



Plenary sitting

A9-0244/2023

24.7.2023

*****I**

REPORT

on the 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 (COM(2022)0461 – C9-0314/2022 – 2022/0279(COD))

Committee on the Internal Market and Consumer Protection

Rapporteur: Andreas Schwab

Symbols for procedures

- * Consultation procedure
- *** Consent procedure
- ***I Ordinary legislative procedure (first reading)
- ***II Ordinary legislative procedure (second reading)
- ***III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ***■*** symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

CONTENTS

	Page
DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION	5
EXPLANATORY STATEMENT	91
ANNEX: LIST OF ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT	95
PROCEDURE – COMMITTEE RESPONSIBLE	96
FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE	97

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

**on the 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
(COM(2022)0461 – C9-0314/2022 – 2022/0279(COD))**

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2022)0461),
 - having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0314/2022),
 - having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
 - having regard to the opinion of the European Economic and Social Committee of 14 December 2022¹,
 - having regard to the opinion of the Committee of the Regions of 8 February 2023²,
 - having regard to Rule 59 of its Rules of Procedure,
 - having regard to the report of the Committee on the Internal Market and Consumer Protection (A9-0244/2023),
1. Adopts its position at first reading hereinafter set out;
 2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
 3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

¹ OJ C 100, 16.3.2023, p. 95.

² OJ C 157, 3.5.2023, p. 82.

Proposal for a regulation
Title

Text proposed by the Commission

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)

Amendment

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 *an internal* market
emergency

(Text with EEA relevance)

Amendment 2

Proposal for a regulation
Recital 1

Text proposed by the Commission

(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.

Amendment

(1) [insert reference to **IMERA**
Regulation] aims to ensure the normal
functioning of the *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.

Amendment 3

Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) The framework established by
[insert reference to **SMEI** Regulation] lays

Amendment

(2) The framework established by
[insert reference to **IMERA** Regulation]

down 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*.

lays down measures, 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 *internal* market .

Amendment 4

Proposal for a regulation Recital 3

Text proposed by the Commission

(3) [insert reference to *SMEI* Regulation] lays down a multi-layered mechanism consisting of contingency planning, vigilance *mode* and *Single Market* emergency *mode*.

Amendment

(3) [insert reference to *IMERA* Regulation] lays down a multi-layered mechanism consisting of contingency planning, *and internal market* vigilance and emergency *modes*.

Amendment 5

Proposal for a regulation Recital 4

Text proposed by the Commission

(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.

Amendment

(4) [insert reference to *IMERA* Regulation] lays down rules with the objective of safeguarding the free movement of goods, services and persons in the *internal* market and to ensure the availability of goods and services that are particularly important also in times of crisis. [insert reference to *IMERA* Regulation] applies to both goods and services.

Amendment 6

Proposal for a regulation Recital 5

Text proposed by the Commission

(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.

Amendment

(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 *IMERA* Regulation] may be swiftly placed on the ***internal*** market in order to contribute to addressing and mitigating the disruptions.

Amendment 7

Proposal for a regulation

Recital 6

Text proposed by the Commission

(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) 2016/424⁴⁰, (EU) 2016/425⁴¹, (EU) 2016/426⁴², (EU) 2019/1009⁴³ and (EU) No 305/2011⁴⁴ 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 provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council⁴⁵.

Amendment

(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) 2016/424⁴⁰, (EU) 2016/425⁴¹, (EU) 2016/426⁴², (EU) 2019/1009⁴³, ***(EU) 2023/1230^{43a}*** and (EU) No 305/2011⁴⁴ 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) 2023/988^{44a}***, ***and (EU) 2023/1230*** are also aligned to the reference provisions laid down by Decision No 768/2008/EC of the European Parliament and of the Council⁴⁵. ***In addition, Regulation (EU) 2023/988 lays down essential rules on the safety of consumer products placed or made available on the market.***

⁴⁰ OJ L 81, 31.3.2016, p. 1.

⁴¹ OJ L 81, 31.3.2016, p. 51.

⁴⁰ OJ L 81, 31.3.2016, p. 1.

⁴¹ OJ L 81, 31.3.2016, p. 51.

⁴² OJ L 81, 31.3.2016, p. 99.

⁴³ OJ L 170, 25.6.2019, p. 1.

⁴⁴ OJ L 88, 4.4.2011, p. 5.

⁴⁵ OJ L 218, 13.8.2008, p. 82.

⁴² OJ L 81, 31.3.2016, p. 99.

⁴³ OJ L 170, 25.6.2019, p. 1.

^{43a} **OJ L 165, 29.6.2023, p. 1.**

⁴⁴ OJ L 88, 4.4.2011, p. 5.

^{44a} **OJ L 135, 23.5.2023, p. 1.**

⁴⁵ OJ L 218, 13.8.2008, p. 82.

Amendment 8

Proposal for a regulation

Recital 7

Text proposed by the Commission

(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.

Amendment

(7) Neither the reference provisions laid down by Decision No 768/2008/EC, nor the specific provisions laid down by the sectoral **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.

Amendment 9

Proposal for a regulation

Recital 8

Text proposed by the Commission

(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

Amendment

(8) Experience from the recent crises that have affected the **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** Regulation].

[insert reference to **IMERA** Regulation].

Amendment 10

Proposal for a regulation

Recital 9

Text proposed by the Commission

(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.

Amendment

(9) In order to overcome the potential effects of disruptions **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.

Amendment 11

Proposal for a regulation

Recital 10

Text proposed by the Commission

(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].

Amendment

(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 **internal** market emergency mode in accordance with [insert reference to **IMERA** Regulation].

Amendment 12

Proposal for a regulation

Recital 11

Text proposed by the Commission

(11) Furthermore, in cases where the disruptions might affect the conformity assessment bodies or in cases 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.

Amendment

(11) Furthermore, in cases where the disruptions might affect the conformity assessment bodies or in cases 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. ***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.***

Amendment 13

Proposal for a regulation
Recital 12

Text proposed by the Commission

(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**

Amendment

(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

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.

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 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 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.*

Amendment 14

Proposal for a regulation Recital 13

Text proposed by the Commission

(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

Amendment

(13) Where *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

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.

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.

Amendment 15

Proposal for a regulation

Recital 14

Text proposed by the Commission

(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, it is appropriate to provide for alternative mechanisms.

Amendment

(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 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 ***such standards*** might be rendered excessively difficult ***as a result of*** the disruptions caused by the crisis, it is appropriate to provide for alternative mechanisms.

Amendment 16

Proposal for a regulation

Recital 15

Text proposed by the Commission

(15) With respect to Regulations (EU)

Amendment

(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 1025/2012⁴⁶ ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements.

⁴⁶ OJ L 316, 14.11.2012, p. 12.

2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009, **(EU) 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 1025/2012⁴⁶ ensuring an equivalent level of protection to that offered by the harmonised European standards comply with the relevant essential health and safety requirements.

⁴⁶ OJ L 316, 14.11.2012, p. 12.

Amendment 17

Proposal for a regulation Recital 16

Text proposed by the Commission

(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.

Amendment 18

Proposal for a regulation Recital 17

Amendment

(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 **internal** market emergency.

Text proposed by the Commission

Amendment

(17) With respect to Regulations (EU) 2016/424, (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.

deleted

Amendment 19

Proposal for a regulation Recital 18

Text proposed by the Commission

Amendment

(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.

Amendment 20

Proposal for a regulation Recital 20

Text proposed by the Commission

Amendment

(20) Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2019/1009

(20) Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU)

and (EU) No 305/2011 should therefore be amended accordingly,

2019/1009, **(EU) 2023/988**, **(EU) 2023/1230** and (EU) No 305/2011 should therefore be amended accordingly,

Amendment 21

Proposal for a regulation

Recital 21

Text proposed by the Commission

(21) In order for this Regulation to apply from the same date as [**SMEI** Regulation], its application should be deferred,

Amendment

(21) In order for this Regulation to apply from the same date as [**IMERA** Regulation], its application should be deferred,

Amendment 22

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43a – paragraph 1

Text proposed by the Commission

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.**

Amendment

1. Articles 43b to 43g **of this Regulation** shall only apply if the Commission has adopted an implementing act pursuant to Article **14(5)** of [the **IMERA** Regulation].

Amendment 23

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43a – paragraph 3 – subparagraph 1

Text proposed by the Commission

Articles 43b to 43g, except as regards provisions concerning the powers of the Commission, shall apply during the **Single** Market emergency mode.

Amendment

Articles 43b to 43g, except as regards provisions concerning the powers of the Commission, shall apply during the **internal** market emergency mode.

Amendment 24

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43a – paragraph 3 – subparagraph 2

Text proposed by the Commission

Amendment

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

Amendment 25

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43a – paragraph 4

Text proposed by the Commission

Amendment

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

Amendment 26

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43b – paragraph 2

Text proposed by the Commission

Amendment

2. The notified bodies shall process all

2. The notified bodies shall ***ensure all***

applications for conformity assessment of subsystems and safety components designated as crisis-relevant goods as a matter of priority.

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.

Amendment 27

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43b – paragraph 4

Text proposed by the Commission

4. The prioritisation of applications for conformity assessment of subsystems and safety components pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

Amendment

4. The prioritisation of applications for conformity assessment of subsystems and safety components pursuant to paragraph 3 shall not give rise to any ***extraordinary*** additional costs for the manufacturers, who have lodged those applications.

