

Product Safety Compliance Update



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Introduction

Japan AZO Restriction updates

In April 2015, the Japan Ministry of Health, Labour and Welfare (MHLW) published Governmental Ordinance No. 175 revising the current “Act on Control of Household Products Containing Harmful Substances” (Act No. 112 of 1973) to include Azo compounds

New Law Labeling requirements

The International Association of Bedding and Furniture Law Officials (IABFLO) recently updated its guidance document outlining the law labeling information requirements set forth by various States for filled bedding and furniture products sold in the U.S.



Laws & Regulations

7 Proposals of new SVHCs

Recently, ECHA launches a public consultation on [seven proposals](#) to identify new SVHCs.

The first substance, 1,3-propanesultone (EC No. 214-317-9) is used in electrolyte fluid of lithium ion batteries.

EU ready to set new limit for toys

Toy manufacturers exporting their goods to the EU should be alerted to new toy safety measures that are expected to enter into force towards the end of 2015, although there will be a period of transition thereafter, so as to help industry adjust to the measures.

New amendment of EN1811:2011

An amendment to EN 1811:2011 has been published. This amendment clarifies the compliance/non-compliance criteria for release of nickel from jewellery and other metal components, which may be in direct and prolonged contact with the skin.

EU will ban use of NPE

On 22 July 2015, the Council of the EU published, on its website, a European Commission draft text restricting nonylphenol ethoxylates (NPE) in textile articles that are placed on the EU market.

Product Safety

ECHA launches a public consultation on seven proposals to identify new SVHCs

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The first substance, 1,3-propanesultone (EC No. 214-317-9) is used in electrolyte fluid of lithium ion batteries.

The second and third substances, 2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327) (EC No. 223-383-8) and 2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350) (EC No. 253-037-1) are UV protection agents in coatings, plastics, rubber and cosmetics.

The fourth, Dicyclohexyl phthalate, is plastisol and in PVC, rubber and plastic articles, and as a phlegmatizer and dispersing agent for formulations of organic peroxides.

The fifth one is Hexamethylene diacrylate (EC No. 235-92-9), which is manufacturing formulations of coatings and inks and as a cross linking agent in polymerisation processes in the production of resins, rubbers, and polymers.

The sixth, Nitrobenzene (EC No. 202-716-0), is the production of chemicals and as processing aid.

The last substance is Perfluorononan-1-oic acid (EC No. 206-801-3) and its sodium and ammonium salts, primarily used as a processing aid for the fluoropolymer manufacture, most notably for polyvinylidene fluoride, also used as lubricating oil additive, surfactant for fire extinguishers, cleaning agent, textile antifouling finishing agent, polish surfactant, waterproofing agent and in liquid crystal display panels.

The deadline for commenting is 15 October 2015.

Amendment to Nickel Release Standard Published - EN 1811:2011 + A1:2015

An amendment to EN 1811:2011 has been published. This amendment clarifies the compliance/non-compliance criteria for release of nickel from jewellery and other metal components, which may be in direct and prolonged contact with the skin. The new criteria will make it easier to assess product for compliance with the REACH Annex XVII requirements for nickel release.

The standard EN 1811:2011 introduced a 'measurement of uncertainty' into the test procedure for metal items in contact with the skin. It specified three categories of results; "compliant, non compliant and no decision". The 'no decision' for results which were situated around the 0.50 µg/cm²/week compliance requirement of the Directive created a level of ambiguity for results in the 'no decision' range. A similar problem was faced for post assemblies around the 0.28 µg/cm²/week.

The new amendment simplifies the requirement for compliance by removing the 'No decision' category and provides a 'PASS' compliance level of 0.88 µg/cm²/week for articles intended to come into prolonged and direct contact with the skin, and 0.35 µg/cm²/week for post assemblies.

The Table below summarises the change resulting from this amendment to the standard.

Result(µg/cm ² /week)	Post assemblies and body piercings			Other Components in direct and prolonged contact with the skin		
	≤0.11	0.11-0.35	≥0.35	≤0.28	0.28 - 0.88	≥0.88
Old Criteria	Pass	No Decision	Fail	Pass	No Decision	Fail
New Criteria	Pass		Fail	Pass		Fail



EU Law to be Adopted Soon, Banning from All Washable Textile Products a Substance Harmful to the Aquatic Environment

On 22 July 2015, the Council of the EU published, on its website, a European Commission draft text restricting nonylphenol ethoxylates (NPE) in textile articles that are placed on the EU market. This soon-to-be-adopted future law will apply to all Hong Kong exporters of clothing and other textile accessories marketed in the EU.

Sweden had initially submitted its proposal to restrict both NPE and nonylphenol (NP), at a Europe-wide level, in September 2013. Since then, NP has been removed from the scope of the future restriction, as it is not used intentionally in textile processing.

