Commission Delegated Directive (EU) 2020/366 of 17 December 2019 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 an exemption for lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases (Text with EEA relevance)

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(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) Article 4(1) of 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) Lead is a restricted substance listed in Annex II to Directive 2011/65/EU.

(4) By Delegated Directive (EU) 2015/573[(2)], the Commission granted an exemption for the use of lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases ('the exemption'), by including that application in Annex IV to Directive 2011/65/EU. The exemption was to expire on 31 December 2018, 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 25 May 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.

(7) Lead in the PVC sensor card of concerned in vitro medical devices (blood analysers) enhances sensor performance which is necessary for the optimum performance of the device in terms of analytical reliability claimed in product publications and thus for fulfilment of requirements laid down in Directive 98/79/EC of the European Parliament and of the Council[(3)].

(8) While lead-free technologies are available on the market for certain analysers of other manufacturers, reliability testing of substitutes for the specific application subject to the current renewal request requires additional time.

(9) Discontinuation of the exemption is expected to avoid a total of 157 kg of lead being placed on the Union market. At the same time, however, it will result in the need to replace the entire diagnostic device, and consequently, is expected to lead to a premature generation of 112 000 kg of waste electrical and electronic equipment. Furthermore, significant socioeconomic impacts on health providers using the devices concerned would be incurred.

(10) The exemption does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 of the European Parliament and of the Council.[(4)] In light of the restriction process on lead in PVC provided for in Regulation (EC) No 1907/2006, the exemption should be granted for a short validity period of 2 years to ensure full alignment with that Regulation once the relevant restriction process is concluded.

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

(12) The exemption concerns category 8 of electrical and electronic equipment to which Directive 2011/65/EU applies and it should be renewed for the duration of 2 years starting from 5 March 2020, in accordance with 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.

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

HAS ADOPTED THIS DIRECTIVE:

(**1**) OJ L 174, 1.7.2011, p. 88.

(**2**) Commission Delegated Directive (EU) 2015/573 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 lead in polyvinyl chloride sensors in in-vitro diagnostic medical devices (OJ L 94, 10.4.2015, p. 4).

(**3**) Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

(**4**) 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 (OJ L 396, 30.12.2006, p. 1).