Amendment 28

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43b – paragraph 5

Text proposed by the Commission

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.

Amendment

5. The notified bodies shall ***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.

Amendment 29

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43c – paragraph 1

Text proposed by the Commission

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 **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.

Amendment

1. By way of derogation from Article 18, **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 State**, the placing on the market or the incorporation into a cableway installation within the territory of **that** Member State, 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.

Amendment 30

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43c – paragraph 2 – subparagraph 1

Text proposed by the Commission

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 Member State, which issued the authorisation.

Amendment

deleted

Amendment 31

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43c – paragraph 3 – introductory part

Text proposed by the Commission

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:

Amendment

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***:

Amendment 32

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43c – paragraph 3 – point c

Text proposed by the Commission

(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;

Amendment

(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 ***internal*** market emergency mode has been activated;

Amendment 33

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43c – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(ea) labelling requirements, including radio frequency identification, indicating that the subsystem or safety component was authorised under the internal market emergency mode.

Amendment 34

Proposal for a regulation

Article 1 – paragraph 1

Text proposed by the Commission

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 3 ***also*** after the deactivation or expiry of the ***Single*** Market Emergency mode.

Amendment

4. By way of derogation from Article 43a(3), where appropriate, the national competent authority may ***also*** amend the conditions ***and requirements*** referred to in paragraph ***3 of this Article*** after the deactivation or expiry of the ***internal*** market emergency mode.

Amendment 35

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43c – paragraph 5

Text proposed by the Commission

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.***

Amendment

deleted

Amendment 36

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43c – paragraph 6

Text proposed by the Commission

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

Amendment

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.

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.***

Amendment 37

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43c – paragraph 7

Text proposed by the Commission

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market of subsystems or safety components in accordance with paragraph 1.

Amendment

7. Member States shall inform the Commission and the other Member States of any decision to authorise the placing on the market ***or incorporation into a cableway installation*** of subsystems or safety components in accordance with paragraph 1.

Amendment 38

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43c – paragraph 8

Text proposed by the Commission

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.***

Amendment

8. The application of Articles 43a to 43g and the use of the authorisation procedure set out in paragraph 1 of this Article ***shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 18.

Amendment 39

Proposal for a regulation
Article 1 – paragraph 1
Regulation (EU) 2016/424
Article 43c – paragraph 8 a (new)

Text proposed by the Commission

Amendment

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.

Amendment 40

Proposal for a regulation
Article 1 – paragraph 1
Regulation (EU) 2016/424
Article 43d – paragraph 1 – point a

Text proposed by the Commission

Amendment

Where

deleted

Amendment 41

Proposal for a regulation
Article 1 – paragraph 1
Regulation (EU) 2016/424
Article 43d – paragraph 1 – point b

Text proposed by the Commission

Amendment

(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

(b) **where** severe disruptions in the functioning of the **internal** market, which were taken into consideration when activating the **internal** market emergency mode in accordance with Article **14** of [the **IMERA** Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering

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.

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.

Amendment 42

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43e– paragraph 1 – point a

Text proposed by the Commission

(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;***

Amendment

(a) where the European ***standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation (EU) No 1025/2012 were not adopted;***

Amendment 43

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43e– paragraph 1 – point a (new)

Text proposed by the Commission

Amendment

(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;***

Amendment 44

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43e – paragraph 1 – point b

Text proposed by the Commission

(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.

Amendment

(b) where severe disruptions in the functioning of the **internal** market, which led to the activation of the **internal** market emergency mode in accordance with Article 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.

Amendment 45

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43e – paragraph 2

Text proposed by the Commission

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 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***

Amendment

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 44(3) and they shall apply to subsystems or safety components placed on the market until the last day of the period for which the **internal** market emergency mode remains active. ***When preparing*** the draft implementing act establishing the common specification, the Commission shall ***take into account*** the views of ***the*** relevant bodies ***and shall duly consult all*** relevant ***stakeholders***.

implementing act.

Amendment 46

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43e – paragraph 4

Text proposed by the Commission

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 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].

Amendment

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 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 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 **internal** market emergency mode in accordance with [the **IMERA** Regulation].

Amendment 47

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43e – paragraph 5

Text proposed by the Commission

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**

Amendment

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, **The**

appropriate, amend *or withdraw* the implementing act establishing the common specification in question.

Commission may amend, *where appropriate*, the implementing act establishing the common specification in question.

Amendment 48

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43f

Text proposed by the Commission

Amendment

Article 43f

deleted

Adoption of mandatory common specifications

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.

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 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.

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 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].

Amendment 49

Proposal for a regulation

Article 1 – paragraph 1

Regulation (EU) 2016/424

Article 43g – paragraph 2

Text proposed by the Commission

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.

Amendment

2. The market surveillance authorities of the Member States shall ***ensure*** best efforts ***are made*** to provide assistance to other market surveillance authorities during ***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.

Amendment 50

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41a – paragraph 1

Text proposed by the Commission

1. Articles 41b to 41g 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.**

Amendment

1. Articles 41b to 43g **of this Regulation** shall only apply if the Commission has adopted an implementing act pursuant to Article **14(5)** of [the **IMERA** Regulation].

Amendment 51

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41a – paragraph 2

Text proposed by the Commission

2. Articles 41b to 41g shall apply exclusively to PPE, which **has** been designated as crisis-relevant goods in the implementing act referred to in paragraph 1.

Amendment

2. Articles 41b to 43g shall apply exclusively to PPE which **has** been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 **of this Article.**

Amendment 52

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41a – paragraph 3 – subparagraph 1

Text proposed by the Commission

Articles 41b to 41g, except as regards provisions concerning the powers of the Commission, shall apply during the **Single** Market emergency mode.

Amendment

Articles 41b to 43g, except as regards provisions concerning the powers of the Commission, shall apply during the **internal** market emergency mode.

Amendment 53

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41a – paragraph 3 – subparagraph 2

Text proposed by the Commission

Amendment

However, Article 41c(2), second subparagraph, and Article 41c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.

deleted

Amendment 54

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41a – paragraph 4

Text proposed by the Commission

Amendment

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 PPE placed on the market in accordance with Articles 41c to 41f. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 44(3).

deleted

Amendment 55

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41b – paragraph 2

Text proposed by the Commission

Amendment

2. The notified bodies shall process all applications for conformity assessment of PPE 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 PPE designated as crisis-relevant goods as a matter of priority.

Amendment 56

Proposal for a regulation
Article 2 – paragraph 1
Regulation (EU) 2016/425
Article 41b – paragraph 4

Text proposed by the Commission

4. The prioritisation of applications for conformity assessment of PPE pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

Amendment

4. The prioritisation of applications for conformity assessment of PPE pursuant to paragraph 3 shall not give rise to any **extraordinary** additional costs for the manufacturers, who have lodged those applications.

Amendment 57

Proposal for a regulation
Article 2 – paragraph 1
Regulation (EU) 2016/425
Article 41b – paragraph 5

Text proposed by the Commission

5. The notified bodies shall **deploy their best** efforts to increase their testing capacities for PPE designated as crisis-relevant goods in respect to which they have been notified.

Amendment

5. The notified bodies shall **ensure all reasonable efforts are made** to increase their testing capacities for PPE designated as crisis-relevant goods in respect to which they have been notified.

Amendment 58

Proposal for a regulation
Article 2 – paragraph 1
Regulation (EU) 2016/425
Article 41c – paragraph 1

Text proposed by the Commission

1. By way of derogation from Article 19, **any** competent national authority may authorise, on a duly justified request, the placing on the market within the territory of the Member State concerned, of a specific PPE which **has** been designated as crisis-relevant **good** for which the conformity assessment procedures

Amendment

1. By way of derogation from Article 19, **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 State**, the placing on the market within the territory of **that** Member State, of a specific PPE which **has** been

requiring mandatory involvement of a notified body referred to in that Article have not been carried out by a notified body but for which the compliance with all the applicable essential health and safety requirements has been demonstrated.

designated as crisis-relevant **goods** for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in that Article have not been carried out by a notified body but for which the compliance with all the applicable essential health and safety requirements has been demonstrated.

Amendment 59

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41c – paragraph 2 – subparagraph 1

Text proposed by the Commission

The manufacturer shall also deploy all reasonable measures to ensure that the PPE, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which issued the authorisation.

Amendment

deleted

Amendment 60

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41c – paragraph 3 – introductory part

Text proposed by the Commission

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market, including:

Amendment

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the PPE may be placed on the market, including ***at least***:

Amendment 61

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425
Article 41c – paragraph 3 – point c

Text proposed by the Commission

(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;

Amendment

(c) an end date of validity, ***unless otherwise specified***, of the authorisation, which cannot go beyond the last day of the period for which the **internal** market emergency mode has been activated;

Amendment 62

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41c – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(ea) labelling requirements, including radio frequency identification, indicating that the PPE was authorised under the internal market emergency mode.

Amendment 63

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41c – paragraph 4

Text proposed by the Commission

Amendment

4. By way of derogation from Article 41a(3), ***first subparagraph***, where appropriate, the national competent authority may amend the conditions ***of the authorisation*** referred to in paragraph 3 of this Article also after the deactivation or expiry of the **Single** Market Emergency mode.

