

# Product Safety Compliance Update



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## Introduction

### ECHA will update guidance

On 10 September 2015, European Court of Justice (ECJ) made [a ruling](#) regarding [REACH Regulation](#) that each single article rather than an assembled article is the reference for the identification of substances of very high concern (SVHC).



## Law & Regulations

### CPSC's new requirements

On 14 October 2015, U.S. Consumer Product Safety Commission ("CPSC") published a final rule that when component part testing can be used and which textile products have been determined not to exceed the allowable lead content limits on the Federal Register.

### Canada issues notification

On 17 October 2015, Canadian government issued notification that [Ministry of Environment published four ministerial conditions](#), which determined the manufacture and import conditions for four chemicals, involving industries of toys, childcare products, textiles and cosmetics.

### EU proposes restrictions on CMRs

The European Commission [asks for public comments](#) on substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1A and 1B that may present in textiles and clothing under REACH Regulation.

### Vietnam released new regulations

The Vietnam Ministry of Industry and Trade (Department of Science and Technology) recently released a new draft Circular Regulation that specifies requirements on the permitted limit of formaldehyde and Azo dyes contents in textile products

## Product Safety

### Vietnam Released New Formaldehyde and Azo Dyes Requirements in Textile Products

The Vietnam Ministry of Industry and Trade (Department of Science and Technology) recently released a new draft Circular Regulation that specifies requirements on the permitted limit of formaldehyde and Azo dyes contents in textile products that are manufactured, imported and traded in the Vietnam market. The new draft Circular will supersede Circular No. 32/2009/TT-BCT dated 5th November 2009 and becomes effective in February 2016.

The Circular No. 32/2009/TT-BCT (2009) temporarily gave the regulated acceptable limits for the content of formaldehyde and content of aromatic amines which can be released from Azo dyes in reduction conditions in textile and apparel products. The new draft Circular states the same permitted limits of formaldehyde and Azo dyes content in textile products, but further specifies requirements on sampling methods, refers to updated international test method standards and provides relevant quality management requirements. Textile products that fall within the scope of the restriction are listed in Annex 1 of the new draft Circular. The restrictions do not apply to untreated yarn, untreated fabric, fabrics imported for processing export products, textile products in transit or stored in custom's warehouses, textile products temporarily imported for re-export and types of products made from textile materials used in

industrial production. All textile products that are imported, distributed and marketed in Vietnam are required to provide a certificate issued by an accredited testing laboratory to ensure conformity in accordance to the regulation.

**Table1** : Test methods and requirements

Test Item	Test Method	Requirement
Formaldehyde	TCVN 7421-1:2013 / ISO 14184-1:2011	Textile products for children under 36 months of age: $\leq 30\text{mg/kg}$
		Textile products in direct contact with skin: $\leq 75\text{mg/kg}$
		Textile products without direct contact with skin: $\leq 300\text{mg/kg}$
Azo Dyes(same 22 items as in REACH)	EN 14362-1:2012 / EN 14362-3:2012 Or ISO 24362-1:2014 / ISO 24362-3:2014	$\leq 30\text{mg/kg}$ (22 items)

### EU proposes restrictions on CMRs in textiles under REACH Annex XVII

The European Commission [asks for public comments](#) on substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), categories 1A and 1B that may present in textiles and clothing under REACH Regulation. The list will be added as a schedule to Annex XVII under regular updates. The public consultation period ends on 22 January 2016.

The list contains 291 chemicals that may present in textiles and clothing, including phthalates, flame retardants and pigments, covering clothing, swimming suits, accessories & footwear, curtains, carpets, towels and bed sheets.

Article 68(2) of REACH provides a simplified procedure, the restriction list skips steps such as the preparation of an Annex XV Dossier to initiate the restriction process, public consultation, opinions by RAC and SEAC and the consultation of Forum so as to confirm the substances in the list as soon as possible.

In addition, the Commission will formulate restrictions for other consumer products. Textiles are selected as the first test case due to their direct contact with consumers during a long period increasing the likelihood for consumers to expose to hazardous substances.



