Basic information

2022/0279(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
Amending certain Regulations as regards the establishment of the Single Market emergency instrument Amending Regulation 2011/305 2008/0098(COD) Amending Regulation 2016/424 2014/0107(COD) Amending Regulation 2016/425 2014/0108(COD) Amending Regulation 2016/426 2014/0136(COD) Amending Regulation 2019/1009 2016/0084(COD) **Subject** 2 Internal market, single market 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 4.60.08 Safety of products and services, product liability **Legislative priorities** Joint Declaration 2022 Joint Declaration 2023-24	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
IMCO Internal Market and Consumer Protection	SCHWAB Andreas (EPP)	16/12/2022
	Shadow rapporteur REPASI René (S&D) CHARANZOVÁ Dita (Renew) CAVAZZINI Anna (Greens/EFA) BIELAN Adam (ECR) PELLETIER Anne-Sophie (The Left)	

Council of the European Union

European Commission

Commission DG	Commissioner
Internal Market, Industry, Entrepreneurship and SMEs	BRETON Thierry

European Economic and Social Committee

Key events

Date	Event	Reference	Summary
19/09/2022	Legislative proposal published	COM(2022)0461	Summary
21/11/2022	Committee referral announced in Parliament, 1st reading		
18/07/2023	Vote in committee, 1st reading		
18/07/2023	Committee decision to open interinstitutional negotiations with report adopted in committee		
24/07/2023	Committee report tabled for plenary, 1st reading	A9-0244/2023	Summary
11/09/2023	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 72)		
13/09/2023	Committee decision to enter into interinstitutional negotiations confirmed by plenary (Rule 72)		
22/02/2024	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE759.092 GEDA/A/(2024)001181	
24/04/2024	Decision by Parliament, 1st reading	T9-0321/2024	Summary
24/04/2024	Results of vote in Parliament		
26/09/2024	Act adopted by Council after Parliament's 1st reading		
09/10/2024	Final act signed		
08/11/2024	Final act published in Official Journal		

Technical information

Procedure reference	2022/0279(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Amendments and repeals	Amending Regulation 2011/305 2008/0098(COD) Amending Regulation 2016/424 2014/0107(COD) Amending Regulation 2016/425 2014/0108(COD) Amending Regulation 2016/426 2014/0136(COD) Amending Regulation 2019/1009 2016/0084(COD)
Legal basis	Treaty on the Functioning of the European Union TFEU 114
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	IMCO/9/10148

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary

Committee draft report		PE745.282	10/03/2023	
Amendments tabled in committee		PE745.535	31/03/2023	
Committee report tabled for plenary, 1st reading/single reading		A9-0244/2023	24/07/2023	Summary
Text agreed during interinstitutional negotiations		PE759.092	16/02/2024	
Text adopted by Parliament, 1st reading/single reading		T9-0321/2024	24/04/2024	Summary

Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2024)001181	16/02/2024	
Draft final act	00047/2024/LEX	09/10/2024	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2022)0461	19/09/2022	Summary
Document attached to the procedure	SWD(2022)0288	19/09/2022	
Document attached to the procedure	SWD(2022)0289	19/09/2022	
Document attached to the procedure	SWD(2022)0290	19/09/2022	
Commission response to text adopted in plenary	SP(2024)394	08/08/2024	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	CZ_CHAMBER	COM(2022)0461	01/12/2022	
Contribution	CZ_SENATE	COM(2022)0461	20/12/2022	
Contribution	RO_SENATE	COM(2022)0461	21/03/2023	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES4098/2022	14/12/2022	

Additional information

Source	Document	Date

European Commission	EUR-Lex	

Final act

Regulation 2024/2748
OJ OJ L 08.11.2024

Summary

Corrigendum to final act 32024R2748R(01)
OJ OJ L 22.04.2025

Amending certain Regulations as regards the establishment of the Single Market emergency instrument

2022/0279(COD) - 08/11/2024 - Final act

PURPOSE: to make targeted amendments to certain Regulations regarding emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency.