4. By way of derogation from Article 41a(3), where appropriate, the national competent authority may ***also*** amend the conditions ***and requirements*** referred to in paragraph 3 of this Article also after the deactivation or expiry of the **internal** market emergency mode.

Amendment 64

Proposal for a regulation
Article 2 – paragraph 1
Regulation (EU) 2016/425
Article 41c – paragraph 5

Text proposed by the Commission

Amendment

5. *By way of derogation from Articles 7 and 17, PPE, 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*

Amendment 65

Proposal for a regulation
Article 2 – paragraph 1
Regulation (EU) 2016/425
Article 41c – paragraph 6

Text proposed by the Commission

Amendment

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 PPE.

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 PPE. ***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.***

Amendment 66

Proposal for a regulation
Article 2 – paragraph 1
Regulation (EU) 2016/425
Article 41c – paragraph 8

Text proposed by the Commission

8. The application of Articles 41a to 41g 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 19 **on the territory of the Member State concerned.**

Amendment

8. The application of Articles 41a to 41g and the use of the authorisation procedure set out in paragraph 1 of this Article **shall** not affect the application of the relevant conformity assessment procedures laid down in Article 19.

Amendment 67

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41c – paragraph 8a (new)

Text proposed by the Commission

Amendment

8a. PPE 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, it shall only be made available on the market after receiving an authorisation under the normal authorisation procedure provided for in this Regulation.

Amendment 68

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41d – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) where 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

(b) where severe disruptions in the functioning of the **internal** market, which were taken into consideration when activating the **internal** market emergency mode in accordance with Article **14** of [the **IMERA** Regulation], significantly restrict the possibilities of manufacturers to make

make use of the harmonised standards covering the relevant essential health and safety 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.

use of the harmonised standards covering the relevant essential health and safety 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.

Amendment 69

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41e – paragraph 1 – point a

Text proposed by the Commission

(a) where ***no reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex II is published in the Official Journal of the European Union in accordance with*** Regulation (EU) No 1025/2012;

Amendment

(a) where the European ***standardisation deliverables addressing a request pursuant to Article 10(1) of*** Regulation (EU) No 1025/2012 ***were not adopted;***

Amendment 70

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41e – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(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;***

Amendment 71

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41e – paragraph 1 – point b

Text proposed by the Commission

(b) where severe disruptions in the functioning of the **Single** Market, which led to the activation **Single** Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety 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.

Amendment

(b) where severe disruptions in the functioning of the **internal** market, which led to the activation **internal** market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety 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.

Amendment 72

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41e – paragraph 2

Text proposed by the Commission

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). They shall remain applicable to PPE 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.***

Amendment

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 44(3). They shall remain applicable to PPE placed on the market until the last day of the period for which the **internal** market emergency mode remains active. ***When preparing*** the draft implementing act establishing the common specification, the Commission shall ***take into account*** the views of ***the*** relevant bodies ***and shall duly consult all*** relevant ***stakeholders.***

Amendment 73

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41e – paragraph 4

Text proposed by the Commission

4. By way of derogation from Article 41a(3), **first subparagraph**, unless there is sufficient reason to believe that the PPE covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the PPE in compliance with those common specifications which has 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].

Amendment

4. By way of derogation from Article 41a(3), unless there is sufficient reason to believe that the PPE covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the PPE in compliance with those common specifications which has 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 **internal** market emergency mode in accordance with [the **IMERA** Regulation].

Amendment 74

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41e – paragraph 5

Text proposed by the Commission

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety 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**, amend **or withdraw** the implementing act establishing the common specification in

Amendment

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety 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. **The Commission may amend, where appropriate**, the implementing act establishing the common

question.

specification in question.

Amendment 75

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41f

Text proposed by the Commission

Amendment

Article 41f

deleted

Adoption of mandatory common specifications

1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential health and safety requirements set out in Annex II for PPE, which has been designated as crisis-relevant goods.

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 experts and in accordance with the examination procedure referred to in Article 44(3). They shall apply to PPE 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.

3. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the PPE covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health

or safety of persons, the PPE in compliance with those common specifications which has 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].

Amendment 76

Proposal for a regulation

Article 2 – paragraph 1

Regulation (EU) 2016/425

Article 41g – paragraph 2

Text proposed by the Commission

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 PPE designated as crisis-relevant goods.

Amendment

2. The market surveillance authorities of the Member States shall ***ensure*** best efforts ***are made*** to provide assistance to other market surveillance authorities during ***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 PPE designated as crisis-relevant goods.’

Amendment 77

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40a – title

Text proposed by the Commission

Application of emergency procedures

Amendment

Application of emergency procedures

Amendment 78

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40a – paragraph 1

Text proposed by the Commission

1. Articles 40b to 40g 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*.

Amendment

1. Articles 40b to 40g *of this Regulation* shall only apply if the Commission has adopted an implementing act pursuant to Article 14(5) of [the *IMERA* Regulation] activating Article 26 of [the *IMERA* Regulation].

Amendment 79

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40a – paragraph 2

Text proposed by the Commission

2. Articles 40b to 40g shall apply exclusively to appliances and fittings, which *has* been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

Amendment

2. Articles 40b to 40g shall apply exclusively to appliances and fittings, which *have* been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

Amendment 80

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40a – paragraph 3 – subparagraph 1

Text proposed by the Commission

Articles 40b to 40g, except as regards provisions concerning the powers of the Commission, shall apply during the *Single* Market emergency mode remains active.

Amendment

Articles 40b to 40g, except as regards provisions concerning the powers of the Commission, shall apply during the *internal* market emergency mode remains active.

Amendment 81

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40a – paragraph 3 – subparagraph 2

Text proposed by the Commission

Amendment

However, Article 40c(2), second subparagraph, and Article 40c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.

deleted

Amendment 82

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40a – paragraph 4

Text proposed by the Commission

Amendment

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 appliances and fittings placed on the market in accordance with Articles 40c to 40f. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 42(3).

deleted

Amendment 83

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40b – paragraph 2

Text proposed by the Commission

Amendment

2. The notified bodies shall process all applications for conformity assessment of

2. The notified bodies shall *ensure all reasonable efforts are made to* process all

appliances and fittings designated as crisis-relevant goods as a matter of priority.

applications for conformity assessment of appliances and fittings designated as crisis-relevant goods as a matter of priority.

Amendment 84

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40b – paragraph 4

Text proposed by the Commission

4. The prioritisation of applications for conformity assessment of appliances and fittings pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

Amendment

4. The prioritisation of applications for conformity assessment of appliances and fittings pursuant to paragraph 3 shall not give rise to any **extraordinary** additional costs for the manufacturers, who have lodged those applications.

Amendment 85

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40b – paragraph 5

Text proposed by the Commission

5. The notified bodies shall **deploy their best** efforts to increase their testing capacities for appliances and fittings designated as crisis-relevant goods in respect to which they have been notified.

Amendment

5. The notified bodies shall **ensure all reasonable** efforts **are made** to increase their testing capacities for appliances and fittings designated as crisis-relevant goods in respect to which they have been notified.

Amendment 86

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – title

Text proposed by the Commission

Derogation from conformity assessment

Amendment

Derogation from conformity assessment

procedures requiring mandatory involvement of a notified **bod**

procedures requiring mandatory involvement of a notified **body**

Amendment 87

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 1

Text proposed by the Commission

1. By way of derogation from Article 14, **any** competent national authority may authorise, on a duly justified request, the placing on the market or putting into service within the territory of **the** Member State **concerned**, of a specific appliance or fitting 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 14, have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated.

Amendment

1. By way of derogation from Article 14, **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 State**, the placing on the market or putting into service within the territory of **that** Member State, of a specific appliance or fitting 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 14, have not been carried out by a notified body but for which the compliance with all the applicable essential requirements has been demonstrated.

Amendment 88

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 2 – subparagraph 1

Text proposed by the Commission

The manufacturer shall also deploy all reasonable measures to ensure that the appliance or fitting, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which issued the authorisation.

Amendment

deleted

Amendment 89

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 3 – introductory part

Text proposed by the Commission

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market, including:

Amendment

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the appliance or fitting may be placed on the market ***or put into service***, including ***at least***:

Amendment 90

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 3 – point c

Text proposed by the Commission

(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;

Amendment

(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 ***internal*** market emergency mode has been activated;

Amendment 91

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(ea) labelling requirements, including radio frequency identification, indicating that the appliance and fitting was authorised under the internal market

emergency mode.

Amendment 92

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 4

Text proposed by the Commission

4. By way of derogation from Article 40a(3), ***first subparagraph***, where appropriate, the national competent authority may amend the conditions ***of the authorisation*** referred to in paragraph 3 ***also*** after the deactivation or expiry of the ***Single*** Market Emergency mode.

Amendment

4. By way of derogation from Article 40a(3), where appropriate, the national competent authority may ***also*** amend the conditions ***and requirements*** referred to in paragraph 3 ***of this Article*** after the deactivation or expiry of the ***internal*** market emergency mode.

Amendment 93

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 5

Text proposed by the Commission

5. ***By way of derogation from Articles 6 and 17, appliances or fittings, 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.***

Amendment

deleted

Amendment 94

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 6

Text proposed by the Commission

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 appliances or fittings.

