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COMMISSION REGULATION (EU) 2023/2482

of 13 November 2023

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards the substance bis(2-ethylhexyl) phthalate (DEHP) in medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([1]), and in particular Articles 58 and 131 thereof,

Whereas:

(1) Commission Regulation (EU) 2021/2045 ([2]) amending Annex XIV to Regulation (EC) No 1907/2006 sets 27 May 2025 as sunset date and 27 November 2023 as latest application date for uses of the substance bis(2-ethylhexyl) phthalate (DEHP) in medical devices. In accordance with Article 56(1) of Regulation (EC) No 1907/2006, such uses of DEHP are not allowed after the sunset date unless an authorisation has been granted for a particular use, or unless an application for authorisation for a given use was submitted before the latest application date and a decision on the application has not yet been taken.

(2) The sunset date and the latest application date for DEHP in Regulation (EU) 2021/2045 were aligned with the transitional provisions laid down in Regulations (EU) 2017/745 ([3]) and (EU) 2017/746 ([4]) of the European Parliament and of the Council. Those transitional provisions provided that medical devices with a valid certificate issued under Council Directives 90/385/EEC ([5]) and 93/42/EEC ([6]) or Directive 98/79/EC of the European Parliament and the Council ([7]) could be placed on the market until 26 May 2024 and continue to be made available on the market or put into service until 26 May 2025.

(3) For certain in vitro diagnostic medical devices, Regulation (EU) 2022/112 of the European Parliament and the Council ([8]) has extended the transitional period laid down in Regulation (EU) 2017/746 until 26 May 2025 for high risk in vitro diagnostics, until 26 May 2026 for medium risk in vitro diagnostics, until 26 May 2027 for lower risk in vitro diagnostics, and until 26 May 2028 for certain provisions concerning devices manufactured and used in health institutions.

([1]) OJ L 396, 30.12.2006, p. 1.
([2]) Commission Regulation (EU) 2021/2045 of 23 November 2021 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 418, 24.11.2021, p. 6).
([3]) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).
([4]) Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).
([5]) Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).
([6]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).
([7]) Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).
([8]) Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and the deferred application of conditions for in-house devices (OJ L 9, 28.1.2022, p.3).

(4) In addition, Regulation (EU) 2023/607 of the European Parliament and of the Council [9] has extended the transitional period laid down in Regulation (EU) 2017/745 applicable to certain medical devices until 31 December 2027 for devices with a higher risk and until 31 December 2028 for medium and lower risk devices, subject to certain conditions. It has also extended the validity of the certificates issued under Directives 90/385/EEC and 93/42/EEC, if the legal conditions are fulfilled. Those measures are intended to ensure that notified bodies can complete the conformity assessment and issue the certificates in accordance with the requirements under Regulation (EU) 2017/745, to ensure a high level of protection of public health and patient safety and to avoid shortages of medical devices needed for health services and patients, without lowering current quality and safety requirements.

(5) Pursuant to Article 55 of Regulation (EC) No 1907/2006, DEHP is to be progressively replaced by suitable alternatives. In accordance with the transitional provisions laid down in Regulations (EU) 2017/745 and (EU) 2017/746, if there is a significant change in the design or intended purpose of the device, which could be a result of DEHP replacement by an alternative, the application of the transitional period, including the extended validity of the certificates, is to cease. That could mean that a medical device, which is subject to a significant change due to the replacement of DEHP with an alternative substance, could only be placed on the market when a new certificate is issued by a notified body in accordance with Regulations (EU) 2017/745 or (EU) 2017/746. It is therefore of major interest for public health and patient safety in the Union to allow production of medical devices containing DEHP until the conformity assessment procedure for DEHP-free medical devices has been finalised and notified bodies have issued the relevant certificates within the new transitional periods provided for in Regulations (EU) 2017/745 and (EU) 2017/746.

(6) Delays caused by the limited capacity of notified bodies should not penalise companies in the process of substituting DEHP in medical devices. The alignment of the latest application date and sunset date in Regulation (EC) No 1907/2006 for uses of DEHP in medical devices is needed to allow companies first to meet the requirements of the regulatory framework for medical devices, prior to deciding on the need for an application for authorisation, as that would only be needed in case the DEHP-free alternative medical device is not ready.

(7) To remain consistent with the intention of the legislator when authorisation requirements became applicable to the uses of DEHP in medical devices, it is appropriate, as an exceptional measure, to postpone the latest application date and the sunset date set for such uses, and align them, once again with the transitional periods in Regulations (EU) 2017/745 and (EU) 2017/746.

(8) Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(9) In order to provide clarity to companies that, due to the postponement of the latest application date and the sunset date, may no longer be required to prepare an application for an authorisation for uses of DEHP in medical devices by the approaching deadline of 27 November 2023, it is appropriate to ensure the entry into force as soon as possible. This Regulation should enter into force as a matter of urgency on the day following its publication in the *Official Journal of the European Union*.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XIV to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

[9] Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices (OJ L 80, 20.3.2023, p. 24).

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 November 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the table in Annex XIV to Regulation (EC) No 1907/2006, entry nr 4 concerning the substance bis(2-ethylhexyl) phthalate (DEHP) is amended as follows:

(1) in column 4 'Latest application date', point (c) is replaced by the following:

'(c) by way of derogation from point (a):

1 January 2029 for uses in medical devices within the scope of Regulations (EU) 2017/745 and (EU) 2017/746.';

(2) in column 5 'Sunset date', point (c) is replaced by the following:

'(c) by way of derogation from point (a):

1 July 2030 for uses in medical devices within the scope of Regulations (EU) 2017/745 and (EU) 2017/746.'.