LEGISLATIVE ACT: Regulation (EU) 2024/2748 of the European Parliament and of the Council amending Regulations (EU) No 305/2011, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/988 and (EU) 2023/1230 as regards emergency procedures for the conformity assessment, presumption of conformity, adoption of common specifications and market surveillance due to an internal market emergency.

CONTENT: the regulation is part of a package of texts establishing the single market instrument for emergency situations (SMEI - Single Market Emergency Instrument Omnibus). It amends the harmonised rules established by a number of EU sectoral frameworks in order to update them with regard to crisis situations.

Neither the reference provisions laid down by Decision No 768/2008/EC on a common framework for the marketing of products, nor the specific provisions laid down by the sectorial Union harmonisation legislation, provide for procedures designed to apply during a crisis. Therefore, this regulation introduces targeted adjustments to the amended Regulations, to allow a response to the impact of crises affecting products that have been designated as crisis-relevant goods in accordance with Regulation (EU) 2024/2747 establishing a framework of measures, related to an internal market emergency and to the resilience of the internal market and covered by the amended Regulations.

The regulation foresees to amend the following sectoral frameworks:

- Regulation (EU) 2016/424 on cableway installations;

- Regulation (EU) 2016/425 on personal protective equipment;

- Regulation (EU) 2016/426 on gas appliances;

- Regulation (EU) 2019/1009 on fertilising products;

- Regulation (EU) 305/2011 on construction products.

- Regulation (EU) 2023/988 laying down essential rules on the general safety of consumer products placed or made available on the market.

- Regulation (EU) 2023/1230 on machinery and equipment.

The main elements of the amending regulation are the following:

- in order to overcome the potential effects of disruptions to the internal market in the event of a crisis and in order to ensure that during an internal market emergency mode crisis-relevant goods can be 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 goods over any pending applications concerning products which have not been designated as crisis-relevant goods;

- the regulation provides for **emergency procedures** in Regulations (EU) No 305/2011, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/988 of the European Parliament and of the Council and Regulation (EU) 2023/1230. Those procedures should become applicable only following the activation of the internal market emergency mode and only when a specific good covered by those Regulations is designated as a crisis-relevant good and the Commission has adopted an implementing act activating those procedures;

- as regards products falling within the scope of the amended Regulations that have been designated as crisis-relevant goods, in the context of an ongoing internal market emergency the national competent authorities should be able to **derogate from the obligation to carry out the conformity**

assessment procedures laid down in the amended Regulations, where the involvement of a notified body is mandatory. In such cases those authorities should be able to issue authorisations for placing on the market, and, as applicable, for putting into service, those products, provided that conformity with all the applicable essential safety requirements is ensured;

- with respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2023/1230, the competent national authorities should be able to **presume** that products manufactured in accordance with European standards, relevant applicable national standards of the Member States, or relevant applicable international standards developed by a recognised international standardisation body, identified by the Commission as suitable to reach conformity and ensuring an equivalent level of protection to that offered by the harmonised standards, comply with the relevant and applicable essential requirements.

ENTRY INTO FORCE: 28.11.2024.

APPLICATION: from 29.05.2026.

Amending certain Regulations as regards the establishment of the Single Market emergency instrument

2022/0279(COD) - 19/09/2022 - Legislative proposal

PURPOSE: to make targeted amendments to certain Regulations regarding emergency procedures for the conformity assessment, adoption of common specifications and market surveillance due to a Single Market emergency.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: recent crises, such as the COVID-19 pandemic or Russia's invasion of Ukraine, have demonstrated some vulnerability of the Single Market and its supply chains in case of unforeseen disruptions and, at the same time, how much the European economy and all its stakeholders rely on a well-functioning Single Market. In the future, in addition to geopolitical instability, climate change and resulting natural disasters, biodiversity loss, and global economic instability may lead to other, new emergency situations. For this reason, **the functioning of the Single Market needs to be guaranteed in times of emergency**.

The impact of a crisis on the Single Market can be two-fold. On the one hand, a crisis can lead to the appearance of obstacles to free movement within the Single Market, thus disrupting its functioning. On the other hand, a crisis can amplify the shortages of crisis-relevant goods and services if the Single Market is fragmented and is not functioning.