Amendment

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 appliances or fittings. ***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.***

Amendment 95

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 8

Text proposed by the Commission

8. The application of Articles 40a to 40g 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 14 ***on the territory of the Member State concerned.***

Amendment

8. The application of Articles 40a to 40g and the use of the authorisation procedure set out in paragraph 1 of this Article ***shall*** not affect the application of the relevant conformity assessment procedures laid down in Article 14.

Amendment 96

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40c – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8a. Appliances and fittings 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.

Amendment 97

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40d – paragraph 1 – point b

Text proposed by the Commission

(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 health and safety requirements set out in Annex I to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

Amendment

(b) **where** severe disruptions in the functioning of the **internal** market, which were taken into consideration when activating the **internal** market emergency mode in accordance with Article **14** of [the **IMERA** Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex I to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

Amendment 98

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40e – paragraph 1 – point a

Text proposed by the Commission

(a) where **no reference to harmonised standards covering the relevant essential requirements set out in Annex I is published in the Official Journal of the European Union in accordance with**

Amendment

(a) where the European **standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation (EU) No 1025/2012 were not adopted;**

Amendment 99

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40e – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(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;

Amendment 100

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40e – paragraph 1 – point b

Text proposed by the Commission

Amendment

(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 **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 I in 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 **internal** market, which led to the activation of the **internal** market emergency mode in accordance with Article **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 I in this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

Amendment 101

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40e – paragraph 2

Text proposed by the Commission

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 42(3). They shall apply to appliances and fittings placed on the market no longer than 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.***

Amendment

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 42(3). They shall apply to appliances and fittings placed on the market no longer than until the last day of the period for which the ***internal*** market emergency mode remains active. ***When preparing*** the draft implementing act establishing the common specification, the Commission shall ***take into account*** the views of ***the*** relevant bodies ***and shall duly consult all*** relevant ***stakeholders.***

Amendment 102

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40e – paragraph 4

Text proposed by the Commission

4. By way of derogation from Article 40a(3), ***first subparagraph***, unless there is sufficient reason to believe that the appliances or fittings covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings in compliance with 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

Amendment

4. By way of derogation from Article 40a(3), unless there is sufficient reason to believe that the appliances or fittings covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings in compliance with 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

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].

paragraph 2 of this Article and after the expiry or deactivation of the **internal** market emergency mode in accordance with [the **IMERA** Regulation].

Amendment 103

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40e – paragraph 5

Text proposed by the Commission

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 I, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information **and, if appropriate**, amend **or withdraw** the implementing act establishing the common specification in question.

Amendment

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 I, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information. **The Commission may** amend, **where appropriate**, the implementing act establishing the common specification in question.

Amendment 104

Proposal for a regulation

Article 3 – paragraph 1

Regulation (EU) 2016/426

Article 40f – title

Text proposed by the Commission

Article 40f

Adoption of mandatory common specifications

1. **In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the essential requirements set out in Annex I for appliances or fittings, which have**

Amendment

deleted

been designated as crisis-relevant goods.

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 experts and in accordance with the examination procedure referred to in Article 42(3) and they shall apply to appliances or fittings placed on the market at the latest until the last day of the period for which the Single Market emergency 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.*

3. *By way of derogation from Article 40a(3), first subparagraph, unless there is sufficient reason to believe that the appliances or fittings covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the appliances or fittings in compliance with 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 Market Emergency mode in accordance with [the SMEI Regulation].*

Amendment 105

Proposal for a regulation
Article 3 – paragraph 1
Regulation (EU) 2016/426
Article 40g – paragraph 2

Text proposed by the Commission

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 appliances and fittings designated as crisis-relevant goods.

Amendment

2. The market surveillance authorities of the Member States shall ***ensure*** best efforts ***are made*** to provide assistance to other market surveillance authorities during ***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 appliances and fittings designated as crisis-relevant goods.

Amendment 106

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41a – paragraph 1

Text proposed by the Commission

1. Articles 41b to 41g 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.***

Amendment

1. Articles 41b to 41g ***of this Regulation*** shall only apply if the Commission has adopted an implementing act pursuant to Article ***14(5)*** of [the ***IMERA*** Regulation].

Amendment 107

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41a – paragraph 2

Text proposed by the Commission

2. Articles 41b to 41g shall apply exclusively to fertilising products, which ***has*** been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

Amendment

2. Articles 41b to 41g shall apply exclusively to fertilising products which ***have*** been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

Amendment 108

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41a – paragraph 3 – subparagraph 1

Text proposed by the Commission

3. Articles 41b to 41g, except as regards provisions concerning the powers of the Commission, shall apply during the **Single** Market emergency mode.

Amendment

3. Articles 41b to 41g, except as regards provisions concerning the powers of the Commission, shall apply during the **internal** market emergency mode.

Amendment 109

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41a – paragraph 3 – subparagraph 2

Text proposed by the Commission

However, Article 41c(2), second subparagraph, and Article 41c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.

Amendment

deleted

Amendment 110

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41a – paragraph 4

Text proposed by the Commission

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 fertilising products placed on the market in accordance with Articles 41c to 41f. Those implementing acts shall be***

Amendment

deleted

adopted in accordance with the examination procedure referred to in Article 45(3).

Amendment 111

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41b – paragraph 2

Text proposed by the Commission

2. The notified bodies shall process all applications for conformity assessment of fertilising products designated as crisis-relevant goods as a matter of priority.

Amendment

2. The notified bodies shall ***ensure all reasonable efforts are made to*** process all applications for conformity assessment of fertilising products designated as crisis-relevant goods as a matter of priority.

Amendment 112

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41b – paragraph 4

Text proposed by the Commission

4. The prioritisation of applications for conformity assessment of fertilising products pursuant to paragraph 3 shall not give rise to any additional costs for the manufacturers, who have lodged those applications.

Amendment

4. The prioritisation of applications for conformity assessment of fertilising products pursuant to paragraph 3 shall not give rise to any ***extraordinary*** additional costs for the manufacturers, who have lodged those applications.

Amendment 113

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41b – paragraph 5

Text proposed by the Commission

5. The notified bodies shall ***deploy***

Amendment

5. The notified bodies shall ***ensure all***

their best efforts to increase their testing capacities for fertilising products designated as crisis-relevant goods in respect of which they have been notified.

reasonable efforts ***are made*** to increase their testing capacities for fertilising products designated as crisis-relevant goods in respect of which they have been notified.

Amendment 114

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41c – paragraph 1

Text proposed by the Commission

1. By way of derogation from Article 15, ***any*** competent national authority may authorise, on a duly justified request, the placing on the market within the territory of ***the*** Member State ***concerned***, of a specific fertilising product 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 15 have not been carried out by a notified body but for which the compliance with the requirements set out in Annexes I and II has been demonstrated.

Amendment

1. By way of derogation from Article 15, ***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 State***, the placing on the market within the territory of ***that*** Member State, of a specific fertilising product 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 15 have not been carried out by a notified body but for which the compliance with the requirements set out in Annexes I and II has been demonstrated.

Amendment 115

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41c – paragraph 2 – subparagraph 2

Text proposed by the Commission

The manufacturer shall also deploy all reasonable measures to ensure that the fertilising product, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of

Amendment

deleted

the Member State, which issued the authorisation.

Amendment 116

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41c – paragraph 3 – introductory part

Text proposed by the Commission

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the fertilising products may be placed on the market, including:

Amendment

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the fertilising products may be placed on the market, including ***at least***:

Amendment 117

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41c – paragraph 3 – point c

Text proposed by the Commission

(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;

Amendment

(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 ***internal*** market emergency mode has been activated;

Amendment 118

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41c – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(ea) labelling requirements, including radio frequency identification, indicating

that the fertilising product was authorised under the internal market emergency mode.

Amendment 119

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41c – paragraph 4

Text proposed by the Commission

4. By way of derogation from Article 41a(3), ***first subparagraph***, where appropriate, the national competent authority may amend the conditions of the authorisation referred to in paragraph ***3 of*** this ***Article*** also after the deactivation or expiry of the ***Single*** Market Emergency mode.

Amendment

4. By way of derogation from Article 41a(3), where appropriate, the national competent authority may ***also*** amend the conditions and requirements referred to in paragraph ***3 of*** this Article also after the deactivation or expiry of the ***internal*** market emergency mode.

Amendment 120

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41c – paragraph 5

Text proposed by the Commission

5. ***By way of derogation from Articles 3 and 18, fertilising products, 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.***

Amendment

deleted

Amendment 121

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

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 fertilising products.

Amendment

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 fertilising products. ***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.***

Amendment 122

Proposal for a regulation
Article 4 – paragraph 1
Regulation (EU) 2019/1009
Article 41c – paragraph 8

Text proposed by the Commission

8. The application of Articles 41a to 41g 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 15 ***on the territory of the Member State concerned.***

Amendment

8. The application of Articles 41a to 41g 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 15.

Amendment 123

Proposal for a regulation
Article 4 – paragraph 1
Regulation (EU) 2019/1009
Article 41c – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8a. Fertilising products 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.

