II

(Non-legislative acts)

DIRECTIVES

COMMISSION DELEGATED DIRECTIVE (EU) 2023/1526

of 16 May 2023

amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in *in vitro* diagnostic medical devices

(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), point (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 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) On 1 December 2021, the Commission received an application made in accordance with Article 5(3) of Directive 2011/65/EU for an exemption to be listed in Annex IV to that Directive, for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in *in vitro* diagnostic medical devices ('the requested exemption').

(5) The *in vitro* diagnostic medical devices described in the requested exemption fall under category 8 'medical devices' of Annex I to Directive 2011/65/EU.

(6) A technical and scientific assessment study ([2]) was carried out to evaluate the requested exemption. The evaluation included stakeholder consultations as required by Article 5(7) of Directive 2011/65/EU. The comments received during those consultations were made publicly available on a dedicated website.

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

([2]) Study to assess request for one (-1-) exemption, for lead as a thermal stabilizer 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 creatinine and blood urea nitrogen (BUN) in whole blood, in Annex IV of Directive 2011/65/EU (Pack 26).

(7) The evaluation of the requested exemption concluded that the substitution of lead in specific sensors is not completed yet. The availability of substitutes for such specific devices is not ensured as current lead substitutions are not reliable for all parameters (for example, creatinine and blood urea nitrogen) or have a low accuracy for such parameters. In addition, the evaluation concluded that rejecting the requested exemption would negatively affect the health service.

(8) The requested exemption thus meets at least one of the relevant conditions specified in Article 5(1), point (a), of Directive 2011/65/EU as the reliability of substitutes for the specific application subject to the exemption request is not ensured. Also, the overall negative environmental, health and consumer safety impacts and the socioeconomic impacts of not granting an exemption are being taken into account.

(9) The requested 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 that Regulation.

(10) It is, therefore, appropriate to grant the requested exemption by including the relevant application in Annex IV to Directive 2011/65/EU with respect to electrical and electronic equipment of category 8.

(11) In light of the expected availability of substitution of lead in the application subject to the exemption and of possible future restrictions on lead in polyvinyl chloride in Regulation (EC) No 1907/2006, it is necessary to grant the exemption for a limited validity period until 31 December 2023. That validity period is set in accordance with Article 5(2), first subparagraph, of Directive 2011/65/EU.

(12) 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 XX.XX.XXXX at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate the text of those provisions to the Commission.

They shall apply those provisions from YY.XX.XXXX.

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*.

([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), 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).

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 16 May 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In Annex IV to Directive 2011/65/EU, the following entry 41a is added:

'41a.	Lead as a thermal stabilizer 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 creatinine and blood urea nitrogen in whole blood. Applies to category 8 and expires on 31 December 2023.'.