

# Product Safety Compliance Update



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## Introduction

### New restrictions for toy directive

The *Official Journal of the European Union* published Commission Directives [\(EU\) 2015/2115](#), [\(EU\) 2015/2116](#) and [\(EU\) 2015/2117](#) to amend Appendix C to Annex II of Directive 2009/48/EC



## Law & Regulations

### ECHA consults 11 new substances

ECHA opens consultation for [the 7th recommendation of 11 new substances](#) that are proposed for authorisation. The consultation period ends on 18 February 2016.

### CEN publishes new test method

On 19 September 2015, the European Committee for Standardisation (CEN) passed EN 16128:2015 ‘Ophthalmic optics - Reference method for the testing of spectacle frames and sunglasses for nickel release’

### US CPSC Delays Enforcement

The U.S. Consumer Product Safety Commission (CPSC) has postponed the enforcement date for the proposed direct final rule clarifying lead in textiles and component part testing.

### Colombia new regulation

On 18 Sept 2015, the Minister of Commerce, Industry and Tourism published Resolution No. 3023 to amend Article 5.2 of Resolution No. 1950, which was published 17 July 2009

## Product Safety

### EU toy directive adopts five new restrictions

The *Official Journal of the European Union* published Commission Directives [\(EU\) 2015/2115](#), [\(EU\) 2015/2116](#) and [\(EU\) 2015/2117](#) to amend Appendix C to Annex II of Directive 2009/48/EC (safety of toys) to include five new restrictions on 24 November 2015.

Appendix C of Annex II to Directive 2009/48/EC provides for 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. After the inclusion of five restrictions, this Appendix includes nine substances in total as the following:

| Substance  | CAS NO     | Limit Value   | Date of Applicability |
|--|------------|---|-----------------------|
| TCEP   | 115-96-8   | 5 mg/kg (content limit)   | 21/12/2015            |
| T CPP  | 13674-84-5 | 5 mg/kg (content limit)   | 21/12/2015            |
| TDCP   | 13674-87-8 | 5 mg/kg (content limit)   | 21/12/2015            |
| Bisphenol A  | 80-05-7    | 0,1 mg/l (migration limit) in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005  | 21/12/2015            |
| * Formamide  | 75-12-7    | 20 µg/m3 (emission limit) after a maximum of 28 days from commencement of the emission testing of foam toy materials containing more than 200 mg/kg (cut-off limit based on content). | 24/05/2017            |
| *1,2-benzisothiazol-3(2H)-one (BIT)  | 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   | 24/05/2017            |
| *reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H-isothiazol-3-one [EC no. 220-239-6] (3:1) | 55965-84-9 | 1 mg/kg (content limit) in aqueous toy materials  | 24/11/2017            |
| * 5-Chloro-2-methylisothiazolin-3(2H)-one (CMI)  | 26172-55-4 | 0,75 mg/kg (content limit) in aqueous toy materials   | 24/11/2017            |
| * 2-methylisothiazolin-3(2H)-one (MI)  | 2682-20-4  | 0,25 mg/kg (content limit) in aqueous toy materials'  | 24/11/2017            |

Substances marked with “\*” means new restrictions

**CEN publishes new test method for nickel release in spectacle frames and sunglasses**

On 19 September 2015, the European Committee for Standardisation (CEN) passed EN 16128:2015 'Ophthalmic optics - Reference method for the testing of spectacle frames and sunglasses for nickel release' to supersede EN 16128:2011 and CEN/TS 16677:2014. Besides, BS EN 16128:2015 has been published on 30 November 2015.



In May 2012, the European Commission included EN 16128:2011 as a harmonised standard for Entry 27 Nickel release in Annex XVII under REACH. The standard is almost the same as EN 1811:1998+A1:2008 technically. CEN passed the EU amendment for nickel release (EN 1811-2011+A1:2015) and amended EN 16128:2015 correspondingly in June.