Amendment 124

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41d – paragraph 1

Text proposed by the Commission

Where 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 requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012, the Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider as complying with requirements set out in Annex I, II or III of this Regulation fertilising products which comply with relevant international standards or any relevant national standards in force in the Member State of manufacture, ensuring a safety level equivalent to that required by the requirements set out in Annex I, II or III.

Amendment

Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market, their competent authorities consider as complying with requirements set out in Annex I, II or III of this Regulation fertilising products which comply with relevant international standards or any relevant national standards in force in the Member State of manufacture, ensuring a safety level equivalent to that required by the requirements set out in Annex I, II or III, ***comply with those essential requirements in either of the following cases:***

Amendment 125

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41d – paragraph 1 – point a (new)

Text proposed by the Commission

Amendment

(a) where a reference to harmonised standards covering the relevant essential requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;

Amendment 126

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41d – paragraph 1 – point b (new)

Text proposed by the Commission

Amendment

(b) where severe disruptions in the functioning of the internal market, which were taken into consideration when activating the internal market emergency mode in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

Amendment 127

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

1. Where EU fertilising products, have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such EU fertilising products for the requirements set out in Annex I, II or III or tests referred to in Article 13(2) ***where severe disruptions in the functioning of the Single Market, which led to the activation of [were taken into consideration when] the Single Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.***

Amendment

1. Where EU fertilising products have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such EU fertilising products for the requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation:

Amendment 128

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41e – paragraph 1 – point a (new)

Text proposed by the Commission

Amendment

(a) where the European standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation (EU) No 1025/2012 were not adopted;

Amendment 129

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009
Article 41e – paragraph 1 – point b (new)

Text proposed by the Commission

Amendment

(b) where a reference to harmonised standards covering the relevant essential requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation 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;

Amendment 130

Proposal for a regulation
Article 4 – paragraph 1
Regulation (EU) 2019/1009
Article 41e – paragraph 1 – point c (new)

Text proposed by the Commission

Amendment

(c) where severe disruptions in the functioning of the internal market, which led to the activation of the internal market emergency mode in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant requirements set out in Annex I, II or III or tests referred to in Article 13(2) of this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

Amendment 131

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

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 45(3). They shall apply to ***EUfertilising*** products placed on the market until the last day of the period for which the ***Single*** Market emergency mode remains active ***in accordance with [the SMEI Regulation]. In the early preparation of*** the draft implementing acts 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.***

Amendment

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 45(3). They shall apply to ***EU fertilising*** products placed on the market until the last day of the period for which the ***internal*** market emergency mode remains active. ***When preparing*** the draft implementing ***act*** establishing the common specification, the Commission shall ***take into account*** the views of ***the*** relevant bodies ***and shall duly consult all*** relevant ***stakeholders.***

Amendment 132

Proposal for a regulation
Article 4 – paragraph 1
Regulation (EU) 2019/1009
Article 41e – paragraph 4

Text proposed by the Commission

4. By way of derogation from Article 41a(3), ***first subparagraph***, unless there is sufficient reason to believe that the fertilising products covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the fertilising products in compliance with 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*** Market

Amendment

4. By way of derogation from Article 41a(3), unless there is sufficient reason to believe that the fertilising products covered by the common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the fertilising products in compliance with 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 ***internal*** market emergency mode in

Emergency mode in accordance with [the **SMEI** Regulation].

accordance with [the **IMERA** Regulation].

Amendment 133

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41e – paragraph 5

Text proposed by the Commission

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the requirements set out in Annexes I and II, it shall inform the Commission thereof with a detailed ***explanation*** and the Commission shall assess that information ***and, if appropriate, amend or withdraw*** the implementing act establishing the common specification in question.

Amendment

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the requirements set out in Annexes I and II, it shall inform the Commission thereof with a detailed ***explanation*** and the Commission shall assess that information. ***The Commission may amend, where appropriate, the implementing act*** establishing the common specification in question.

Amendment 134

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41f

Text proposed by the Commission

Article 41f

Adoption of mandatory common specifications

1. ***In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications for EU fertilising products to cover the requirements set out in Annexes I and II which have been designated as crisis-relevant goods.***

2. ***The implementing acts referred to in paragraph 1 shall be adopted following***

Amendment

deleted

a consultation of the sectoral experts and in accordance with the examination procedure referred to in Article 45(3) and they shall apply to EU fertilising products 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.

3. By way of derogation from Article 41a(3), first subparagraph, unless there is sufficient reason to believe that the EU fertilising products covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of persons, the fertilising products in compliance with 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 Market Emergency mode in accordance with [the SMEI Regulation].

Amendment 135

Proposal for a regulation

Article 4 – paragraph 1

Regulation (EU) 2019/1009

Article 41g – paragraph 2

Text proposed by the Commission

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

Amendment

2. The market surveillance authorities of the Member States shall **ensure** best efforts **are made** to provide assistance to other market surveillance authorities during **an internal** market emergency,

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 fertilising products designated as crisis-relevant goods.

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 fertilising products designated as crisis-relevant goods.’

Amendment 136

Proposal for a regulation

Article 4 a (new) – paragraph 1 – point 1 (new)

Regulation (EU) 2023/988

Article 2 – paragraph 1 – point b

Present text

(b) Chapter III, Section 1, Chapters V and VII and Chapters IX to XI do not apply.

Amendment

Article 4 a

Amendments to Regulation (EU) 2023/988

Regulation (EU) 2023/988 is amended as follows:

(1) In Article 2(1), point (b) is replaced by the following:

“(b) **Chapter IIa**, Chapter III, Section 1, Chapters V and VII and Chapters IX to XI do not apply.”

Amendment 137

Proposal for a regulation

Article 4 a (new) – paragraph 1 – point 2 (new)

Regulation (EU) 2023/988

Chapter II a (new)

Text proposed by the Commission

Amendment

(2) The following chapter is inserted:

‘CHAPTER IIa

EMERGENCY PROCEDURES

Article 8a

Activation of the emergency procedures, relationship with other provisions of this

Regulation and deactivation

1. Articles 8b to 8d shall only apply if the Commission has adopted an implementing act pursuant to Article 14(5) of [the IMERA Regulation].

2. Articles 8b to 8d shall only apply to products which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Articles 8b to 8d shall apply during the internal market emergency mode, except with respect to provisions concerning the powers of the Commission.

Article 8b

Presumption of safety based on national and international standards

Member States shall take all appropriate measures to ensure that, for the purpose of placing products on the market, their competent authorities consider that the products which comply with the relevant international standards or any national standards in force in the Member State of manufacture, and which ensure the safety level required by this Regulation, meet the general safety requirement laid down in this Regulation as far as the risks and risk categories covered by those standards are concerned in any of the following cases:

(a) where a reference to European standards is not published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012;

(b) where severe disruptions to the functioning of the internal market, which were taken into consideration when the internal market emergency mode was activated in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibility for manufacturers to make use of the European standards already published in the Official Journal of the European Union in accordance

with Regulation (EU) No 1025/2012.

Article 8c

Adoption of common specifications enabling a presumption of safety for the risks and aspects covered by common specifications

1. With respect to products covered by this Regulation that have been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common technical specifications in either of the following cases:

(a) where no specific safety requirements in accordance with Article 7 paragraph 2 have been adopted;

(b) where the European standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation No 1025/2012 were not adopted;

(c) where a reference to European standards 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;

(d) where severe disruptions in the functioning of the internal market, which were taken into consideration when the internal market emergency mode was activated in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibility for manufacturers to make use of the European standards covering the relevant essential safety requirements already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 46(3) and

they shall remain applicable at the latest until the last day of the period for which the internal market emergency mode has been activated in accordance with Article 14 of [the IMERA Regulation].

3. When preparing the draft implementing act establishing the common specification, the Commission shall take into account the views of the Consumer Safety Network, referred to in Article 30 and shall duly consult relevant stakeholders.

4. Products covered by this Regulation which are in conformity with common specifications adopted pursuant to paragraph 1 of this Article shall be presumed to be in conformity with the general safety requirement laid down in Article 5 for the risks and risk categories covered by those common specifications or parts thereof.

5. Products covered by this Regulation, which comply with the common specifications adopted pursuant to paragraph 1 and have been placed on the market, shall not be affected by the subsequent expiry or withdrawal of an implementing act adopted pursuant to paragraph 2, which has laid down those common specifications, unless there is sufficient reason to believe that goods covered by those common specifications present a risk to the health or safety of persons.

6. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the general safety requirement laid down in Article 5, it shall inform the Commission thereof with a detailed explanation and the Commission shall consider that information. The Commission may amend, where appropriate, amend the implementing act establishing the common specification in question.

Article 8d

Prioritisation of market surveillance

activities and mutual assistance among authorities

1. Member States shall prioritise market surveillance activities for products covered by this Regulation, which have been 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 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 products covered by this Regulation which have been designated as crisis-relevant goods.

Amendment 138

Proposal for a regulation

Article 4 b (new)

Regulation (EU) 2023/1230

Chapter VI a (new)

Text proposed by the Commission

Amendment

Article 4b

***Amendments to Regulation (EU)
2023/1230***

***In Regulation (EU)2023/1230, the
following chapter is inserted:***

‘CHAPTER VIa

EMERGENCY PROCEDURES

Article 46a

Application of emergency procedures

***1. Articles 46b to 46f of this Regulation
shall only apply if the Commission has
adopted an implementing act pursuant to
Article 14(5) of [the IMERA Regulation].***

2. Articles 46b to 46f shall apply

exclusively to machinery which has been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

3. Articles 46b to 46f shall apply during the internal market emergency mode, except with respect to provisions concerning the powers of the Commission.