### ECHA will update guidance on substances in articles

On 10 September 2015, European Court of Justice (ECJ) made a [ruling](#) regarding [REACH Regulation](#) that each single article rather than an assembled article is the reference for the identification of substances of very high concern (SVHC). [ECHA will update guidance on substances in articles.](#)

In the judgment, ECJ made notes to the definition of “article” as the following: “article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”. Consequently, it lacks theoretic basis for the point that “It ceases to be an article when it is assembled or joined with other objects in order to form with them a complex product”. Under such circumstance, ECJ ruled that it was not reasonable to determine SVHC content by taking the final imported products as the reference.

There are two conclusions in the ruling:

1. Article 7(2) of REACH Regulation, it is for the producer to determine whether a substance of very high concern is present in a concentration above 0.1% weight by weight of any article it produces and, for the importer of a product made up of more than one article, to determine for each article whether such a substance is present in a concentration above 0.1% weight by weight of that article.
2. Article 33 of REACH Regulation, it is for the supplier of a product one or more constituent articles of which contain(s) a

substance of very high concern in a concentration above 0.1% weight by weight of that article, to inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question.

Following the judgment of the Court of Justice, ECHA will update its *Guidance on requirements for substances in articles* in two stages:

1. A quick update in the coming months restricted to correcting the parts with references to the 0.1% limit that are no longer consistent with the conclusions of the Court judgment. This will be carried out using a fast-track procedure – only the competent authorities for REACH and CLP (the CARACAL) will be consulted on the update.
2. A more comprehensive exercise to allow for a general update and restructuring of the document. It is foreseen to include a review of the current

examples against the experience gained and questions received by ECHA since the guidance was published, as well as development of new examples that are fully aligned with the Court judgment. This update will be subject to the normal three-step guidance consultation process, including consultation of accredited stakeholders.

The move of ECHA has settled the ruling result that the determination of SVHC content should be based on parts not the assembled article.

## CPSC clarifies dyed textiles require no lead testing

On 14 October 2015, U.S. Consumer Product Safety Commission ("CPSC") published a final rule that when component part testing can be used and which textile products have been determined not to exceed the allowable lead content limits on the Federal Register. The rule is effective on 14 December 2015 if CPSC receives no significant adverse comment before 13 November 2015.

The final rule amends 16CFR 1500.91 that dyed textile require no test for lead or total lead in coating no matter what dye technique is employed.

CPSC held that dyes and dyed textiles did not contain lead. So those products require no third-party testing. However, textiles after-treatment applications, including screen prints, transfers, decals, or other prints, need lead testing.

## Canada issues conditions for manufacture and import of four substances

On 17 October 2015, Canadian government issued notification that [Ministry of Environment published four ministerial conditions](#), which determined the manufacture and import conditions for four chemicals, involving industries of toys, childcare products, textiles and cosmetics.

The four chemicals are as the following:

NO.	Substance	CAS No.	Conditions for Manufacture and Import	Effective Date
No. 18111	1,2-benzenedicarboxylic acid, mixed C8-11-alkyl and 2-ethylhexyl and hexyl and isononyl diesters	1415043-91-2	These may not be used to manufacture vinyl in a toy or childcare article at concentrations over 1% by weight.	28 July 2015
No. 17432	Alcohols, C12-18, ethoxylated, reaction products with 1,6-diisocyanatohexane and polyethylene-polypropylene glycol	72968-35-5	These may not be used in the manufacture of consumer products in unreacted form.	30 July 2015
No. 18178	1,2-propanediol, 1,2-dibenzoate	19224-26-1	(i) plastics, coatings, adhesives, caulks and sealants, (ii) industrial lubricants, (iii) fabrics, textiles, apparels and leather finishing, (iv) industrial vinyl and vinyl leather cloth, (v) ink for printing and for graphic arts, (vi) floorings, (vii) plastisols, (viii) gasket swell additives, and (ix) wall coverings	9 October 2015
No. 18306	1,2-cyclohexanedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester	1200806-67-2	These may not be used in a toy or childcare articles, in cosmetics, or in natural health products	13 October 2015

Producers should record the use and quantity of the above four substances and obtain written confirmation of the Ministry of Environment. As for the substance, CAS No. 1200806-67-2, producers must submit a written notification to the Ministry of Environment at least 120 days in advance.