Regulation], publish the references to the European standards that provide presumption of conformity in accordance with paragraph 3;**	
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1a), point (c)				

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70d			**(c) if there is no relevant applicable international or European standard as referred to in points a and b, that cover the essential requirements set out in Annex II [to this Regulation], establish common specifications established by the Commission that provide presumption of conformity in accordance with paragraph 3;**	
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1a), point (d)				
70e			**(d) if there is no relevant applicable international standard, European standard or common specifications as referred to in points a, b and c, publish the reference to national standards that provide presumption of conformity in accordance with paragraph 3.**	
Article 1, first paragraph, point (2), amending provision, numbered paragraph (2)				
71	2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 44(3) and they shall	2. The implementing acts referred to in paragraph 1 of this Article shall be adopted ~~*following a consultation of the sectoral experts and*~~ in accordance with the examination procedure referred to in Article 44(3) and they shall apply to subsystems or safety	2. The implementing acts referred to in paragraph 1 ~~of this Article~~ shall be adopted ~~following a consultation of the sectoral experts and~~ in accordance with the examination procedure referred to in Article 44(3) and they shall apply ~~to subsystems or safety~~	2. The implementing acts referred to in paragraph 1-shall be adopted in accordance with the examination procedure referred to in Article 44(3) and they shall apply until the last day of the period for which the Single Market emergency mode remains active**,** unless amended or

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
	apply to subsystems or safety components placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.	components placed on the market until the last day of the period for which the ~~*Single*~~***internal*** market emergency mode remains active. ~~*In the early preparation of*~~***When preparing*** the draft implementing act establishing the common specification, the Commission shall ~~*gather*~~***take into account*** the views of ~~*relevant bodies or expert groups established under*~~***the*** relevant ~~*sectoral Union legislation. Based on that consultation, the Commission*~~***bodies and*** shall ~~*prepare the draft implementing act*~~***duly consult all relevant stakeholders***.	~~components placed on the market~~ until the last day of the period for which the Single Market emergency mode remains active~~. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act~~**, unless amended or repealed in accordance with paragraph 5**.	repealed in accordance with paragraph 5.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (2a)				
71a			**2a. Before preparing the draft implementing act referred to in paragraph 1 , the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation**	2a. Before preparing the draft implementing act referred to in paragraph 1, the Commission shall inform the committee referred to in Article 22 of Regulation (EU) No 1025/2012 that it considers that the conditions in paragraph 1 have been fulfilled. When preparing the draft implementing act referred to in paragraph 1, the Commission shall take into account the views of relevant bodies or expert groups established under this Regulation and shall duly consult all relevant stakeholders.

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			and shall duly consult all relevant stakeholders. based on COM text above, line 72	
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3)				
72	3. Without prejudice to Article 17, subsystems and safety components which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those common specifications or parts thereof.	3. Without prejudice to Article 17, subsystems and safety components which are in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those common specifications or parts thereof.	3. Without prejudice to Article 17, subsystems and safety components which are in conformity with **the standards or** common specifications ~~adopted pursuant to~~**referred to in** paragraph ~~2 of this Article~~**1, or parts thereof,** shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those **standards,** common specifications or parts thereof. **The presumption of conformity provided by the standards or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.**	3. Without prejudice to Article 17, subsystems and safety components which are in conformity with the standards or common specifications referred to in paragraph 1, or parts thereof, shall be presumed to be in conformity with the essential requirements set out in Annex II covered by those standards, common specifications or parts thereof. The presumption of conformity provided by the standards, parts thereof or the common specifications referred to in the implementing act referred to in paragraph 1 shall automatically cease to apply on the day the Single Market Emergency mode expires or is deactivated.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (4)				
73	4. By way of derogation from Article 43a(3), first subparagraph, unless there is sufficient reason to believe that the subsystems or safety	4. By way of derogation from Article 43a(3), ~~*first subparagraph,*~~ unless there is sufficient reason to believe that the subsystems or safety components covered by the	4. By way of derogation from Article 43a(3), first subparagraph, unless there is sufficient reason to believe that the subsystems or safety components covered by the	4. By way of derogation from Article 43a(3), unless there is sufficient reason to believe that the subsystems or safety components covered by the standards or

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	components covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the subsystems or safety components in compliance with the said common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].	common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the subsystems or safety components in compliance with ~~*the said*~~***those*** common specifications which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the ~~*Single*~~***internal*** market emergency mode in accordance with [the ~~*SMEI*~~***IMERA*** Regulation].	**standards or** common specifications referred to in paragraph 1 ~~of this Article~~ present a risk to the health or safety of persons, the subsystems or safety components **which are in conformity** ~~in compliance~~ with the ~~said~~**standards or** common specifications **and** which have been placed on the market shall be deemed compliant with ~~this Regulation~~ **the essential requirements set out in Annex II** after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 ~~of this Article~~ and after the expiry or deactivation of the Single Market Emergency mode in accordance with ***[the SMEI Regulation]***~~[the SMEI Regulation]~~.	common specifications referred to in paragraph 1 present a risk to the health or safety of persons, the subsystems or safety components which are in conformity with those standards or common specifications and which have been placed on the market shall be deemed compliant with the essential requirements set out in Annex II after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI/IMERA Regulation].
Article 1, first paragraph, point (2), amending provision, numbered paragraph (5)				
74	5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex II, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information and, if appropriate,	5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential requirements which it aims to cover and which are set out in Annex II, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information ~~*and, if appropriate,*~~***, The Commission may*** amend***, where appropriate,*** ~~*or*~~	5. When a Member State considers that a **standard or** common specification referred to in paragraph 1 does not entirely satisfy the essential requirements ~~which it aims to cover and which are~~ set out in Annex II, it shall inform the Commission thereof **by submitting** ~~with~~ a detailed explanation ~~and~~**.** The Commission shall assess that ~~information~~**detailed explanation**	5. When a Member State considers that a standard or common specification referred to in paragraph 1 does not entirely satisfy the essential requirements set out in Annex II, it shall inform the Commission thereof by submitting a detailed explanation. The Commission shall assess that detailed explanation and, where appropriate, amend or repeal the implementing act listing the