Article 46b

Prioritisation of the conformity assessment of crisis-relevant machinery

1. This Article shall apply to machinery designated as crisis-relevant goods, which is subject to conformity assessment procedures in accordance with Article 21, requiring mandatory involvement of a notified body.

2. The notified bodies shall ensure all reasonable efforts are made to process all applications for a conformity assessment of machinery designated as crisis-relevant goods, as a matter of priority.

3. All pending applications for a conformity assessment of machinery designated as crisis-relevant goods shall be processed as a matter of priority, ahead of any other applications for conformity assessment of machinery which has not been designated as crisis-relevant goods. This priority requirement shall apply to all applications for conformity assessments of machinery designated as crisis-relevant goods, irrespective of whether they have been lodged before or after the activation of the emergency procedures pursuant to Article 46a.

4. The prioritisation of applications for a conformity assessment of machinery pursuant to paragraphs 2 and 3 shall not give rise to any extraordinary additional costs for the manufacturers who have lodged those applications.

5. The notified bodies shall ensure all reasonable efforts are made to increase

their testing capacities for machinery designated as crisis-relevant goods in respect of which they have been notified.

Article 46c

Derogation from third party conformity assessment procedures requiring mandatory involvement of a notified body

1. By way of derogation from Article 21, 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 State, the placing on the market or putting into service within the territory of that Member State, of specific machinery which has been designated as crisis-relevant goods and for which the conformity assessment procedures requiring mandatory involvement of a notified body referred to in Article 21 have not been carried out by a notified body but for which the compliance with all the applicable essential health and safety requirements has been demonstrated.

2. The manufacturer of machinery, subject to the authorisation procedure referred to in paragraph 1, shall declare on his sole responsibility that the machinery concerned complies with all the applicable essential health and safety requirements set out in Annex III and shall be responsible for the fulfilment of all the conformity assessment procedures indicated by the national competent authority.

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the machinery may be placed on the market or put into service, including at least:

(a) a description of the procedures, by means of which the compliance with the applicable essential health and safety requirements of this Regulation was

successfully demonstrated;

(b) specific requirements regarding the traceability of the machinery concerned;

(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 internal market emergency mode has been activated;

(d) any specific requirements regarding the need to ensure the continuous conformity assessment with respect to the machinery concerned;

(e) measures to be taken with respect to the machinery concerned upon expiry of the authorisation in order to ensure that the machinery concerned is brought back in compliance with all the requirements of this Regulation;

(f) labelling requirements, including radio frequency identification, indicating that the machinery was authorised under the internal market emergency mode.

4. By way of derogation from Article 46(3), where appropriate, the national competent authority may also amend the conditions and requirements referred to in paragraph 3 of this Article after the deactivation or expiry of the internal market emergency mode.

5. 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 machinery. 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. Member States shall inform the Commission and the other Member States of any decision to authorise the placing

on the market or putting into service of machinery in accordance with paragraph 1.

7. The application of Articles 46a to 46g and the use of the authorisation procedure set out in paragraph 1 of this Article shall not affect the application of the relevant conformity assessment procedures laid down in Article 21.

8. Machinery 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 46d

Presumption of conformity based on national and international standards

Member States shall take all appropriate measures to ensure that, for the purposes of placing on the market or putting into service, their competent authorities consider that the machinery which complies 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 health and safety requirements set out in Annex III to this Regulation, complies with those essential health and safety requirements in either of the following cases:

a) where a reference to harmonised standards covering the relevant essential health and safety requirements set out in Annex III to this Regulation is not 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 internal market, which were taken into consideration when the internal market emergency mode was

activated in accordance with Article 14 of [the IMERA Regulation] significantly restrict the possibilities of manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex III to this Regulation and already published in the Official Journal of the European Union in accordance with Regulation (EU) No 1025/2012.

Article 46e

Adoption of common specifications conferring a presumption of conformity

1. Where machinery has been designated as crisis-relevant goods, the Commission is empowered to adopt implementing acts establishing common specifications for such machinery to cover the essential health and safety requirements set out in Annex III to this Regulation, in either of the following cases:

a) where the European standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation No 1025/2012 were not adopted;

b) where a reference to harmonised standards covering the relevant essential requirements set out in Annex III 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;

c) where severe disruptions in the functioning of the internal market, which led to the activation the internal market emergency mode in accordance with Article 14 of [the IMERA Regulation], significantly restrict the possibility for manufacturers to make use of the harmonised standards covering the relevant essential health and safety requirements set out in Annex III to this Regulation and already published in the Official Journal of the European Union

in accordance with Regulation (EU) No 1025/2012.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 48(3). They shall apply to machinery placed on the market until the last day of the period for which the internal market emergency mode remains active. When preparing the draft-implementing act establishing the common specification, the Commission shall take into account the views of the relevant bodies and shall duly consult all relevant stakeholders.

3. Without prejudice to Article 17, machinery which is in conformity with common specifications adopted pursuant to paragraph 2 of this Article shall be presumed to be in conformity with the essential health and safety requirements set out in Annex III covered by those common specifications or parts thereof.

4. By way of derogation from Article 46a(3), unless there is sufficient reason to believe that the machinery covered by the common specifications referred to in paragraph 1 of this Article presents a risk to the health or safety of persons, the machinery in compliance with those common specifications which has 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 internal market emergency mode in accordance with [the IMERA Regulation].

5. When a Member State considers that a common specification referred to in paragraph 1 does not entirely satisfy the essential health and safety requirements which it aims to cover and which are set out in Annex III, it shall inform the Commission thereof with a detailed

explanation and the Commission shall assess that information. The Commission may amend, where appropriate, the implementing act establishing the common specification in question.

Article 46f

Prioritisation of market surveillance activities and mutual assistance among authorities

1. Member States shall prioritise the market surveillance activities for machinery, 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 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 machinery designated as crisis-relevant goods.'

Amendment 139

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59a – paragraph 1

Text proposed by the Commission

1. Articles 59b to 59f 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.**

Amendment

1. Articles 59b to 59f **of this Article** shall only apply if the Commission has adopted an implementing act pursuant to Article **14(5)** of [the *IMERA* Regulation].

Amendment 140

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59a – paragraph 2

Text proposed by the Commission

2. Articles 59b to 59f shall apply exclusively to construction products, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

Amendment

2. Articles 59b to 59f shall apply exclusively to construction products, which have been designated as crisis-relevant goods in the implementing act referred to in paragraph 1 of this Article.

Amendment 141

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59a – paragraph 3 – subparagraph 1

Text proposed by the Commission

3. Articles 59b to 59f, except as regards provisions concerning the powers of the Commission, shall apply during the *Single* Market emergency mode.

Amendment

3. Articles 59b to 59f, except as regards provisions concerning the powers of the Commission, shall apply during the *internal* market emergency mode.

Amendment 142

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59a – paragraph 3 – subparagraph 2

Text proposed by the Commission

However, Article 59c(2), second subparagraph, and Article 59c(5) shall apply during the Single Market emergency mode and after its deactivation or expiry.

Amendment

deleted

Amendment 143

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59a – paragraph 4

Text proposed by the Commission

Amendment

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 construction products placed on the market in accordance with Articles 59b to 59f. These implementing acts shall be adopted in accordance with the examination procedure referred to in Article 64(2a)

deleted

Amendment 144

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59b – paragraph 2

Text proposed by the Commission

Amendment

2. The notified bodies shall process requests for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods as a matter of priority.

2. The notified bodies shall *ensure all reasonable efforts are made to* process requests for third party tasks related to the assessment and verification of constancy of performance of construction products designated as crisis-relevant goods as a matter of priority.

Amendment 145

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59b – paragraph 4

Text proposed by the Commission

Amendment

4. The prioritisation of applications for third party tasks related to the

4. The prioritisation of applications for third party tasks related to the

assessment and verification of constancy of performance of construction products pursuant to paragraph 3 shall not give rise to any additional costs for the **manufacturers** who have lodged those applications.

assessment and verification of constancy of performance of construction products pursuant to paragraph 3 shall not give rise to any **extraordinary** additional costs for the **manufacturers, who** have lodged those applications.

Amendment 146

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59b – paragraph 5

Text proposed by the Commission

5. The notified bodies shall **deploy their best** efforts to increase their respective assessment and verification capacities regarding construction products designated as crisis-relevant goods.

Amendment

5. The notified bodies shall **ensure all reasonable** efforts **are made** to increase their respective assessment and verification capacities regarding construction products designated as crisis-relevant goods.

Amendment 147

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 1

Text proposed by the Commission

1. By way of derogation from Article 28(1), the competent national authority may exceptionally authorise, on a duly justified request, the placing on the market within the territory of **the** Member State **concerned**, of a specific construction product which has been designated as crisis-relevant good for which the required third-party assessment and verification of constancy of performance procedures referred to in **that** Article have not been carried out by a notified body.