Hong Kong traders may know that since 2005, the use of NPE (and NP) as substances or in mixtures, in concentrations of 0.1% or more, is restricted within the EU in the processing of textiles and leather. However, a majority of textiles purchased within the EU are imported from manufacturers and suppliers outside the EU, including from Hong Kong and mainland China.

Sweden claims that suppliers worldwide still use such substances today, for example as a detergent or as an emulsifying agent, in the manufacturing of their textiles. After being imported into the EU, the textile articles are washed and substance residues are thereby released into waste water, eventually ending up in the aquatic environment.

An EU-wide restriction of NPE in the case of textile articles is therefore felt to be justified, as the environmental risks have to be dealt with uniformly, in respect of all EU Member States.

The law, once adopted and published, will therefore introduce the following provisions:

NPE shall not be allowed after a cut-off date (currently scheduled to be 60 months from entry into force of the future law). This restriction will be imposed on textile articles which can reasonably be expected to be washed in water during their normal lifecycle, in concentrations equal to or greater than 0.01% by weight of that textile article or of each part of the textile article.

Hong Kong traders may be relieved to learn that the above restriction shall not apply to the placing on the market of second-hand textile articles, or to new textile articles which are produced, without the use of NPE, exclusively from recycled textiles.

As for the definition of “textile article”, this shall mean “any unfinished, semi-finished or finished product which is composed of at least 80% textile fibres by weight, or any other product that contains a part which is composed of at least 80% textile fibres by weight, including products such as clothing, accessories, interior textiles, fibres, yarn, fabrics and knitted panels”.

As the already-existing restriction on the use of NE and NPE as substances or in mixtures, during textile and leather processing within the EU, is set out in Entry 46 of Annex XVII of the REACH Regulation, the new restriction will be introduced as that Annex’s Entry 46a.

Given that the expected implementation of the restriction is to occur only after a grace period of 60 months from the law’s entry into force, Hong Kong’s clothing and accessories exporters should have sufficient time in which to take the appropriate compliance measures.

Regarding the law’s adoption process, if the Council or the European Parliament do not oppose the future restriction (using a process called “Regulatory committee with scrutiny”), the Commission will adopt the Regulation, and add the restriction to the REACH Regulation’s Annex XVII.



EU Ready to Limit the use of Preservatives and Solvents in Toys

Toy manufacturers exporting their goods to the EU should be alerted to new toy safety measures that are expected to enter into force towards the end of 2015, although there will be a period of transition thereafter, so as to help industry adjust to the measures.

Recently, the Safety of Toys Committee agreed to an amendment of the Toy Safety Directive (Directive 2009/48/EC), implementing restrictions on the use of certain chemicals in toys which are intended for children under 36 months, and in other toys intended to be placed in the mouth.

The measures concern the incorporation of new limit values, for the use of certain chemicals in toys, within the Toy Safety Directive. As is well-known by now among the toy industry, this Directive establishes requirements with regard to potentially harmful chemical substances (among other matters). It empowers the European Commission to adopt specific limit values for the abovementioned categories of toys in order to ensure adequate protection against a high degree of exposure to harmful chemical substances.

The chemicals concerned by the future measures are:

- (1) Chloromethylisothiazolinone (CMI),
- (2) Methylisothiazolinone (MI),
- (3) CMI and MI combined in a ratio of 3:1,
- (4) Benzisothiazolinone (BIT), and
- (5) Formamide.

CMI and MI combined in a ratio of 3:1, as well as CMI and MI individually, are mainly used as preservatives in water-based toys such as hobby paints, finger paints, window/glass paints, glues and soap bubbles. They are considered to be "extreme contact allergens in humans" and allergic

reactions have been observed due to the inclusion of these substances in cosmetics. These allergic reactions have led to notable controversies recently, especially in Denmark.

CMI and MI in a ratio of 3:1 will, according to the relevant draft Directive, have a limit value of 1 mg/kg (content limit) in aqueous toy materials. Furthermore, CMI individually will have a limit value of 0.75 mg/kg (content limit) in aqueous toy materials, while MI individually will have a limit value of 0.25 mg/kg (content limit) in aqueous toy materials.

The transitional period for the Member States to implement this future Directive is 24 months from the publication of the Directive in the Official Journal.

BIT is also used as a preservative in water-based toys including hobby paints and finger paints. It is considered to be a major contact allergen for consumers. In cosmetics, the use of BIT is already prohibited.

The limit value for the use of BIT will be 5 mg/kg in aqueous toy materials, in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.

Formamide is used in the plastics and polymers industry as a solvent, plasticiser or as a substance associated with a blowing agent used in the production of foam. It is used in a range of foam toys, such as puzzle mats. It can be inhaled by children, as it can be emitted into the air.

The limit value for Formamide will be 20 $\mu\text{g}/\text{m}^3$ (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 limit). This is equal to the limit value for Formamide that is already applicable in France.

The transitional period for the Member States to implement the future Directives concerning BIT and Formamide is scheduled to be 18 months from the date of their publication in the Official Journal.