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	amend or withdraw the implementing act establishing the common specification in question.	~~*withdraw*~~ the implementing act establishing the common specification in question.	and, if appropriate, amend or ~~withdraw~~**repeal** the implementing act **listing the standard or** establishing the common specification in question.	standard or establishing the common specification in question.
Article 1, first paragraph, point (2), amending provision, Article				
75	Article 43f Adoption of mandatory common specifications	*deleted*	*deleted*	*deleted*
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1)				
76	*1.* In exceptional and duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential requirements set out in Annex II for subsystems or safety components, which have been designated as crisis-relevant goods.	*deleted*	*deleted*	*deleted*
Article 1, first paragraph, point (2), amending provision, numbered paragraph (2)				
77	*2.* The implementing acts establishing mandatory common specifications, referred to in paragraph 1 of this Article shall be adopted following a consultation of the sectoral	*deleted*	*deleted*	*deleted*

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	experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to subsystems or safety components placed on the market until the last day of the period for which the Single Market emergency mode remains active. In the early preparation of the draft implementing act establishing the common specification, the Commission shall gather the views of relevant bodies or expert groups established under relevant sectoral Union legislation. Based on that consultation, the Commission shall prepare the draft implementing act.			
Article 1, first paragraph, point (2), amending provision, numbered paragraph (3)				
78	*3.* By way of derogation from Article 43a(3), first subparagraph, unless there is sufficient reason to believe that the subsystems or safety components covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the subsystems or safety components in compliance with those common specifications	*deleted*	*deleted*	*deleted*

	Commission Proposal	EP Mandate	Council Mandate	Draft compromise text
	which have been placed on the market shall be deemed compliant with this Regulation after the expiry or repeal of an implementing act adopted pursuant to paragraph 2 of this Article and after the expiry or deactivation of the Single Market Emergency mode in accordance with [the SMEI Regulation].			
Article 1, first paragraph, point (2), amending provision, Article				
79	Article 43g Prioritisation of market surveillance activities and mutual assistance among authorities	Article 43g Prioritisation of market surveillance activities and mutual assistance among authorities	**Article 43g** ~~Article 43g~~ Prioritisation of market surveillance activities and mutual assistance among authorities	**Green**
Article 1, first paragraph, point (2), amending provision, numbered paragraph (1)				
80	1. Member States shall prioritise the market surveillance activities for subsystems and safety components designated as crisis-relevant goods.	1. Member States shall prioritise the market surveillance activities for subsystems and safety components designated as crisis-relevant goods.	1. Member States shall prioritise the market surveillance activities for subsystems and safety components designated as crisis-relevant goods. **The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.**	1. Member States shall prioritise the market surveillance activities for subsystems and safety components designated as crisis-relevant goods. The Commission shall facilitate coordination of these efforts through the Union Product Compliance Network established under Article 29 of Regulation (EU) 2019/1020.
Article 1, first paragraph, point (2), amending provision, numbered paragraph (2)				

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81	2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods. ‘	2. The market surveillance authorities of the Member States shall ~~*deploy their*~~***ensure*** best efforts ***are made*** to provide assistance to other market surveillance authorities during ~~*a Single*~~***an internal*** market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods. ‘	2. The market surveillance authorities of the Member States shall deploy their best efforts to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods. ‘	2. The market surveillance authorities of the Member States shall ensure best efforts are made to provide assistance to other market surveillance authorities during a Single Market emergency, including by mobilising and dispatching expert teams to temporarily reinforce the staff of market surveillance authorities requesting assistance or by providing logistical support such as reinforcement of the testing capacity for subsystems and safety components designated as crisis-relevant goods.

LT written comments on SMEI-Omnibus

Regarding the content – only a few remarks, because we expect to be given a proper place and time (a WP) to state our position/ask concrete questions.

a) General Product Safety Regulation and inclusion of non-harmonised goods. We need a better explanation on why there is a need of such an extension of the scope. Non-harmonised goods enjoy free movement based on the mutual recognition principle; they are not subject to conformity assessment procedures, therefore some of SME Omnibus Articles are even not relevant to these goods and could hinder their free movement.

b) Honestly ,we don't understand the second issue, raised in the flash. What EP wants/what is the outcome of the technical trilogues/what is the acceptable position for the EP?

c) Standards. We consider the general approach, which lists the hierarchy of the standards, a right way forward. GA text is legally sound and clear. In addition, we find the wording of the draft compromise text of Art 43e (Presumption of conformity based on standards and common specifications) para 1a. chapeau unnecessary and repeating the previous para 1. We can only repeat that we are against the mandatory COM tech specifications, especially during the crisis mode.

FI written comments on the main issues 1 and 3 (SMEI-Omnibus)

1. Scope

THE GPSR does not have type approval or other third party procedure, so we don't see the benefits of including it. Textile masks, for example, are constantly circulating freely on the EU market without any prior approval. Meeting the presumption of conformity is not a precondition for marketing of a product for most harmonised product sectors, let alone for GPSR.

FI supports the Council General Approach of the scope. The focus of the SMEI omnibus should remain on harmonised products.

3. Standards

We are supportive of a hierarchical approach to standards as in the Council General Approach. Use of common specifications should only be the last resort.