Amendment

1. By way of derogation from Article 28(1), the competent national authority, **after carrying out a risk assessment**, may exceptionally authorise, on a duly justified request **from an economic operator established in its Member State**, the placing on the market within the territory of that Member State, of a specific construction product which has been designated as crisis-relevant good for which the required third-party assessment and verification of constancy of performance procedures referred to in Article **28(1)** have not been carried out by a notified body.

Amendment 148

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 2 – subparagraph 2

Text proposed by the Commission

Amendment

The manufacturer shall also deploy all reasonable measures to ensure that the construction product, which has been granted an authorisation pursuant to paragraph 1 does not leave the territory of the Member State, which issued the authorisation.

deleted

Amendment 149

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 3 – introductory part

Text proposed by the Commission

Amendment

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the construction products may be placed on the market, including:

3. Any authorisation issued by a national competent authority pursuant to paragraph 1 shall set out the conditions and requirements under which the construction products may be placed on the market, including ***at least***:

Amendment 150

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 3 – point c

Text proposed by the Commission

Amendment

(c) an end date of validity of the authorisation, which cannot go beyond the last day of the period for which the ***Single***

(c) an end date of validity, ***unless otherwise specified***, of the authorisation, which cannot go beyond the last day of the

Market emergency mode has been activated;

period for which the *internal* market emergency mode has been activated;

Amendment 151

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 3 – point e a (new)

Text proposed by the Commission

Amendment

(ea) labelling requirements, including radio frequency identification, indicating that the construction product was authorised under the internal market emergency mode.

Amendment 152

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 4

Text proposed by the Commission

Amendment

4. By way of derogation from Article 54a(3), **first subparagraph**, where appropriate, the national competent authority may amend the conditions **of the authorisation issued** referred to in paragraph 3 of this Article, **also** after the deactivation or expiry of the **Single** Market Emergency mode.

4. By way of derogation from Article 54a(3), where appropriate, the national competent authority may **also** amend the conditions **and requirements** referred to in paragraph 3 of this Article after the deactivation or expiry of the **internal** market emergency mode.

Amendment 153

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 5

Text proposed by the Commission

Amendment

5. Construction products, 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

Amendment 154

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 6

Text proposed by the Commission

Amendment

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 construction products.

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 construction products. ***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.***

Amendment 155

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 8

Text proposed by the Commission

Amendment

8. The application of Articles 59a to 59f and the use of the authorisation

8. The application of Articles 59a to 59f and the use of the authorisation

procedure set out in paragraph 1 of this Article **does** not affect the application of the relevant procedures for the assessment and verification of constancy of performance required by Article 28 **on the territory of the Member State concerned**.

procedure set out in paragraph 1 of this Article **shall** not affect the application of the relevant procedures for the assessment and verification of constancy of performance required by Article 28.

Amendment 156

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59c – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8a. Construction products 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.

Amendment 157

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59d – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) where **no reference to harmonised standards covering the relevant methods and criteria for assessing the performance of those products in relation to their essential characteristics is published in the Official Journal of the European Union in accordance with Article 17(5);**

(a) where the European **standardisation deliverables addressing a request pursuant to Article 10(1) of Regulation (EU) No 1025/2012 were not adopted;**

Amendment 158

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59d – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(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;

Amendment 159

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59d – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) where the severe disruptions in the functioning of the **Single** Market, which led to the activation of the **Single** Market emergency mode significantly restrict the possibilities of manufacturers to make use of the harmonised standards, providing the relevant methods and criteria for assessing the performance of those product in relation to their essential characteristics, and already published in the Official Journal of the European Union in accordance with **Article 17(5)**.

(b) where the severe disruptions in the functioning of the **internal** market, which led to the activation of the **internal** market emergency mode **in accordance with Article 14 of [the IMERA Regulation]**, significantly restrict the possibilities of manufacturers to make use of the harmonised standards, providing the relevant methods and criteria for assessing the performance of those product in relation to their essential characteristics, and already published in the Official Journal of the European Union in accordance with **Regulation (EU) No 1025/2012**.

Amendment 160

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59d – paragraph 2

Text proposed by the Commission

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted ***following a consultation of the Standing Committee on Construction and*** in accordance with the examination procedure referred to in Article 64(2a). They shall apply to construction products 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.***

Amendment

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted in accordance with the examination procedure referred to in Article 64(2a). They shall apply to construction products placed on the market until the last day of the period for which the ***internal*** market emergency mode remains active. ***When preparing*** the draft implementing act establishing the common specification, the Commission shall ***take into account*** the views of relevant bodies ***and shall duly consult all relevant stakeholders.***

Amendment 161

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59d – paragraph 5

Text proposed by the Commission

5. When a Member State considers that a common specification referred to in paragraph 1 is incorrect in terms of criteria and methods for the assessment of performance in relation to essential characteristics, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information ***and, if appropriate,*** amend ***or withdraw*** the implementing act establishing the common specification in question

Amendment

5. When a Member State considers that a common specification referred to in paragraph 1 is incorrect in terms of criteria and methods for the assessment of performance in relation to essential characteristics, it shall inform the Commission thereof with a detailed explanation and the Commission shall assess that information. ***The Commission may amend, where appropriate,*** the implementing act establishing the common specification in question.

Amendment 162

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59e

Text proposed by the Commission

Amendment

Article 59e

deleted

Adoption of mandatory common specifications

1. In duly justified cases, the Commission is empowered to adopt implementing acts establishing mandatory common specifications to cover the methods and the criteria for assessing the performance of construction products which have been designated as crisis-relevant goods.

2. The implementing acts referred to in paragraph 1 of this Article shall be adopted following a consultation of the Standing Committee on Construction and in accordance with the examination procedure referred to in Article 64(2a). They shall apply to construction products placed on the market until the last day of the period for which the Single Market emergency remains active. In the early preparation of the draft implementing acts establishing the common specifications, 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.

3. By way of derogation from Article 59a(3), first subparagraph, unless there is sufficient reason to believe that the construction products covered by the mandatory common specifications referred to in paragraph 1 of this Article present a risk to the health or safety of

persons, the construction products in compliance with 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 Market Emergency mode in accordance with [the SMEI Regulation].

Amendment 163

Proposal for a regulation

Article 5 – paragraph 1 – point 1

Regulation (EU) No 305/2011

Article 59f – paragraph 2

Text proposed by the Commission

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 construction products designated as crisis-relevant goods.

Amendment

2. The market surveillance authorities of the Member States shall ***ensure*** best efforts ***are made*** to provide assistance to other market surveillance authorities during ***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 construction products designated as crisis-relevant goods.’

Amendment 164

Proposal for a regulation

Article 6 – paragraph 2

Text proposed by the Commission

It shall apply from [OP- please insert the date identical to that of the entry into application of the ***SMEI*** Regulation].

Amendment

It shall apply from [OP- please insert the date identical to the date of application of the ***IMERA*** Regulation].

EXPLANATORY STATEMENT

1. Introduction

On 19 September 2022, the European Commission published the proposal for the “Single Market Emergency Instrument” (SMEI) and two legislative proposals with targeted amendments to sectoral legislation. SMEI provides a general framework for EU crisis response in the internal market and complements other sector-specific crisis response mechanisms such as the Union Civil Protection Mechanism and sector-specific crisis frameworks in the areas of health, semiconductors or food security.

SMEI was drawn up in response to the fragmentation of the internal market during the Covid-19 pandemic where ad-hoc, unilateral border closures impinged on the freedom of movement of goods, services and workers, and exacerbated supply chain disruptions. The unprecedented crisis led to a chaotic initial response by the Member States, marked by a lack of coordination and solidarity, and the introduction of unjustified restrictions, without fully taking into consideration their devastating effect on the proper functioning of the internal market. The new instrument provides for a horizontal crisis governance framework to make sure that the internal market remains open and that supply chains are more resilient.

2. The Draft Report

The Rapporteur fully supports the objective of the Regulation of safeguarding free movement of goods, workers and services. At the same time, the Rapporteur believes that resilience is key to ensuring that the internal market delivers on its ultimate goal of supporting the EU’s economy. The Rapporteur therefore proposes to **change the title to “Internal Market Emergency and Resilience Act” (IMERA) and to introduce additional changes to strengthen the Union’s resilience**. The Rapporteur welcomes IMERA’s approach to preserving the free movement of goods, services and workers. During the Covid-19 pandemic, the rights of workers and companies as enshrined in the Treaties were disproportionately limited. The Rapporteur would like to highlight that the Treaty freedoms are not suspended in times of crises: unilateral limitations to free movement often even hampered the crisis response, such as limiting the mobility of health workers, hospital machinery maintenance service providers or the availability of food supplies. Therefore, the Rapporteur emphasizes the important role that “Fast lanes” played during the pandemic and highlights that the new instrument should further develop such measures.

During the Covid 19 pandemic and the EU’s response to Russia’s illegal war in Ukraine, the government-led crisis responses were complemented by the rapid adjustments companies made to their supply chains and production lines. The Rapporteur believes that market interventions must remain instruments of last resort, while market-based mechanisms such as procurement and cooperation between the government and the industry are better, faster and more efficient crisis responses.

In view of these considerations, the Rapporteur strengthens some elements, in particular pertaining to resilience and the free movement of workers, goods and services. At the same time, he wants to ensure that during a crisis, the spirit of cooperation and solidarity governs the relationship between governments and companies willing to help.