The proposal therefore aims to address two separate but interrelated problems: obstacles to free movement of goods, services and persons in times of crisis and shortages of crisis-relevant goods and services.

It is part of a package of proposal establishing the single market instrument for emergencies (SMEI) and responds to the request, expressed by the European Council in its conclusions of 1-2 October 2020, to draw lessons from the COVID-19 crisis and to address the fragmentation, barriers and weaknesses of the Single Market in facing emergency situations.

CONTENT: the proposal aims to **amend the harmonised rules established by a number of EU sectoral frameworks**. These frameworks do not provide for the possibility for Member States to adopt crisis response measures by derogation from the harmonised rules.

The proposal is based on Article 114 TFEU, which is the original legal basis for the adoption of the following **five sectoral frameworks**, which this proposal aims to amend:

- Regulation (EU) 2016/424 on cableway installations;

- Regulation (EU) 2016/425 on personal protective equipment;

- Regulation (EU) 2016/426 on gas appliances;

- Regulation (EU) 2019/1009 on fertilising products;

- Regulation (EU) 305/2011 on construction products.

The EU sectoral frameworks, which are considered in the context of this proposal are the ones, which are among the so-called 'harmonised products'. These sectoral frameworks lay down harmonised rules regarding the design, manufacture, conformity assessment and placing on the market of such products. Essentially, these sectoral frameworks introduce for each respective sector/product category the **essential safety requirements** which the products should meet and the procedures how to assess the compliance with these requirements. These rules lay down full harmonisation and therefore the Member States cannot derogate from these rules, even in a case of emergency, unless the respective framework provides for such a possibility.

Another common feature of these frameworks is that they are more or less closely aligned to the general principles laid down in Decision No 768/2008 /EC of the European Parliament and of the Council of 9 July 2008 on a **common framework for the marketing of products**, which lays down reference provisions for the drawing up of Community legislation harmonising the conditions for the marketing of products.

The **changes** that this proposal aims to introduce cover the following aspects:

(1) prioritisation by the notified bodies of the conformity assessment of products designated as crisis-relevant;

(2) possibility for the national competent authorities to issue temporary authorisations for crisis relevant products, which have not undergone the standard conformity assessment procedures, provided that the products comply with all the applicable essential requirements and provided that the authorisation is limited to the duration of the Single Market emergency and to the territory of the issuing Member State;

(3) possibility for the manufacturers to rely on relevant international and national standards during an emergency if no harmonised standards are available and if the alternative standards ensure an equivalent level of safety;

(4) possibility for the Commission to adopt via delegated acts voluntary or mandatory common technical specifications for crisis-relevant products;

(5) prioritisation of the market surveillance activities for crisis-relevant goods.

The general objective of the initiative is to lay down the mechanisms and procedures, which would allow to prepare for and to address potential crises and disruptions to the proper functioning of the Single Market. Such measures are also aimed to minimise the intra-EU obstacles to the free movement in times of crisis.

Amending certain Regulations as regards the establishment of the Single Market emergency instrument

2022/0279(COD) - 24/07/2023 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Internal Market and Consumer Protection adopted the report by Andreas SCHWAB (EPP, DE) 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.

The proposal aims to address two distinct but interrelated problems: obstacles to the free movement of goods, services and persons in times of crisis, and shortages of crisis-relevant goods and services. It is part of a package of texts establishing the single market instrument for emergencies, which Members propose to rename the Internal Market Emergency and Resilience Act (IMERA regulation).

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows.

The proposal aims to amend the harmonised rules established by a number of EU sectoral frameworks. These frameworks do not provide for the possibility for Member States to adopt crisis response measures by way of derogation from the harmonised rules.

The Commission proposes to amend the following sectoral frameworks:

- Regulation (EU) 2016/424 on cableway installations;

- Regulation (EU) 2016/425 on personal protective equipment;

- Regulation (EU) 2016/426 on gas appliances;

- Regulation (EU) 2019/1009 on fertilising products;

- Regulation (EU) 305/2011 on construction products.

Members believe that this proposal should also amend:

- Regulation (EU) 2023/988 laying down essential rules on the general safety of consumer products placed or made available on the market.