Here is a comparison list between the new standard EN 16128:2015 and EN 16128:2011:

|                   | EN 16128:2015  | EN 16128:2011   |
|-------------------|--|---|
| Title             | Ophthalmic optics - Reference method for the testing of spectacle frames and sunglasses for nickel release   | Reference test method for release of nickel from those parts of spectacle frames and sunglasses intended to come into close and prolonged contact with the skin |
| Test Method       | For parts with organic coating: the test is based on Electrochemical Impedance Spectroscopy (EIS)<br>For parts without organic coating: a migration test using artificial sweat solution into a test paper (incubation at defined conditions for 1 week) and subsequent quantitative analytical detection of nickel released into the test paper | Parts to be tested are placed in an artificial sweat solution for 1 week follow by analytical detection   |
| Result Assessment | EIS Test<br>Impedance $\geq 3.0 \times 10^5 \Omega \cdot \text{cm}^2$ is deemed compliant<br>Migration Test $< 0.76 \mu\text{g}/\text{cm}^2/\text{week}$ is deemed compliant   | Test result x 0.1 (adjusted value) follow by comparison with regulatory requirements  |
| Requirement       | Entry 27 Nickel release in Annex XVII under REACH $\leq 0,5 \mu\text{g}/\text{cm}^2/\text{week}$   |   |
| Implementation    | It becomes a national standard by May 2016;<br>All conflicting standards will be repelled by November 2018.  | It became a harmonised standard in May 2015.  |

**ECHA consults on the 7th recommendation of 11 new substances for the Authorisation List**

ECHA opens consultation for [the 7th recommendation of 11 new substances](#) that are proposed for authorisation. The consultation period ends on 18 February 2016.

ECHA considers recommending the following substances for the Authorisation List:

| Substance  | CAS No.  | SVHC-relevant intrinsic properties   | Application  |
|--|--|--|--|
| 1,2- Benzenedicarboxylic acid, dihexyl ester, branched and linear  | 68515-50-4   | Toxic for Reproduction (category 1B)   | Plasticiser in PVC                                   |
| Cyclohexane-1,2- dicarboxylic anhydride [1], cis-cyclohexane-1,2-dicarboxylic anhydride [2], trans-cyclohexane- 1,2-dicarboxylic anhydride [3] [The individual cis-[2] and trans- [3] isomer substances and all possible combinations of the cis- and trans-isomers [1] are covered by this entry]   | 85-42-7<br>13149-00-3<br>14166-21-3                  | Equivalent level of concern having probable serious effects to human health (Article 57 f) | Hardener for epoxy resins                            |
| Dihexyl phthalate  | 84-75-3  | Toxic for Reproduction (category 1B)   | Plasticiser in PVC                                   |
| Hexahydromethylphthalic anhydride [1], Hexahydro-4-methylphthalic anhydride [2], Hexahydro-1-methylphthalic anhydride [3], Hexahydro-3-methylphthalic anhydride [4] [The individual isomers [2], [3] and [4] (including their cis- and trans-stereoisomeric forms) and all possible combinations of the isomers [1] are covered by this entry] | 25550-51-0<br>19438-60-9<br>48122-14-1<br>57110-29-9 | Equivalent level of concern having probable serious effects to human health (Article 57 f) | Hardener for epoxy resins                            |
| Lead monoxide (lead oxide)   | 1317-36-8  | Toxic for Reproduction (category 1A)   | Batteries and rubber production, in adsorbents       |
| Orange lead (lead tetroxide)   | 1314-41-6  | Toxic for Reproduction (category 1A)   | Batteries and rubber production, in adsorbents       |
| Pentalead tetraoxide sulphate  | 12065-90-6   | Toxic for Reproduction (category 1A)   | Batteries and rubber production, in adsorbents       |
| Sodium perborate; perboric acid, sodium salt   | -  | Toxic for Reproduction (category 1B)   | Detergents and bleaching products                    |
| Sodium peroxometaborate  | 7632-04-4  | Toxic for Reproduction (category 1B)   | Detergents and bleaching products                    |
| Tetralead trioxide sulphate  | 12202-17-4   | Toxic for Reproduction (category 1A)   | Batteries and rubber production, in adsorbents       |
| Trixylyl phosphate   | 25155-23-1   | Toxic for Reproduction (category 1B)   | Lubricants, hydraulic fluids and plastics production |

The exemption period for the 11 new substances is 18 months. If these substances are included in the Authorisation List (Annex XIV of REACH), it can be placed on the market or used after a given date only if an authorisation is granted for a specific use. Companies can apply for authorisation.