2.1 Resilience during the contingency mode

The Rapporteur believes that IMERA must increase the resilience of supply chains by fostering cooperation between businesses, the Commission and Member States on a voluntary basis. The Rapporteur therefore proposes to ensure the crisis-preparedness of all actors through biennial stress tests, trainings and crisis protocols involving not only all relevant national authorities, but also stakeholders such as businesses, social partners and experts.

Companies possess critical knowledge and resources for crisis responses, as highlighted by the Covid pandemic. In the Rapporteur's opinion, the inclusion of companies must be an integral part of any crisis response mechanism. The Rapporteur wants to foster greater involvement of companies by allowing them to provide advice on crisis-measures through an online platform. Moreover, to address common sector-specific vulnerabilities at a European level, the Commission should conduct supply chain stress tests on a voluntary basis, thereby giving both the Commission and businesses the opportunity to develop best practices on supply chain resilience.

The Rapporteur believes that strategic reserves must become a more permanent consideration in increasing the Union's resilience, and increased cooperation and exchange of best practices between the Commission and the Member States is needed. At the same time, the Rapporteur notes that the pro-cyclical creation of reserves during the "Vigilance Mode" or "Emergency Mode" risks increased scarcity, rising prices, affecting competition and the level playing field, and an exacerbation of the situation. Moreover, strategic reserves require established relationships between economic operators and administrative arrangements specific to each sector. Member States are better placed to accomplish that as they already have well-established mechanisms to administer strategic reserves. Therefore, the Rapporteur suggests giving the Commission a permanent role in ensuring coordination, information exchange and promoting solidarity between Member States in the administration of strategic reserves, while removing the empowerment to prescribe mandatory stockpiles during the "Vigilance Mode".

2.2 Emergency Mode

The Rapporteur believes that the focus of IMERA during a crisis **must be to safeguard the free movement of goods, services and workers as enshrined in the treaties, especially in case of emergencies.** The Rapporteur proposes to strengthen the elements of the first chapter of the emergency mode and align it with the treaties and with case law. Moreover, the Rapporteur wants to draw more attention to the situation of border regions as they are the most affected by limitations to free movement. Hence, he would like to aim for a unified definition of "working from home".

To the Rapporteur, companies and market forces are central to any crisis response in the Internal Market. While he sees the necessity for priority rated orders, he suggests improvements to provide further leeway to companies and ensure more legal certainty. Since businesses delivered despite uncoordinated actions by public authorities during the pandemic, the Rapporteur suggests more limited and voluntary requests for information. Moreover, to provide legal certainty, the Rapporteur improves the rules governing the use of data and the protection of trade and business secrets, and of intellectual property. Furthermore, the Rapporteur proposes procedural elements to ensure that priority rated orders remain an instrument of last resort and will not endanger the economic viability of companies. Recalling that companies during the

Covid pandemic were under a heavy strain, the Rapporteur suggests adjustments to the sanctions regimes to reflect the lower revenues likely generated during a crisis.

The Rapporteur considers solidarity to be the key for the mutual trust and, ultimately, for the smooth free movement of goods, services and workers. Therefore, he suggests a mechanism whereby Member States may launch a call for solidarity in case of shortages of crisis-relevant goods and services. During Covid, export restrictions and joint procurement pitted EU-members against like-minded neighbours that were equally in need of crisis-relevant goods. To avoid such situations in the future and to strengthen European solidarity, the rapporteur proposes to open up the joint procurement to Andorra, Monaco and San Marino, accession candidate countries and countries of the European Free Trade Area.

2.3 Digital Tools and harmonisation of administrative procedures

During the Covid pandemic, nationally divergent requirements and administrative procedures for entering another Member State created great confusion and frustration for citizens, especially workers and service providers, in particular in border regions. **The Rapporteur therefore foresees that the Commission must immediately develop digital tools similar to the successful interoperable Covid-19 certificate to guarantee the functioning of “fast lanes” for critical goods and services.** The Commission must provide a digital portal, covering all registration or authorisation forms for cross-border activities, especially for crisis-relevant declarations similar to Covid Certificates, and for crisis-relevant professional services to accelerate authorisation, registration or declaration procedures.

2.4 Governance

Covid highlighted the importance of good cooperation between all governments in the EU's internal market, but also the importance of parliamentary scrutiny. Therefore, the Rapporteur proposes to **model the advisory group after an expert group within the well-known and established rules for such groups, thereby giving the European Parliament and EEA/EFTA countries a more permanent seat at the table as observers.** Given the general nature of IMERA, the Rapporteur also suggests improvement to key definitions, thereby increasing legal certainty and predictability.

3. Accompanying proposals

The Rapporteur suggests targeted changes to the two accompanying proposals to make sure that free movement of harmonised and non-harmonised goods is facilitated across the EU. As regards the crisis instruments at the Commission's disposal, the Rapporteur suggests providing a mechanism also for the rapid placing on the market for non-harmonized products, which would have increased the availability of safe personal protection equipment during the Covid pandemic. Furthermore, to incentivize companies to ramp up production during a crisis, the Rapporteur proposes to permit the continued sale of goods that were put on the market under emergency procedures for a limited period of time after the end of the single market emergency, without compromising on the safety of the products.

It is the Rapporteur's belief that IMERA should primarily improve the resilience of the internal market, ensuring constant coordination between Member States and ensuring readiness for the event of sudden shocks at all times. Thereby, in times of crisis, the Internal Market must stay open and functional and protect consumers, workers and businesses alike from emergencies.

ANNEX: LIST OF ENTITIES OR PERSONS FROM WHOM THE RAPPORTEUR HAS RECEIVED INPUT

The following list is drawn up on a purely voluntary basis under the exclusive responsibility of the rapporteur. The rapporteur has received input from the following entities or persons in the preparation of the draft report:

Affordable Medicines Europe
APPLiA - Home Appliance Europe
BDA - Bundesvereinigung der Deutschen Arbeitgeberverbände e.V.
BDI - Bundesverband der Deutschen Industry e.V.
Business Europe
BWL - Bundesamt für wirtschaftliche Landesversorgung der Schweiz
Dutch Ministry of Economic Affairs
Eurochambres
Eurocommerce
France Industrie
Germany Ministry of Climate and Economics
Independent Retail Europe
Mission of the United Kingdom to the European Union
NESA - National Emergency Supply Agency of Finland
Orgalim
Prof. Dr. iur. Jan Bergmann
SME United

PROCEDURE – COMMITTEE RESPONSIBLE

Title	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		
References	COM(2022)0461 – C9-0314/2022 – 2022/0279(COD)		
Date submitted to Parliament	19.9.2022		
Committee responsible Date announced in plenary	IMCO 21.11.2022		
Rapporteurs Date appointed	Andreas Schwab 16.12.2022		
Discussed in committee	28.3.2023	25.4.2023	28.6.2023
Date adopted	18.7.2023		
Result of final vote	+: 35 -: 3 0: 2		
Members present for the final vote	Andrus Ansip, Pablo Arias Echeverría, Alessandra Basso, Brando Benifei, Adam Bielan, Biljana Borzan, Vlad-Marius Botoș, Markus Buchheit, Anna Cavazzini, Deirdre Clune, David Cormand, Alexandra Geese, Sandro Gozi, Maria Grapini, Svenja Hahn, Krzysztof Hetman, Virginie Joron, Eugen Jurzyca, Kateřina Konečná, Maria-Manuel Leitão-Marques, Antonius Manders, Leszek Miller, Anne-Sophie Pelletier, René Repasi, Christel Schaldemose, Andreas Schwab, Tomislav Sokol, Ivan Štefanec, Róza Thun und Hohenstein, Tom Vandenkendelaere, Kim Van Sparrentak, Marion Walsmann		
Substitutes present for the final vote	Claude Gruffat, Ivars Ijabs, Karen Melchior, Tsvetelina Penkova, Kosma Złotowski		
Substitutes under Rule 209(7) present for the final vote	Eric Minardi, Paulo Rangel, Grzegorz Tobiszowski		
Date tabled	24.7.2023		

FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

35	+
ECR	Adam Bielan, Grzegorz Tobiszowski, Kosma Złotowski
PPE	Pablo Arias Echeverría, Deirdre Clune, Krzysztof Hetman, Antonius Manders, Paulo Rangel, Andreas Schwab, Tomislav Sokol, Ivan Štefanec, Tom Vandenkendelaere, Marion Walsmann
Renew	Andrus Ansip, Vlad-Marius Botoș, Sandro Gozi, Svenja Hahn, Ivars Ijabs, Karen Melchior, Róza Thun und Hohenstein
S&D	Brando Benifei, Biljana Borzan, Maria Grapini, Maria-Manuel Leitão-Marques, Leszek Miller, Tsvetelina Penkova, René Repasi, Christel Schaldemose
The Left	Kateřina Konečná, Anne-Sophie Pelletier
Verts/ALE	Anna Cavazzini, David Cormand, Alexandra Geese, Claude Gruffat, Kim Van Sparrentak

3	-
ID	Markus Buchheit, Virginie Joron, Eric Minardi

2	0
ECR	Eugen Jurzyca
ID	Alessandra Basso

Key to symbols:

+ : in favour

- : against

0 : abstention