- Regulation (EU) 2023/1230 on machinery and equipment.

The proposal provides for the possibility for competent national authorities to exceptionally and temporarily authorise the placing on the market of products that have not been subject to the usual conformity assessment procedures required by the Union. Members specified that the authorisation granted for products on an exceptional and temporary basis should remain valid for six months after the deactivation or expiration of the internal market emergency mode, where it does not affect the health and safety of consumers. After this period, products should only be made available on the market after having received authorisation under the normal authorisation procedure provided for under the applicable rules.

In addition, the national competent authorities should be able, in the context of an ongoing 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. The principle of mutual recognition should apply to goods placed on the market under that derogation.

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.

Amending certain Regulations as regards the establishment of the Single Market emergency instrument

2022/0279(COD) - 24/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 409 votes to 60, with 157 abstentions, a 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.

The European Parliament adopted its position at first reading under the ordinary legislative procedure.

The proposed regulation is part of a package of texts establishing the single market instrument for emergency situations. It amends the harmonised rules established by a number of EU sectoral frameworks. These frameworks do not provide for the possibility for Member States to adopt crisis response measures by way of derogation from the harmonised rules.

It is foreseen to amend the following sectoral frameworks:

- Regulation (EU) 2016/424 on cableway installations;

- Regulation (EU) 2016/425 on personal protective equipment;

- Regulation (EU) 2016/426 on gas appliances;

- Regulation (EU) 2019/1009 on fertilising products;

- Regulation (EU) 305/2011 on construction products.

- Regulation (EU) 2023/988 laying down essential rules on the general safety of consumer products placed or made available on the market.

- Regulation (EU) 2023/1230 on machinery and equipment.

Experience from previous crises that have affected the internal market has shown that the procedures laid down in the sectorial Union legal acts are not designed to cater to 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 in order to complement the measures adopted under the Regulation establishing a single market instrument for emergency situations.

In order to overcome the potential effects of disruptions to the internal market in the event of a crisis and in order to ensure that during an internal market emergency mode crisis-relevant goods can be 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 goods over any pending applications concerning products which have not been designated as crisis-relevant goods. In the context of such prioritisation, the conformity assessment body should not be allowed to charge additional disproportionate costs to the manufacturer.

Emergency procedures should be laid down in Regulations (EU) No 305/2011, (EU) 2016/424, (EU) 2016/425, (EU) 2016/426, (EU) 2023/988 of the European Parliament and of the Council and Regulation (EU) 2023/1230. Those procedures should become applicable only following the activation of the internal market emergency mode and only when a specific good covered by those Regulations is designated as a crisis-relevant good and the Commission has adopted an implementing act activating those procedures.

As regards products falling within the scope of the amended Regulations that have been designated as crisis-relevant goods, in the context of an ongoing internal market emergency the national competent authorities should be able to derogate from the obligation to carry out the conformity assessment procedures laid down in the amended Regulations, where the involvement of a notified body is mandatory. In such cases those authorities should be able to issue authorisations for placing on the market, and, as applicable, for putting into service, those products, provided that conformity with all the applicable essential safety requirements is ensured.

With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2023/1230, the competent national authorities should be able to presume that products manufactured in accordance with European standards, relevant applicable national standards of the Member States, or relevant applicable international standards developed by a recognised international standardisation body, identified by the Commission as suitable to reach conformity and ensuring an equivalent level of protection to that offered by the harmonised standards, comply with the relevant and applicable essential requirements.

With respect to Regulation (EU) 2023/988, the competent national authorities should be able to presume that products manufactured in accordance with European or national standards of the Member States, or with relevant international standards developed by a recognised international standardisation body comply with the general safety requirement.

With respect to Regulations (EU) 2016/424, (EU) 2016/425, (EU) 2016/426 and (EU) 2023/1230, the Commission should have the possibility to adopt, by means of implementing acts, common specifications, on which the manufacturers should be able to rely in order to benefit from a presumption of conformity with the applicable essential requirements. Products placed on the market on the basis of the presumption of conformity established by demonstrating compliance with those common specifications should not be withdrawn automatically when the implementing act laying down such common specifications ceases to apply.