Commission Directive (EU) 2015/2116 of 23 November 2015 amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards benzisothiazolinone (Text with EEA relevance)

COMMISSION DIRECTIVE (EU) 2015/2116

of 23 November 2015

amending, for the purpose of adopting specific limit values for chemicals used in toys, Appendix C to Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards benzisothiazolinone

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys[(1)], and in particular Article 46(2) thereof,

Whereas:

(1) In order to ensure a high level of protection of children against risks caused by chemical substances in toys, Directive 2009/48/EC establishes certain requirements with regard to chemical substances such as those classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council[(2)], allergenic fragrances and certain elements. In addition, Directive 2009/48/EC empowers the Commission to adopt specific limit values for chemicals used in toys which are intended for children under 36 months and in other toys intended to be placed in the mouth in order to ensure adequate protection in the case of toys involving a high degree of exposure. The adoption of such limit values takes the form of an inclusion in Appendix C to Annex II to Directive 2009/48/EC.

(2) For a number of chemicals, currently applicable limit values are either too high in the light of available scientific evidence or do not exist. Specific limit values should therefore be adopted for them, taking into account the packaging requirements for food as well as the differences between toys and food contact materials.

(3) In order to advise the European Commission in the preparation of legislative proposals and policy initiatives in the area of toy safety, the Commission established the Expert Group on Toys Safety. The mission of its subgroup ‘Chemicals’ is to provide such advice with regard to chemical substances which may be used in toys.

(4) 1,2-Benzisothiazol-3(2H)-one (1,2-benzisothiazolin-3-one, BIT, CAS number 2634-33-5) is used as a preservative in water-based toys[(3)] including hobby paints and finger paints[(4)], as shown by the results of a market survey involving economic operators

Status: *EU Directives are being published on this site to aid cross referencing from UK legislation. After exit day no further amendments will be applied to this version.*

and their trade associations, consumer representatives and allergy centres as well as through internet searches and shop visits[5].

(5) In its deliberations about BIT the subgroup 'Chemicals' took as a basis the related opinion of the Scientific Committee on Consumer Safety (SCCS) noting that BIT is a well-documented contact allergen[6]. Although the opinion considers BIT as only a moderate sensitiser with a lower potency than other marketed cosmetic preservatives[7], it concludes that isothiazolinones are important contact allergens for the consumer in Europe[8]. The use of BIT in cosmetics is not allowed[9].

(6) BIT is classified under Regulation (EC) No 1272/2008 as a skin sensitiser. Directive 2009/48/EC has currently no specific limit value for BIT, nor a general limit value for sensitisers.

(7) In the light of the above, the subgroup 'Chemicals' considered that BIT should not be used in toys. In accordance with European Standard EN 71-9:2005+A1:2007, substances not to be used should be limited to the limit of quantification (LOQ) of an appropriate test method[10]. Accordingly the subgroup 'Chemicals' recommended, at its meeting of 26 March 2014, that BIT in toys be limited to its LOQ, namely to a maximum concentration of 5 mg/kg. The use of BIT is not regulated for food contact materials.

(8) In view of the above, Appendix C of Annex II to Directive 2009/48/EC should be amended to include a content limit for BIT in toys.

(9) The content limit laid down by this Directive should be reviewed at the latest five years after the date on which Member States are to apply this Directive.

(10) The measures provided for in this Directive are in accordance with the opinion of the Committee established in Article 47 of Directive 2009/48/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Appendix C of Annex II to Directive 2009/48/EC, the following entry shall be added:

Substance	CAS No	Limit value
'1,2-benzisothiazol-3(2H)-one	2634-33-5	5 mg/kg (content limit) in aqueous toy materials, in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005'

Article 2

1 Member States shall adopt and publish, by 24 May 2017 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 24 May 2017.