DIRECTIVES

COMMISSION DELEGATED DIRECTIVE (EU) 2021/884

of 8 March 2021

amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards the validity period of an exemption for the use of mercury in electric rotating connectors used in intravascular ultrasound imaging systems

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ([1]), and in particular Article 5(1)(a) thereof,

Whereas:

(1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That restriction does not apply to certain exempted applications which are specific to medical devices and monitoring and control instruments and are listed in Annex IV to that Directive.

(2) The categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.

(3) Mercury is a restricted substance listed in Annex II to Directive 2011/65/EU.

(4) By Delegated Directive (EU) 2015/574 ([2]), the Commission granted an exemption for the use of mercury in intravascular ultrasound imaging systems ('the exemption'), by including that application in Annex IV to Directive 2011/65/EU. The exemption was to expire on 30 June 2019, in accordance with the third subparagraph of Article 5(2) of that Directive.

(5) The Commission received an application for renewal of the exemption ('the renewal request') on 6 October 2017 that is within the time limit laid down in Article 5(5) of Directive 2011/65/EU. In accordance with that provision, the exemption remains valid until a decision on the renewal request has been adopted.

(6) The evaluation of the renewal request included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU. The comments received during these consultations were made publicly available on a dedicated website.

(7) Mercury is used in electric rotating connectors of intravascular ultrasound imaging systems which provide the electrical conduction path between the rotating transducer and stationary electronic equipment. The use of mercury enables, inter alia, higher frequency operation which allows obtaining higher resolution imaging beneficial for patients.

(8) Due to the lack of alternatives, a substitution or elimination of mercury in the applications concerned is currently scientifically and technically impracticable. The exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]) and thus does not weaken the environmental and health protection afforded by it.

([1]) OJ L 174, 1.7.2011, p. 88.

([2]) Commission Delegated Directive (EU) 2015/574 of 30 January 2015 amending, for the purposes of adapting to technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for mercury in intravascular ultrasound imaging systems (OJ L 94, 10.4.2015, p. 6).

([3]) 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) and 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 (OJ L 396, 30.12.2006, p. 1).

(9) It is, therefore, appropriate to grant the renewal of the exemption.

(10) The exemption should be renewed for the maximum duration of 7 years until 30 June 2026, in accordance with Article 4(3) and the third subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

(11) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex IV to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 30 June 2022 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 July 2022.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In entry 42 of Annex IV to Directive 2011/65/EU, the second paragraph is replaced by the following:

'Expires on 30 June 2026.'