Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2021/0323(COD)
Transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices Amending Regulation 2017/746 2012/0267(COD) Subject 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 3.40.11 Precision engineering, optics, photography, medical 4.20.05 Health legislation and policy 4.60.08 Safety of products and services, product liability	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ENVI Environment, Public Health and Food Safety		
	Committee for opinion	Rapporteur for opinion	Appointed
	IMCO Internal Market and Consumer Protection	The committee decided not to give an opinion.	
	EMPL Employment and Social Affairs		
Council of the European Union			
European Commission	Commission DG	Commissioner	
	Health and Food Safety	KYRIAKIDES Stella	
European Economic and Social Committee			
European Committee of the Regions			

Key events

14/10/2021	Legislative proposal published	COM(2021)0627	Summary
18/10/2021	Committee referral announced in Parliament, 1st reading		
27/10/2021	Decision by committee, without report		
13/12/2021	Debate in Parliament		
15/12/2021	Decision by Parliament, 1st reading	T9-0498/2021	Summary
20/12/2021	Act adopted by Council after Parliament's 1st reading		
25/01/2022	Final act signed		
28/01/2022	Final act published in Official Journal		

Technical information

Procedure reference	2021/0323(COD)

Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation 2017/746 2012/0267(COD)
Legal basis	Treaty on the Functioning of the EU TFEU 114; Treaty on the Functioning of the EU TFEU 168-p4; Rules of Procedure EP 163
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/9/07442

Documentation gateway

Legislative proposal		COM(2021)0627	14/10/2021	EC	Summary
Economic and Social Committee: opinion, report		CES5475/2021	08/12/2021	ESC	
Text adopted by Parliament, 1st reading/single reading		T9-0498/2021	15/12/2021	EP	Summary
Draft final act		00079/2021/LEX	25/01/2022	CSL	

Final act

Regulation 2022/112
OJ L 019 28.01.2022, p. 0003

Transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices

PURPOSE: to propose a progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 to prevent disruption in the supply of these essential healthcare products.

PROPOSED ACT: Regulation of the European Parliament and 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: Regulation (EU) 2017/746 on in vitro diagnostic medical devices establishes a new regulatory framework for in vitro diagnostic medical devices, such as HIV tests, pregnancy tests or SARS-CoV-2 tests. The new Regulation will replace the current Directive 98/79/EC on in vitro diagnostic medical devices from 26 May 2022 and introduce substantial changes in the sector.

One of the main changes concerns the involvement of independent conformity assessment bodies (notified bodies). Currently, only a relatively small number of high-risk devices (about 8% of all in vitro diagnostics on the market) is subject to notified body control under Directive 98/79/EC. Under the Regulation, around 80% of in vitro diagnostic medical devices will be under the control of notified bodies, the vast majority of them for the first time.

The COVID-19 public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as increased availability of vitally important in vitro diagnostic medical devices, that could not reasonably have been anticipated at the time of adoption of Regulation (EU) 2017/746. Data on market readiness collected by the European Commission show that Member States, health institutions, notified bodies and economic operators will not be in a position to comply with the new rules within the timeframe foreseen.

In vitro diagnostic medical devices are essential for the health and safety of Union citizens and SARS-CoV-2 tests, in particular, are vital for the fight against the pandemic. Therefore, it is necessary to revise the transitional arrangements to allow for a gradual implementation of the Regulation in order to ensure an uninterrupted supply of these devices on the Union market.

The European Parliament, in a cross-party letter of 11 May 2021 signed by several political groups, called on the Commission to present a legislative proposal to smooth the transition to the new regulatory framework and to ensure the availability of in vitro diagnostic medical devices on the EU market.

CONTENT: in order to ensure legal certainty and to avoid potential market disruption, the Commission proposes to extend the existing transitional period for devices covered by a certificate issued under Directive 98/79/EC and to introduce tailored transitional periods for devices that are to be subject to conformity assessment involving notified bodies for the first time under Regulation (EU) 2017/746.

The length of the transitional period should depend on the risk class of the device concerned:

- for high-risk devices such as HIV or hepatitis tests (class D) and certain influenza tests (class C), the transitional period ends on 26 May 2025 and 26 May 2026, and

- for low-risk devices such as Class B and A sterile devices, 26 May 2027.

The Commission proposes to also introduce a transitional period for the requirements for devices manufactured and used within the same health institution (in-house devices). This will give health institutions extra time to comply with the new requirements and ensure that in-house tests, which are often essential especially for rare diseases, can continue to be developed in clinical laboratories.

Transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices

The European Parliament adopted by 687 votes to 6, with 4 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices.

The European Parliament adopted its position at first reading under the ordinary legislative procedure by taking over the Commission's proposal.

The objectives of this amending Regulation are to extend the transitional periods provided for in Regulation (EU) 2017/746 on in vitro diagnostic medical devices, to introduce additional transitional provisions in that Regulation and to defer the application of the provisions of that Regulation with regard to devices manufactured and used internally.

In vitro diagnostic medical devices are essential for the health and safety of EU citizens and SARS-CoV-2 tests are particularly important for the fight against the COVID-19 pandemic. Given the unprecedented scale of the current challenges, it is very likely that Member States, healthcare

institutions, notified bodies, economic operators and other stakeholders will not be in a position to ensure the proper implementation and full application of that Regulation from 26 May 2022.

In order to ensure legal certainty and to avoid any disruption in the supply of these essential health products, this Regulation extends the existing transitional period for devices covered by certificates issued under Directive 98/79/EC and introduces tailor-made transitional periods for devices that are to be subject to conformity assessment involving notified bodies for the first time in accordance with Regulation (EU) 2017/746.

The length of the transitional period should depend on the risk class of the device concerned:

- for high-risk devices such as HIV or hepatitis tests (class D) and certain influenza tests (class C), the transitional period ends on 26 May 2025 and 26 May 2026 respectively, and

- for low-risk devices such as Class B devices and Class A sterile marketed devices, 26 May 2027.

The amending regulation also introduces a transitional period for the requirements applicable to devices manufactured and used within the same health institutions (in-house devices).