Hong Kong's toy exporters should be alerted to the fact that the EU's Safety of Toys Committee might restrict the use of Phenol in the near future, as the vote as regards Phenol was postponed from the Committee meeting held in June, to a future meeting of the Committee. This is because further discussion in the subgroup "Chemicals" was felt to be necessary. The Commission's proposed restriction in relation to Phenol is as follows: 5 mg/l (migration limit) in polymeric materials, 10 mg/kg (content limit) as a preservative, Compliance with both limits to be determined in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.

All the amendments are to be introduced in appendix C of the Toy Safety Directive's Annex II. This appendix sets out specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth. The amendments will enter into force twenty days after the publication of the respective Directives in the EU's Official Journal. This publication is likely to take place shortly after a three-month term comes to an end (expected to be this September), in which the Council of Ministers and the Parliament are expected to scrutinise the future measures.

Please click on the following for the latest versions of the respective draft Directives:

- 1) [Draft Directive restricting CMI and MI](#)
- 2) [Draft Directive restricting BIT](#)
- 3) [Draft Directive restricting Formamide](#)
- 4) [Draft Directive restricting Phenol](#)

Update - Japan Azo Restriction in Textile Products

In April 2015, the Japan Ministry of Health, Labour and Welfare (MHLW) published Governmental Ordinance No. 175 revising the current “Act on Control of Household Products Containing Harmful Substances” (Act No. 112 of 1973) to include azo compounds, classified as hazardous substances and banned from use in household products in amounts exceeding the established limit. The proposed effective date is 1st April, 2016.

In July 2015, the Ministerial Ordinance (No. 124) with detailed technical requirements also has been announced by the MHLW. The Act designates azo compounds as hazardous substances, and restricts the presence of any of the twenty-four (24) specified aromatic amines to less than 30 ug/g (mg/kg). The testing is to be performed using Gas Chromatograph Mass Spectrometer (GC-MS).

In accordance with the provision, the scope of household products that are regulated in the Ordinance include:

Textile products with azo dyes: diapers, diaper covers, underwear, sleepwear, gloves, socks, intermediate garments, outer garments, caps, hats, bedding, floor coverings, tablecloths, collar ornaments, handkerchiefs, towels, bath mats and related products

Leather and/or fur products with azo dyes: underwear, gloves, intermediate garments, outer garments, caps, hats and floor coverings

Recommended Test Method:

JIS L 1940-1:2014 (ISO 24362-1:2014) – Textiles – Methods for determination of certain aromatic amines derived from azo colorants – Part 1: Detection of the use of certain azo colorants accessible with and without extracting the fibres

JIS L 1940-3:2014 (ISO 24362-3:2014) – Textiles – Methods for determination of certain aromatic amines derived from azo colorants – Part 3: Detection of the use of certain azo colorants, which may release 4-aminoazobenzene.

Maine: designation of Formaldehyde as a Priority Chemical and Regulation of Formaldehyde in Children's Products

A new rule has recently been adopted by the Maine's Department which require manufacturers to report the use of formaldehyde (rule chapter 885), when intentionally added to certain categories of children's products which are sold in the State of Maine.

Reports (forms to be available soon) for the use of the formaldehyde must be submitted to Maine DEP by **December 18, 2015**.

<http://www.maine.gov/dep/safechem/rules.html>

U.S. – Law Labeling Requirements Updates for Filled Bedding and Furniture Products IABFLO Revises Law Label Guidance

The International Association of Bedding and Furniture Law Officials (IABFLO) recently updated its guidance document outlining the law labeling information requirements set forth by various States for filled bedding and furniture products sold in the U.S.

Key updates are as follows:

Highlight that the lines separating the text must extend to the edges of the law label.

Specify that the 3-inch length requirement of a law label starts at the beginning of the word “UNDER” and ends at the country of origin on the bottom of the law label.

Provide the formatting requirements regarding the font height, abbreviations, bold print and capital letters in several sections. Example ALL NEW MATERIAL must be in capital letters and that entire section must be in bold print; Similarly REG. NO., MADE BY or MADE FOR also must be in capital letters, bold print and 1/8” in height. There is no such formatting requirement for certification section that begins with “Certification is made...” and the “other information section” except the country of origin in the “other information section” must be 1/8” font, all in capital letters and in bold type.

Provide law label example for upholstered residential furniture that incorporates the State of California SB 1019 requirements for presence or absence of flame retardants.

Remind:

Texas Passes the SB202 Rescinding its Bedding Law Requirements

Texas passed Senate Bill 202 that effective September 1, 2015, will no longer require bedding operators (manufacturers, distributors, importers, etc.) to hold a license with the Department of State Health Services (DSHS). Bedding licenses issued by DSHS will no longer be valid or renewed on or after August 31, 2015. It is anticipated that in the fall of 2015, the DSHS will begin the process of formally repealing the existing Bedding Rules.

If manufacturer is using the Texas's Uniform Registry Number (URN) as their Registration Number (REG. NO.) on law labels they will need to obtain new URN from another State.

