Commission Delegated Directive 2014/70/EU of 13 March 2014 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 micro-channel plates (MCPs) (Text with EEA relevance)

COMMISSION DELEGATED DIRECTIVE 2014/70/EU

of 13 March 2014

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 micro-channel plates (MCPs)

(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 prohibits the use of lead in electrical and electronic equipment placed on the market.

(2) Micro-channel plates (MCPs) are used for the detection and amplification of ions and electrons in medical devices and monitoring and control instruments. The substitution of lead in MCPs is scientifically and technically impracticable.

(3) The substitution of MCPs as components with alternative detectors is not viable under conditions where extreme miniaturisation, very short response times or very high signal multiplication factors are required. The use of lead in those cases where the performance and specific features of MCPs exceed alternative detectors should therefore be exempted from the prohibition. As currently no lead-free alternatives are in sight, pursuant to Article 5(2) of Directive 2011/65/EU, the validity period of the exemption should be 7 years from the relevant compliance dates for medical devices, monitoring and control instruments, in vitro medical devices and industrial monitoring and control instruments, as laid down in Article 4(3) of Directive 2011/65/EU. In view of the innovation cycles for all medical devices and monitoring and control instruments 7 years is a relatively short transition period which is unlikely to have adverse impacts on innovation.

(4) 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 bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by the last day of the sixth month after entry into force at the latest. They shall forthwith communicate to the Commission the text of those provisions.

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, 13 March 2014.

For the Commission

The President

José Manuel BARROSO

ANNEX

In Annex IV to Directive 2011/65/EU the following point 39 is added:

39. Lead in micro-channel plates (MCPs) used in equipment where at least one of the following properties is present:

(a) a compact size of the detector for electrons or ions, where the space for the detector is limited to a maximum of 3 mm/MCP (detector thickness + space for installation of the MCP), a maximum of 6 mm in total, and an alternative design yielding more space for the detector is scientifically and technically impracticable;

(b) a two-dimensional spatial resolution for detecting electrons or ions, where at least one of the following applies:

(i) a response time shorter than 25 ns;

(ii) a sample detection area larger than 149 mm^2;

(iii) a multiplication factor larger than $1{,}3 \times 10^3$.

(c) a response time shorter than 5 ns for detecting electrons or ions;

(d) a sample detection area larger than 314 mm^2 for detecting electrons or ions;

(e) a multiplication factor larger than $4{,}0 \times 10^7$.

The exemption expires on the following dates:

(a) 21 July 2021 for medical devices and monitoring and control instruments;

(b) 21 July 2023 for in-vitro diagnostic medical devices;

(c) 21 July 2024 for industrial monitoring and control instruments.

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