

DIRECTIVES

COMMISSION DIRECTIVE 2014/84/EU

of 30 June 2014

amending Appendix A of Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards nickel

(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(3) thereof,

Whereas:

- (1) Directive 2009/48/EC establishes general requirements for substances which are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽²⁾. CMR substances category 2 may not be used in toys, in components of toys or in micro-structurally distinct parts of toys, except if those substances are contained in individual concentrations equal to or smaller than the relevant concentrations established for the classification of mixtures containing them as CMRs, they are inaccessible to children or their use has been permitted. The Commission may permit the use of CMR substances category 2 in toys if the use of the substance has been evaluated by the Scientific Committee and found to be safe, in particular in view of exposure, and the substance is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006 of the European Parliament and of the Council ⁽³⁾. Appendix A of Annex II to Directive 2009/48/EC contains the list of CMR substances and their permitted uses.
- (2) Nickel (CAS No 7440-02-0) is a typical metal. Its main primary uses are in the production of nickel-containing alloys (including stainless steel), in nickel plating, in the production of nickel-containing products such as batteries and welding electrodes, and in the production of chemicals containing nickel. Nickel is also used in toys for its resistance to corrosion and its high electrical conductivity, for example in model railway tracks and for battery contacts.
- (3) Nickel is classified under Regulation (EC) No 1272/2008 as carcinogenic category 2. In the absence of any specific requirements, nickel can be contained in toys in concentrations equal to or smaller than the relevant concentration established for the classification of mixtures containing it as CMRs, namely 1 %.
- (4) Nickel was comprehensively evaluated under Council Regulation (EEC) No 793/93 ⁽⁴⁾. The 2008 European Union Risk Assessment Report (EU RAR) ⁽⁵⁾ concluded that, with regard to the occupational assessment regarding carcinogenicity, there was a need for further studies to evaluate the inhalation carcinogenicity of nickel. The 2009 Addendum ⁽⁶⁾ to the EU RAR, prepared for the purpose of the transitional measures under Regulation (EC) No 1907/2006, concluded that no further measures at Union level were required, as the results from the two-year carcinogenicity study with inhalation exposure of rats to metallic nickel did not point towards a revision of the existing carcinogenicity classification.

⁽¹⁾ OJ L 170, 30.6.2009, p. 1.

⁽²⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽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).

⁽⁴⁾ Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances (OJ L 84, 5.4.1993, p. 1).

⁽⁵⁾ <http://echa.europa.eu/documents/10162/cefda8bc-2952-4c11-885f-342aac769b3>

⁽⁶⁾ http://echa.europa.eu/documents/10162/13630/nickel_denmark_en.pdf

- (5) Appendix A of Annex II to Directive 2009/48/EC already permits the use of nickel in stainless steel in toys, as nickel in stainless steel has proven to be safe regarding its carcinogenic properties.
- (6) To assess the risk to health from the presence of metallic nickel in electric toys (plating, coating and alloys enabling electrical conductivity), the Commission asked the Scientific Committee on Health and Environmental Risks (SCHER) for an opinion. SCHER notes in its opinion 'Assessment of the Health Risks from the Use of Metallic Nickel (CAS No 7440-02-0) in Toys', adopted on 25 September 2012, that a tumour risk due to nickel exposure when handling toys is not present since inhalation of metallic nickel from toys is extremely unlikely. SCHER further concludes that the use of nickel in parts of toys allowing the correct electric function of toys will result in a very low potential for exposure to nickel by oral and dermal intake, due to the restrictions on nickel release applicable to metal-containing parts in toys, the limited accessibility of the metal-containing parts and the small surface area of the nickel-containing parts allowing the correct function of electric toys. Thus, health risks are not expected by SCHER.
- (7) In accordance with point 5(c)(ii) of Part III of Annex II to Directive 2009/48/EC, the use of CMR substances category 2 cannot be permitted if the substance is prohibited for use in consumer articles under Regulation (EC) No 1907/2006. Entry 27 of Annex XVII to that Regulation only restricts the use of nickel in post assemblies which are inserted into pierced ears and other pierced parts of the human body, in articles intended to come into direct and prolonged contact with the skin and in articles intended to come into direct and prolonged contact with the skin where those have a non-nickel coating. The restrictions of entry 27 of Annex XVII to Regulation (EC) No 1907/2006 do not amount to a full ban for use in all consumer articles under that Regulation. This Directive should not affect the application of entry 27 of Annex XVII to Regulation (EC) No 1907/2006 to toys which are articles intended to come into direct and prolonged contact with the skin.
- (8) Directive 2009/48/EC should therefore be amended accordingly.
- (9) 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

Appendix A of Annex II to Directive 2009/48/EC is replaced by the following:

'Appendix A

List of CMR substances and their permitted uses in accordance with points 4, 5 and 6 of Part III

Substance	Classification	Permitted use
Nickel	CMR 2	In toys and toy components made of stainless steel. In toy components which are intended to conduct an electric current.'

Article 2

1. Member States shall adopt and publish, by 1 July 2015 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 1 July 2015.

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, 30 June 2014.

For the Commission
The President
José Manuel BARROSO