Testing



Inspection



Audit

## Colombia – Amendment to Labeling of Garments and Textile Products

On 18 Sept 2015, the Minister of Commerce, Industry and Tourism published Resolution No. 3023 to amend Article 5.2 of Resolution No. 1950, which was published 17 July 2009, on labeling of garments. This resolution will enter into force 18 Dec 2015. The major amendments are highlighted as follows:

Eliminate the labeling requirement to provide the Superintendence of Industry and Commerce (SIC) on the label, requiring that the manufacturer's or importer's tax identification number (NIT) shall be provided instead.

Clarify that the country of origin, the name of the manufacturer and/or importer, composition of the products and care instructions will be required on a permanent label. Any other information such as size of the product shall be included on a non-permanent label.

Clarify that sectional disclosure

is required if the product's components are made of different fiber content.

The labeling requirements for garments and textile products are summarized as below following the amendments:

General Requirements:

Label and label lettering shall be durable.

The information shall be indicated on the labels with clear characters, visible and easy to read for the consumer.

When the products are sold in pairs with the same fiber content and design, such as socks or gloves, only one item of the pair needs to be labeled.

If the products consists of two or more pieces or parts, each piece or part need to be labeled.

For products where a label would harm the appearance due to the nature of the product and marketed in closed packaging that does not allow consumers to see the content, a sticker containing the required information must be attached on the packaging. Examples are pantyhose, socks, tights, wristband, ties, reversible disposable (two sided) garments.

The information shall be in Spanish, notwithstanding that the information can also presented additionally in another language.

The information presented on the label shall be truthful and not misleading or deceptive to the consumer.

The Label Shall Contain the Following Minimum Information:

Country of origin.

Name of the manufacturer and/or importer, including NIT (importer's tax identification number).

Care instructions.

The composition of product (if a product has separate sections with different fiber compositions, the content of each section should be identified separately on the label).

Size and dimension, if applicable.

If the product has lining, the content of the lining shall be disclosed as a sectional disclosure.

When the product is imperfect, it shall bear a label, or other information to advise the consumer.

Remarks: The country of origin, the name of the manufacturer and/or importer, composition of the product and care instructions will be required on a permanent label. Any other information such as size of the product shall be included on a non-permanent label.

## US CPSC Delays Enforcement of Proposed Direct Final Rule to Clarify Component Part Testing and Lead in Textiles

The U.S. Consumer Product Safety Commission (CPSC) has postponed the enforcement date for the proposed direct final rule clarifying lead in textiles and component part testing. The amendment will now be enforced starting 13 January 2016.

In October 2015, we informed you that the CPSC published an amendment in the Federal Register clarifying two existing rules:

Which textile products have been determined not to exceed the 100 ppm lead content limits (16 CFR 1500.91(d)(7)) and

When component part testing can be used (16 CFR part 1109)

This proposed direct final rule would have been effective starting 14 December 2015 if adverse comments were not received by 13 November 2015.

On 19 November 2015, the CPSC published an amendment at 80 Federal Register 72342 extending the comment period for this proposed direct final rule from 13 November 2015 to 14 December 2015. The potential effective date is now delayed until 13 January 2016. If significant adverse comments are received in the comment period, the CPSC will withdraw the direct final rule by publishing a notification in the Federal Register before the effective date.

Highlights of the amendment for the proposed direct final rule are summarized in Table 1.

| Authority | Citation             | Clarification Parameter  | Proposed Effective Date | Amended Proposed Effective Date   |
|-----------|----------------------|--|-------------------------|---|
| CPSC      | 16 CFR 1500.91(d)(7) | Which textile products have been determined not to exceed 100 ppm lead | 14 December 2015        | 13 January 2016<br>(unless a significant adverse comment is received by 14 December 2015) |
|           | 16 CFR 1109          | When component part testing can be used                                | 14 December 2015        | 13 January 2016<br>(unless a significant adverse comment is received by 14 December 2015) |