Commission Directive (EU) 2015/2117 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 chloromethylisothiazolinone and methylisothiazolinone, both individually and in a ratio of 3:1 (Text with EEA relevance)

COMMISSION DIRECTIVE (EU) 2015/2117

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 chloromethylisothiazolinone and methylisothiazolinone, both individually and in a ratio of 3:1

(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) 5-Chloro-2-methylisothiazolin-3(2H)-one (CMI) and 2-methylisothiazolin-3(2H)-one (MI) in a ratio of 3:1 (CAS number 55965-84-9)[(3)] as well as its individual components CMI (CAS number 26172-55-4) and MI (CAS number 2682-20-4) are used as

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.*

preservatives in water-based toys[4] including hobby paints, finger paints, window/glass paints, glues and soap bubbles[5].

(5) In its deliberations about CMI and MI in a ratio of 3:1 as well as the individual components CMI and MI the subgroup 'Chemicals' took as a basis the related opinion of the Scientific Committee on Health and Environmental Risks (SCHER) noting that neither CMI and MI in a ratio of 3:1 nor the individual components CMI or MI are recommended for use in toys, due to contact allergic reactions observed with these substances in cosmetics[6]. The subgroup 'Chemicals' also took account of the related SCCS opinion which considers CMI and MI in a ratio of 3:1 an extreme contact allergen in humans as demonstrated by available data[7].

(6) CMI and MI in a ratio of 3:1 is classified under Regulation (EC) No 1272/2008 as a skin sensitiser; CMI and MI individually are not classified under the Regulation. Directive 2009/48/EC has currently no specific limit value for CMI/MI 3:1, nor for CMI or MI individually, nor a general limit value for sensitisers.

(7) In the light of the above the subgroup 'Chemicals' recommended at its meeting of 15 February 2012 that CMI and MI in a ratio of 3:1 should not be used in toys.

(8) According to the German Federal Institute for Risk Assessment (BfR, Bundesinstitut für Risikobewertung)[8] limit values for CMI and MI, which are strongly allergenic, should be set at a concentration considered protective for individuals who are already sensitised. This is the strictest way to limit allergens, since already sensitised individuals suffer from an allergy outbreak at even lowest allergen concentrations. According to the abovementioned SCCS opinion such concentration is below 2 mg/kg[9].

(9) According to the BfR, market surveillance is able to routinely quantify CMI down to 0,75 mg/kg and MI down to 0,25 mg/kg[10] (limits of quantification, LOQs).

(10) In the light of the above, the Expert Group on Toys Safety recommended at its meeting of 23 May 2014 to also limit the uses of CMI and MI individually to their LOQs.

(11) While there is a specific migration limit for MI individually as an additive for use in certain food contact materials, the basic assumptions for deriving that migration limit are different from those for the content limit for MI in toys. The uses of CMI and MI in a ratio of 3:1 and of CMI individually are not regulated for food contact materials.

(12) In view of the above, Appendix C of Annex II to Directive 2009/48/EC should be amended to include content limits for CMI and MI in a ratio of 3:1, as well as for CMI and MI individually, in toys.

(13) 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 entries shall be added: