



Bureau Veritas Consumer Products Services

CPS Regulatory Bulletins / Newsbytes

2011 Archive - [EMEA](#)

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EMEA – 2011 Bulletins & Newsbytes

Month of release	Reference number	Topic	Location
Jan	11B-102	Revised RoHS Directive Adopted by European Parliament	EU
Feb	11B-107	Focus on EMF: EU Regulatory and Standards Requirements for Electromagnetic Fields	EU
Feb	11B-108	New EU Regulation for Plastic Materials in Contact with Food	EU
Feb	11B-110	REACH: Six Dangerous Substances to Be Phased Out by the EU	EU
Feb	11NB-012	EU Restricts Bisphenol A in Infant Feeding Bottles	EU
Mar	11B-111	Measuring Methods with Regard to Energy Efficiency Labelling of Household Refrigerating Appliances	EU
Mar	11B-112	EU Proposes to Tighten Controls on Imports of Plastic Chinese Kitchenware	EU
Mar	11B-113	REACH: Consultation on Seven New Potential SVHC	EU
Mar	11NB-015	EU Extends the Validity of Dimethylfumarate Ban	EU
Mar	11NB-016	France Extends the Validity of Formamide Ban in Puzzle Mats	France
Apr	11B-116	EU Extends Ban on Non-Child Resistant Lighters and Novelty Lighters	EU
Apr	11B-117	Sound Level Limits for Personal Music Players and Mobile Phones: A New European Standard Planned for 2011	EU
Apr	11B-118	REMINDER: Updated European Standards for Appliances and Electrical Products Taking Effect	EU
Apr	11NB-019	EU Commission Adopts Regulation on New Importation Procedure for Plastic Chinese Kitchenware	EU
Apr	11NB-023	European Commission Adopts Regulation on the Restriction of Use of Bisphenol A in Plastic Infant Feeding Bottles	EU
May	11B-122	EU: Publication of New Guidance Documents for the Revised Toy Safety Directive	EU
May	11B-124	EU Textile Labelling Issues from Parliament Session	EU
May	11B-126	New Cadmium Restrictions under REACH	EU
Jun	11B-127	REACH: Seven New SVHC Expand ECHA Candidate List	EU
Jun	11B-131	REACH: French Opinion on Definition of 'Articles' impacts Obligations for SVHC	EU
Jun	11B-132	EC Publishes Guidance Document on Plastic Chinese Kitchenware	EU
Jun	11NB-037	European Union - Publication of EN 71-1:2011 under Revised Toy Safety Directive	EU
Jul	11B-134	European Commission Publishes Revised RoHS Directive	EU
Jul	11B-138	European Union - Publication of EN 71-2: 2011 under Revised Toy Safety Directive	EU
Jul	11B-139	France Publishes New Requirements for Placing Foam Puzzle Mats on the Market	EU
Aug	11B-142	EU: New Nickel Release Test Methods Published	EU
Aug	11B-144	Two EU Directives Add New Fibre Name and Amend Quantitative Analysis Methods	EU
Aug	11NB-052	EU Publishes List of Harmonised Standards Under the Revised Toy Safety Directive	EU
Sep	11B-147	REACH – Consultation on 20 New Potential SVHC	EU
Sep	11B-148	Sweden Proposes Restriction on Nonylphenol and Nonylphenol	EU

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		Ethoxylates in the European Union	
Sep	11B-149	REACH: Danish Proposal for New Phthalates Restrictions	EU
Sep	11NB-055	European Commission Proposes Draft Regulation amending Regulation (EU) No 10/2011	EU
Sep	11NB-059	Two New RoHS Exemptions Added by European Commission	EU
Oct	11NB-065	EU Announces Ban of Dimethylfumarate under EC 1907/2006	EU
Nov	11B-152	GS Mark - List of PAHs Expands by Two Substances	Germany
Nov	11B-154	REMINDER: The New Version of the Norms of Transformers, EN 61558:2009 will Replace EN 61558:1997 on 1 July 2012	EU
Nov	11B-155	European Union Publishes a New Regulation for Fibre Content Labelling and Testing	EU
Nov	11B-156	Denmark Announces Dossier regarding Hexavalent Chromium in Leather	EU
Nov	11B-158	Proposed EU Restriction on Lead in Jewellery – RAC and SEAC Finalize Opinions	EU
Dec	11B-161	REACH – 20 New Substances of Very High Concern (SVHC)	EU
Dec	11NB-069	French National Assembly Passes Ban of Bisphenol A in All Food Contact Packaging	France
Jan	11NB-070	GS Mark – PAHs List Officially Expanded	Germany
Feb	11NB-072	European Commission Publishes New Regulation Amending Regulation (EU) No 10/2011	EU

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Revised RoHS Directive Adopted by European Parliament

The European Parliament (EP) adopted at first reading on 24 November 2010 the recast of RoHS Directive 2002/95/EC. The EP reached a compromise agreement on the revised Directive with the European Council which must now formally adopt it. The new Directive will enter into force 20 days after its publication in the *Official Journal of the European Union* and Member States will then have 18 months to transpose it into national law. Some key objectives of the recast are implementation of RoHS into the CE Declaration and to extend the scope to all electrical and electronic equipment.



Scope

Under the revised Directive, the scope of application has been extended to **ALL electrical and electronic equipment** (including medical devices, monitoring and control instruments).

☒ *Under Article 2 and Annex I of revised Directive 2002/95/EC*

Equipment that was outside the scope of the original Directive 2002/95/EC, and which would not be in compliance with this revised Directive, may continue to be sold on the market until eight years after the entry into force of this revised Directive.

New Definitions

Some important definitions are now included while others have been modified. Some examples:

- Definitions of economic operators: "manufacturer", "importer", "distributor"...
- Definition of "homogeneous material": Defined as one material of uniform composition throughout. Or, a material consisting of a combination of materials that can not be mechanically disjointed into different materials. This means that the materials can not be separated by mechanical actions such as unscrewing, cutting, crushing, grinding or abrasive processes.
- New definition of "electrical and electronic equipment" (EEE): Defined as equipment that is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields; designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current; where "dependent" is defined as "needing electric currents or electromagnetic fields to fulfill at least one intended function".

Note: With this new definition, the determination of the electric/electronic primary function would no longer allow excluding such electric products as musical plush toys from the scope of the revised Directive 2002/95/EC.

☒ *Under Article 3 of this revised Directive 2002/95/EC*

Text continued on following page...

Key Requirements for Economic Operators

Overview of obligations of manufacturers:

- Create technical documentation that will show compliance with Article 4 Prevention (Restricted substances) and Annex II (current restrictions of cadmium, lead, mercury, chromium VI, PBB and PBDE);
- Implement an internal production control procedure; ensure procedures are in place for series production to remain in conformity; draw up an EC Declaration of Conformity and affix the **CE marking** on the EEE; and
- Mark electrical and electronic equipment (EEE) with the following: CE marking, equipment identification (type, batch or serial number or other element providing their identification), name, registered trade name or registered trade mark, and address.

Overview of obligations of importers:

- Ensure that the manufacturers have complied with their obligations as listed above;
- Retain an available copy of the EC Declaration of Conformity for the market surveillance authorities and ensure that the technical documentation can be readily available to those authorities, upon request; and
- Ensure that the marking of EEE has been affixed by the manufacturer and that their name, registered trade name or registered trade mark, and address are affixed.

Presumption of Conformity

Materials, components and EEE for which tests and measurements have been performed to demonstrate their compliance with the requirements of Article 4 (Restricted substances), or which have been assessed in accordance with harmonised standards, (the references of which have been published in the *Official Journal of the European Union*), shall be presumed to comply with the requirements of this Directive.

Additional information

View the European Parliament's position on the revised Directive 2002/95/EC in document T7-0431/2010 within the following link: <http://www.europarl.europa.eu/oeil/file.jsp?id=5723432>

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Focus on EMF: EU Regulatory and Standards Requirements for Electromagnetic Fields

Since they impact a wide variety of equipment from household appliances to cell phones, electromagnetic fields (EMF) must be taken into consideration in increasing numbers of European standards and regulations. When these requirements are updated, it is important to quickly inform manufacturers so they can ensure their products are compliant with the latest information before being sold in the EU market.



Overview and Definitions

- EMF (Electromagnetic Fields) – A term used to describe the electric and magnetic radiation emitted by an electrical appliance. They occur in many applications like home, office or factory, car, trucks and buses, and overhead tram and train lines.
- EMF and EMC (Electromagnetic Compatibility) – Although both these phenomena deal with electromagnetic emissions, they have two different types of requirements. EMF concerns the safety of people; whereas EMC addresses the impact of electromagnetic interferences with regards to appliance operation.
- Exposure of people to electromagnetic fields – Under European regulations, EMF requirements fix the limiting thresholds of exposure which can differ for the general public and workers.

Exposure of the General Public to EMF

- **Regulatory context**
 - The Council Recommendation 1999/519/EC fixes the limiting thresholds of exposure of the general public to electromagnetic fields in the frequency range 0Hz to 300GHz.
 - Recommendation requirements are included in the essential requirements mentioned in the Article 2 of the Low Voltage Directive 2006/95/EC (Protection of electrical safety of user).
 - Recommendation requirements are covered by the essential requirement of Radio Equipment and Telecommunications Terminal Equipment (R&TTE) Directive 1999/5/EC in article 3.1a (Protection of health of user).
 - Specific Absorption Rate (SAR): New regulations in France were published as Decree No. 2010-1207 and Decree of 12 October 2010. In order to measure the maximum exposure level to the public by electromagnetic fields emitted by radio terminal equipment (including mobile phones), the Decree makes it mandatory to display the SAR value on all radio terminal equipment at the point of sale.
- **Standards**
To date, there are many EMF standards published as harmonized standards under LVD and R&TTE Directives that cover various categories of products. A list of harmonized standards is published in the *Official Journal of European Union* and is frequently updated. See below for examples of EMF standards:

Standards references	Product category	DOW	Comments
EN 50366: 2003 + A1: 2006	Household and similar appliances	2006-02-01	Cancelled and replaced by EN 62233: 2008 by 1 December 2012
EN 62233: 2008	Household and similar appliances	2012-12-01	Will cancel and replace definitively EN 50366: 2003 + A1: 2006 by 1 December 2012
EN 62493: 2010	Lighting equipment	2013-02-01	Standard not harmonized under R&TTE Directive but highly recommended
EN 62311: 2008	Electrical and electronic products	2011-01-01	Generic standard
EN 50371: 2002	Low power electric and electronic products	2002-10-01	Generic standard
EN 50364: 2010	RFID Radio Frequency Identification Devices	2012-11-01	
EN 50385: 2002	Radio base stations and fixed terminal stations for wireless telecommunication systems	2005-07-01	
EN 62209-1: 2006	Hand-held and body-mounted wireless communication devices	2009-03-01	Procedure to determine SAR for hand-held devices used in close proximity to the ear (frequency range of 300 MHz to 3 GHz).

... Table continued on following page

Standards references	Product category	DOW	Comments
EN 62209-2: 2010	Hand-held and body-mounted wireless communication devices	2013-06-01	Procedure to determine the SAR for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz).

DOW: Date on which national standards conflicting with the EN have to be withdrawn.

Exposure of Workers to EMF

- Regulatory context**

Directive 2004/40/E covers the minimum health and safety requirements regarding exposure of workers to the risks arising from physical agents (electromagnetic fields). The application date is expected in April 2012. The Directive deals with the prevention and short-term effects of exposure to electromagnetic fields (0 to 300 GHz) for workers and specifies employer obligations:

- Obligations of employers**

- o Determination of exposure and assessment of risks
- o Provisions aimed at avoiding or reducing risks
- o Worker information and training

Unlike the R&TTE Directive that requires the use of limit of exposure values for the general public, Directive 2004/40/EC can authorize a higher limit of exposure values for workers under the responsibility and decision of the employer. The employer in such cases must establish special provisions.

- Standards**

See below for examples of EMF standards concerning the exposure of workers.

Standards references	Activities	DOW	Comments
EN 50499: 2008		1/11/2011	Procedure for the assessment of exposure of workers to EMF
EN 50496: 2008		1/09/2011	Determination of workers' exposure to EMF and assessment of risk at a broadcast site.
EN 60601-2-33: 2002 + A1: 2005 + A2: 2008	Medical electrical equipment	1/07/2005	Safety of magnetic resonance equipment.

Additional information

- o Text of Recommendation 1995/9/EC: <http://tiny.cc/t9hf1>
- o Text of Directive 2006/95/EC: <http://tiny.cc/63azz>
- o Text of Directive 1999/5/EC: <http://tiny.cc/e6zla>
- o Text of Decree No. 2010-1207: <http://tiny.cc/mqxrh>
- o Text of Decree of 12 October 2010: <http://tiny.cc/qty45>
- o Text of Directive 2004/40/EC: <http://tiny.cc/hs8vk>

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New EU Regulation for Plastic Materials in Contact with Food

On 14 January 2011, the European Commission (EC) adopted a new Regulation on plastic materials and articles intended to come into contact with food. Materials such as rubber, silicones and ion exchange resins do not fall under its scope. The new Regulation introduces several changes to the legal requirements for these products and entered into force on 4 February 2011 and shall apply from 1 May 2011.

In order to provide sufficient time for manufacturers who need to change their processes in order to comply with the new requirements, the EC has defined a number of transitional provisions from 1 May 2011 to 31 December 2015.



Background

This new European Regulation No.10/2011 is a specific measure within the context of Article 5 (1) of Regulation (EC) No.1935/2004 and establishes the Rules to be applied for the safe use of plastic materials and articles in contact with food. As a Regulation, it is directly applicable to all Member States and did not have to enter the lengthy process, (often 12 months are necessary), required for national legislation to be transposed into law. The previous directive on this topic (Commission Directive 2002/72/EC of 6 August 2002) is also repealed. It was felt that the authorisation of new substances was delayed by the transposition process, and therefore it was appropriate to instead adopt Rules regarding plastic materials and articles allowing for more innovation and faster application.

Major Changes and Highlights of the Regulation

- **Expansion of Scope**
The scope was expanded in comparison to Directive 2002/72/EC to include plastic layers in multi-material layer materials and articles.
- **Union List of Authorized Substances (Annex I)**
The Union list set out in Annex I is now complete and contains the 885 substances authorised at EU level that may be used in the manufacture of plastic materials and articles with regard to their specific migration limits (SML).
- **Restrictions on Materials and Articles (Annex II)**
Annex II limits the migration of several metals (eg. barium, iron, zinc) as well as the migration of primary aromatic amines.
- **Choice of Food Simulants for Specific Migration (Annex III)**
New food simulants, such as ethanol (10%, 20% and 50%), vegetable oil, and poly(2,6-diphenyl-p-phenylene oxide) are defined as to their use within migration testing.
- **Declaration of Compliance**
According to Article 15 and 16, it is required that supporting documentation that substantiates the declaration of compliance, be kept available for the enforcement authorities at each stage of manufacture.

Additional Information

For more details, view Text of Regulation:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>

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REACH: Six Dangerous Substances to Be Phased Out by the EU

On 17 February 2011, the European Union announced that the first six substances from the ECHA Candidate List have been added to the EC 1907/2006 Annex XIV of the REACH regulation. This means that these six substances will be banned within the next three to five years unless an authorisation is granted to individual companies for their use. These requirements apply regardless of the tonnage at which the substance is placed on the market or used. Some uses of substances, such as intermediates, are excluded from the authorisation requirement.



Background

By adding six substances of very high concern (SVHC) to Annex XIV, the next step of REACH, authorisation, comes into force. Substances for authorisation are selected from the Candidate list based on recommendations made by the European Chemicals Agency (ECHA) and will be banned unless an authorisation is granted to an individual company. Requests for authorisation must be submitted to ECHA and final decisions will be made by the European Commission. Without authorisation, these substances will not be allowed to be used or placed on the market. Requirements apply regardless of the tonnage used or placed on the market. Applicable dates for each substance range from 2014 to 2015. Further information will be available soon on the ECHA webpage.

Substances on Annex XIV:

Substance name	CAS Number (EC Number)	Remarks & additional information (examples)
4,4' Methylendianiline(4,4'-diaminodiphenylmethane, MDA)	101-77-9 (202-974-4)	Raw material to produce methylenediphenyl diisocyanate for PUR (main application). Hardener in epoxy resins, adhesives
Benzylbutylphthalate (BBP)	85-68-7 (201-622-7)	Plasticizer (i.e. PVC), adhesives, inks, lacquers, small use in package, cosmetics
Hexabromocyclododecane, (HBCDD)	25637-99-4 (247-148-4)	Flame retardant (mainly in PS). In constructions, buildings also in flame-retard textiles and E&E products
5-tert-butyl-2,4,6-trinitro-m-xylene	81-15-2 (201-329-4)	Cosmetics, fragrances
Di(2-ethylhexyl)phthalate (DEHP)	117-81-7 (204-211-0)	Plasticizer in resins and polymers (i.e. PVC)
Dibutylphthalate (DBP)	84-74-2 (201-557-4)	Plasticizer in resins and polymers (i.e. PVC) Also used in printing inks, adhesives (e.g. paper, package), sealant/grouting agents, nitrocellulose paints, film coatings, glass fibers, & consumer products

Additional Information

Rapid Press Release is available (select language):

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/196&format=HTML&aged=0&language=DE&guiLanguage=en>

Bureau Veritas Solutions and Services for REACH Compliance

Bureau Veritas offers a wide range of chemical management solutions to help you comply with the challenges of the REACH Regulation. To find out how we can assist your business, email: marketingmail@hk.bureauveritas.com

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Newsbytes

NEWSBYTE: EU Restricts Bisphenol A in Infant Feeding Bottles

The European Commission (EC) published a new Directive 2011/8/EU amending 2002/72/EC to restrict Bisphenol A in feeding bottles that are intended for use by infants under the age of 12 months. The directive entered into force on February 1, 2011. According to this new directive, member states are required to prohibit the manufacture of polycarbonate feeding bottles containing Bisphenol A from March 1, 2011. From June 1, 2011, the import into the EU and placing on the EU market of feeding bottles containing Bisphenol A will also be prohibited. For other polycarbonate food contact materials and articles, the specific migration limit of Bisphenol A is retained as 0.6mg/kg.

Additional Information

Full text of the directive:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:026:0011:0014:EN:PDF>

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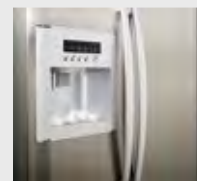
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11NB-012, February 2011

Measuring Methods with Regard to Energy Efficiency Labelling of Household Refrigerating Appliances

On 16 February 2011, the EU Commission published a Communication in the framework of the implementation of Regulation (EU) No 1060/2010 with regard to energy labelling of household refrigerating appliances. The Communication includes a list of transitional methods of measurement relevant to the energy efficiency labelling of those products.



Summary

The Commission Communication provides a list of titles and references of transitional methods of measurement relevant to energy efficiency labelling of and the provision of supplementary information on household refrigerating appliances. It is intended that the listed transitional methods will ultimately be replaced by harmonised standards

Two types of information are provided in this document:

1) A list of titles and references of methods of measurement for household refrigerating appliances

Measured parameters:

- Terms, definitions, symbols and classification
- General test conditions
- Collection and disposal of defrost water
- Storage temperatures
- Determination of linear dimensions, volumes and areas
- Energy consumption
- Temperature rise time
- Freezing capacity
- Built-in refrigerating appliances
- Rated characteristics and control procedure
- Elements for the test report, marking

Listed references*: Standard EN 153, Regulation (EC) n° 643/2009

- Noise

Listed references*: Standards IEC 60704-1, IEC 60704-2-14, IEC 60704-3

- Power consumption

Listed references*: Regulation (EC) n° 1275/2008

2) General test conditions and methods of measurement for wine storage appliances only

Measured parameters:

- Average storage temperature of each compartment
- Temperature amplitude
- Relative humidity of each compartment
- Rated capacity in number of standard bottles of 75 centilitres

***Titles of the measuring methods references:**

- **EN 153** Methods of measuring the energy consumption of electric mains operated household refrigerators, frozen-food storage cabinets, food freezers and their combinations, together with associated characteristics.
- **IEC 60704-1** Household and similar electrical appliances - Test code for the determination of airborne acoustical noise – General requirements.
- **IEC 60704-2-14** Household and similar electrical appliances - Test code for the determination of airborne acoustical noise – Particular requirements for refrigerators, frozen-food storage cabinets and food freezers.
- **IEC 60704-3** Household and similar electrical appliances - Test code for the determination of airborne acoustical noise – Procedures for determining and verifying declared noise emission values.
- **Regulation (EC) n° 1275/2008** Commission Regulation implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for standby and off mode electric power consumption of electrical and electronic household and office equipment.
- **Regulation (EC) n° 643/2009** Commission Regulation implementing Directive 2005/32/EC of the European Parliament and of the Council with regard to ecodesign requirements for household refrigerating appliances.

Additional Resources

To view the full text of the Communication:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:049:0006:0011:EN:PDF>

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EU Proposes to Tighten Controls on Imports of Plastic Chinese Kitchenware

Polyamide and melamine plastic kitchenware, originating in or consigned from China and Hong Kong, can only be imported into the EU member states if the importer submits a declaration to the competent authority confirming that the products meet the requirements concerning the release of primary aromatic amines (PAA) and formaldehyde laid down in Directive 2002/72/EC. This regulation on specific import conditions for Chinese kitchenware is proposed to be applied from July 1, 2011.



Background

In recent years, member states have been notifying, through the Rapid Alert System for Food and Feed (RASFF), a consistently high number of non-compliance kitchenware originating from China. The EU Food and Veterinary service, in its inspections in China and Hong Kong noted shortcomings in the Chinese system to control plastic kitchenware exported to EU. Therefore, the EU has now decided to tighten the rules for these products.

Import Procedure

- Importers shall submit to the competent authority for each consignment a declaration, which shall be in the official language, or in one of the official languages of the member state in which the consignment is imported, accompanied with a laboratory report demonstrating the following analytical results:

Kitchenware from Hong Kong and China	Release of substance	Requirement
Polyamide	Primary Aromatic Amines (PAA)	ND (0.01 mg/kg food)
Melamine	Formaldehyde	Not exceeding 15 mg/kg food

- Importers or their representatives shall notify the competent authority at the first point of introduction at least two working days in advance of the estimated date and time of physical arrival of consignments originating in, or consigned from, China and Hong Kong.
- The competent authorities at the first point of entry shall carry out:
 - Documentary checks on all consignments within two working days of arrival.
 - Identity and physical checks, including laboratory analysis of 10% of consignments, in such a way that it is not possible for the importers or their representative to predict whether any particular consignment will be subjected to such checks.

Definitions:

- "Document check"** – checking of the documents including declarations and laboratory report
 - "Identity check"** – visual inspection to ensure that the documents accompanying the consignment tally with the contents of the consignment
- "Physical check"** – sampling for analysis and laboratory testing and any other check necessary to verify compliance with the requirements concerning the release of PAA and formaldehyde per Directive 2002/72/EC
- If the laboratory analysis identifies non-compliance, the competent authorities shall immediately inform the Commission of the results through the RASFF.
- The release for free circulation of polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong will be allowed when all the checks have been completed

Additional Resources

Full Text of draft regulation:

http://www.europa-nu.nl/9353000/1/j4nvgs5kjg27kof_j9vvikqpopjt8zm/vile9rins9t7/f=/pdf

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March 2011, Bulletin 11B-112

REACH: Consultation on Seven New Potential SVHC

On 21 February 2011, the European Chemicals Agency (ECHA) published proposals identifying seven additional substances as Substances of Very High Concern (SVHC) and possible candidates for authorization. Interested parties are invited to comment on these proposals by 7 April 2011. Comments will be taken into account when deciding whether the substances will be added to the actual ECHA Candidate List.



Background

Once on the List, producers, importers or suppliers may have communication obligations (as per Article 33 of REACH regulation) that require them to provide business clients and consumers with information on the safe use of any product containing the SVHC that exceeds 0.1% (w/w). Retailers have 45 days to respond to an inquiry by consumers in regards to the presence of an SVHC in a product. In addition to the communication obligations, producers or importers may also have to notify ECHA if their article products contain SVHC exceeding 0.1% (w/w) and with total weight over 1 tonne per year (Article 7(2) of REACH regulation).

Seven New Potential SVHC plus Cobalt dichloride [‡]

Substance name	EC no. (CAS no.)	Reason for proposing	Applications
2-ethoxyethyl acetate	203-839-2 (111-15-9)	CMR*	In paints, adhesives, glues, cosmetics, leather, wood stains, semi-conductors, photographic and photolithographic
Strontium chromate	232-142-6 (7789-06-2)	CMR*	In paints, varnishes and oil colors, metal conditioners or in aluminum flake coatings
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	271-084-6 (68515-42-4)	CMR*	Plasticizer in PVC, electrical cables and adhesives
Hydrazine	206-114-9 (7803-57-8; 302-01-2)	CMR*	In metal coatings, on glass and plastics, in plastics, rubber, PU and dyes
1-methyl-2-pyrrolidone	212-828-1 (872-50-4)	CMR*	Solvent in coatings, surface treatment of textiles & resins and metal coated plastics
1,2,3-trichloropropane	202-486-1 (96-18-4)	CMR*	Solvent in degreasers, cleaning solutions, paint thinners, pesticides, resins and glues
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	276-158-1 (71888-89-6)	CMR*	Plasticizer in PVC, sealants and printing inks
Cobalt dichloride [‡]	231-589-4 (7646-79-9)	CMR*	Absorber for gases, humidity indicator, dye mordant for glass industry, invisible inks, electroplating and additive in rubber

Note:

[‡] Cobalt dichloride was originally identified and included in the ECHA Candidate List in October 2008. The purpose of the second consultation is due to the update of its classification.

* CMR means Carcinogenic, Mutagenic or toxic to Reproduction

Additional Information

http://echa.europa.eu/news/pr/201102/pr_11_04_svhc_consultation_20110221_en.asp

Bureau Veritas Solutions and Services for REACH Compliance

Bureau Veritas offers a wide range of chemical management solutions to help you comply with the challenges of the REACH Regulation. To find out how we can assist your business, email: marketingmail@hk.bureauveritas.com

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Newsbytes

NEWSBYTE: EU Extends the Validity of Dimethylfumarate Ban

On 1 March 2011, the European Commission published a Decision 2011/135/EU extending the validity of Decision 2009/251/EC for the restriction of Dimethylfumarate (CAS 624-49-7).

Dimethylfumarate (DMFu) is restricted temporarily in the EU under Directive 2009/251/EC and was amended for the first time by Decision 2010/153/EU. Now this restriction is again extended to 15 March 2012 by Decision 2011/135/EU.

Dimethylfumarate has antifungal properties and may be used to limit mould growth during rainy periods such as the monsoon. Dimethylfumarate has been found to be an allergic sensitizer even at very low concentrations. As a result, several reports were published in the EU's rapid alert system for dangerous consumer products (RAPEX) that contain DMFu. Therefore, in 2009 the EU banned all types of consumer articles containing DMFu. The limit was set as 0.1 mg/kg which applies for each component part of the article.

Additional Information

Full text of the Decision:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:057:0043:0043:EN:PDF>

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11NB-015, March 2011



Newsbytes

NEWSBYTE: France Extends the Validity of Formamide Ban in Puzzle Mats

On 14 March 2011, France published a Decree extending the validity of the ban on Formamide (CAS 75-12-7) in puzzle mats. In December 2010, France banned formamide in puzzle mats temporarily for three months. Now this ban is extended until 15 July 2011.

Formamide is a solvent and is used as a reduction agent and industrial chemical for several applications. In foams, it might be formed as well from blowing agents. In the production of foams, blowing agents are used to produce gases to blow up the plastic material. Formamide might be formed from these blowing agents as a side-product. Formamide is classified as toxic to reproduction according to European Directive 67/548/EEC.

Additional Information

The French Arrete can be found under:

<http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023708355&dateTexte=&categorieLien=id>

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11NB-016, March 2011

EU Extends Ban on Non-Child Resistant Lighters and Novelty Lighters

On 11 May 2006, by Decision 2006/502/EC, the European Commission required Member States to take measures to ensure that only child-resistant lighters be placed on the market and to prohibit placing novelty lighters on the market altogether.

As that Decision was adopted under article 13 of Directive 2001/95/EC on General Product Safety, it could only be valid for one year. Decision 2011/176/EU is now amending the GPS Directive for the fifth time, thus extending its validity for another year until 11 May 2012.



Complying with the General Safety Requirements

The European and International Standard EN ISO 9994:2006 establishes specifications for quality, reliability and safety of lighters while the European Standard EN 13869:2002 establishes child-resistance specifications for lighters. Lighters that comply with these standards are presumed to be in conformance with the Decision.

Child-resistance requirements of non-EU countries, if such requirements are equivalent to those established by the Decision, (such as those in the US), are also presumed to be in compliance with the child-resistance requirements. For lighters to be excluded from the child-resistance requirements they must fulfill a number of technical criteria outlined in the Decision.

In addition, the Decision bans the placing on the market of lighters which resemble objects that are especially appealing to children (so-called "novelty lighters") such as toys, mobile phones, food, cars, etc. and therefore present a high risk of misuse.

Hazards

Cigarette lighters are consumer products which are inherently hazardous, since they produce a flame or heat, and contain fuel. This is particularly true in the case of disposable lighters, which are sold in large numbers, often in multi-packs, and used as low-value, throw-away products. Children may play with them and accidentally cause fires, serious injuries and deaths.

Misuse of cigarette lighters by children causes a significant number of fire accidents. It is estimated that between 1,500 and 1,900 injuries and 34 to 40 fatalities per year in the EU are due to fire-related accidents caused by children playing with lighters. Child-resistance mechanisms exist to prevent such accidents and their use has been mandatory in the US, Canada, Australia and New Zealand for some 10 years.

Bureau Veritas Participation

In 2009, Bureau Veritas Consumer Products Services in the UK carried out test work on behalf of Stichting PROSAFE (the Product Safety Enforcement Forum of Europe). Our test work was focused on lighter performance and behavior. The joint surveillance approach tested lighter batches to requirements from EN ISO 9994 that addressed the most serious safety issues. The testing found a very high failure rate for lighters, in excess of 50% failing to meet the requirements.

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Sound Level Limits for Personal Music Players and Mobile Phones: A New European Standard Planned for 2011



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With the issuing of amendments to existing standards (EN 60065:2002 and EN 60950-1:2006) in early 2011, progress has been made on the European Commission mandate to ensure that personal listening devices for consumers would be safe. A transition period of 24 months will follow, during which the amended standards will be published as national standards.



By the end of this two year transition period, industry should have started to apply the standards newly prescribed sound level limits to their products.

Background

The EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) issued an Opinion on October 13, 2008 concluding that permanent hearing damage can be caused by regularly listening to personal music players at a high volume over a sustained period of time. As a result, in September 2009 CENELEC (European Committee for Electrotechnical Standardization) accepted a mandate from the European Commission to develop standards to address this issue. The new standards were to ensure that under reasonably foreseeable conditions of use, such devices must be inherently safe and must not cause hearing damage.

CENELEC Technical Committee 108X on 'Safety of electronic equipment within the fields of Audio/video, Information Technology and Communication Technology' was tasked to execute the mandate and obtain input from a dedicated working group that would include representatives and experts from market surveillance authorities, consumer interest organisations, research institutes, certification bodies and manufacturers.

New Requirements

The working group proposed a new approach that resulted in the issuing of two amendments to already existing standards: *Safety of audio, video and similar electronic apparatus* (EN 60065:2002) and *Safety of information technology equipment* (EN 60950-1:2006). This proposal passed a formal vote by the National Standardisation Committees at the end of 2010 and the revised standards were released in early 2011.

The amended standard is based on a sound level limit of 85 dBA that is considered to be safe under all reasonable foreseeable conditions of use. However, there is the possibility for the user to choose to override this limit allowing the sound level to be increased up to a maximum of 100 dBA. In this case, the user must be provided with warnings about the risks and the warnings that need to be repeated following every 20 hour period of listening time.

Ongoing Work

CENELEC and the working group are expected to continue the mandated work of improving the safety of personal listening devices. The next step is expected to address the development of "smart" methods of providing hearing protection.

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REMINDER: Updated European Standards for Appliances and Electrical Products Taking Effect



Move Forward with Confidence

Some European standards covering household appliances, lighting, power tools, apparatus and EMC will be updated and/or modified during the next six months. **IMPORTANT:** These standard modifications will become compulsory from the date of withdrawal and the new versions will then apply. See the following table for the designated standards and the withdrawal dates.



Definition: Date of Withdrawal (DOW)

The date of withdrawal (DOW) is the date on which the previous version of the standard is replaced by the new or modified standard. Previous versions must be withdrawn.

STANDARDS DOW AND EFFECTIVE DATES FOR SIX MONTHS

*IMPORTANT: Information written in **red** becomes compulsory on the dates listed below.*

CATEGORY	STANDARDS	PRODUCTS	CURRENT VERSION	DOW CURRENT VERSION	
TOOLS	EN 60745-2-9	Particular requirements for tappers	EN 60745-2-9: 2009	April	2011
TOOLS	EN 60745-2-18	Particular requirements for strapping tools	EN 60745-2-18: 2009	April	2011
LIGHTING	EN 61347-1	Luminaires - Part 1: General requirements and tests for lamp control gear	EN 61347-1: 2008	May	2011
LIGHTING	EN 60432-3	Tungsten-halogen lamps (non-vehicle)	EN 60432-3: 2003 +A1: 2005+A2: 2008	May	2011
APPARATUS	EN 60730-1	Automatic electrical controls for household and similar use	EN 60730-1: 2000+A17: 2000+A12: 2003+A13: 2004 +A1: 2004+A14: 2005+A15: 2007 +A16: 2007+A2: 2008	June	2011
HOUSEHOLD	EN 60335-2-11	Particular requirements for tumble dryers	EN 60335-2-11: 2003 +A1: 2004+A2: 2006+A11: 2008	July	2011
LIGHTING	EN 60238	Edison screw lamp holders	EN 60238: 2004+A1: 2008	August	2011
LIGHTING	EN 60838-1	Miscellaneous lamp holders -Part 1: General requirements and tests	EN 60838-1: 2004+A1: 2008	August	2011

LIGHTING	EN 60400	Lamp holders for tubular fluorescent lamps and starter holders	EN 60400: 2008	August	2011
HOUSEHOLD	EN 60335-2-75	Particular requirements for commercial dispensing appliances and vending machines	EN 60335-2-75:2004+ A1: 2005 +A11: 2006 +A2: 2008 +A12: 2010	August	2011
LIGHTING	EN 62471	Photo-biological safety of lamps and lamp systems	EN 62471: 2008	September	2011
HOUSEHOLD AND TOOLS	EN 55014-2	Electromagnetic compatibility (EMC) - Requirements for household appliances, electric tools and similar apparatus - Part 2 : Immunity – Product family standard	EN 55014-2: 1997 +A1: 2001+A2: 2008	September	2011
ALL ELECTRICAL PRODUCTS	EN 61000-3-3	Electromagnetic compatibility (EMC)- Part 3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems for equipment with rated current < 16 A per phase and not subject to conditional connection	EN 61000-3-3 : 2008	September	2011

NOTE: The standards listed above are the versions that must be used from the dates listed. Bureau Veritas Electrical and Electronic Products would be pleased to provide our testing service according to any of the above safety / EMC tests. If you have questions about any of these changes, or wish to check if your reports need to be updated, please contact us.

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Newsbytes

NEWSBYTE: EU Commission Adopts Regulation on New Importation Procedure for Plastic Chinese Kitchenware

On March 22, 2011, the European Commission adopted regulation EU No. 284/2011 that lays down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from China and Hong Kong. These two types of plastic Chinese kitchenware can only be imported into the EU member states with a declaration certifying their compliance with EU requirements on primary aromatic amines (PAAs) and formaldehyde as per Directive 2002/72/EC. This regulation will enter into force on April 12, 2011 and will apply from July 1, 2011.

Additional Information

Full Text of the Commission Regulation:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:077:0025:0029:EN:PDF>

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11NB-019, March 2011



Newsbytes

NEWSBYTE: European Commission Adopts Regulation on the Restriction of Use of Bisphenol A in Plastic Infant Feeding Bottles

On April 1, 2011, the European Commission adopted regulation EU No 321/2011 that amends regulation EU No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles. This action was necessary as the current regulation (EU No 10/2011) does not contain the restrictions concerning Bisphenol A that were introduced in Directive 2002/72/EC by Directive 2011/8/EU.

The new regulation will apply from May 1, 2011 to prohibit the use of Bisphenol A in the manufacture of polycarbonate infant feeding bottles and will apply from June 1, 2011 to prohibit the placing on the market and importation into the European Union of infant feeding bottles made of or containing Bisphenol A.

Additional Information

Full Text of the European Commission Regulation:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:087:0001:0002:EN:PDF>

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11NB-023, April 2011

EU: Publication of New Guidance Documents for the Revised Toy Safety Directive

The European Commission (EC) has recently published three guidance documents relative to the revised Toy Safety Directive (TSD), Directive 2009/48/EC. The first document is the third revision to the TSD explanatory guidance document; the second is the initial publication of the technical documentation guidance document; and the third is a guidance document for the classification of toy crafts. A summary of the contents follows.



Summary of Guidance Documents

- **Revised Toy Safety Directive 2009/48/EC (TSD) – Publication of the Explanatory Guidance Document – Version 1.3 (05/04/2011)**

The European Commission has published Version 1.3 of the explanatory guidance document which can be viewed at this link on their website:

http://ec.europa.eu/enterprise/sectors/toys/files/tsd_explanatory_guidance_document_en.pdf

This document provides detailed explanations of the meanings under various requirements of the revised Toy Safety Directive. Particularly, this guidance includes specific information on the obligations of the economic operators relative to marking requirements and obligations. *To note:* On page 23, Version 1.3 provides clarification on the identification number that needs to be affixed on toys. It provides examples where the identification number can be affixed on the toy packaging instead of the toy itself.

- **Publication of Technical Documentation Guidance Document – Version 1.00 (05/04/2011)**

The European Commission published this document which can be viewed at this link on their website:

http://ec.europa.eu/enterprise/sectors/toys/files/guidance-documents/technical_documentation_guidance_document_rev_1.0_en_.pdf

The purpose of this guidance is to provide explanations on the technical documentation that need to be issued by the manufacturer. It gives detailed requirements for the content of the technical documentation and some examples of information that needs to be provided (e.g., BOM - Bill of Materials.) It also includes explanatory information on the purpose of the safety assessment and how to conduct it.

- **Publication of the Crafts Guidance Document N°13 – 19 April 2011**

http://ec.europa.eu/enterprise/sectors/toys/files/guidance-documents/guidance_document_on_crafts_en.pdf

This document clarifies the classification of craft products. For example, hobby kits classified as toys versus educational creative kits subject to the General Safety Requirement of Directive 2001/95/EC.

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EU Textile Labelling Issues from Parliament Session

The European Parliament focused on three main issues in its May 2011 plenary sessions: labelling regarding use of materials of animal origin in textile products; country of origin labelling for textile products imported into the EU; and possible harmonization of labelling requirements for care-code labeling. Parliament also considered uniform sizing codes and the indication of the presence of allergenic substances in textiles. More details on the outcome of the sessions follow.



Key Results from the Session

Fur and Leather Labelling:

New textile labelling rules for textile products containing materials of animal origin were approved on 11 May 2011. The rationale for this type of labelling is that fur is often used as trim in garments and it is often difficult for consumers to distinguish between real animal fur and good quality synthetic fur manufactured from synthetic fibres. Allergy sufferers and consumers who wish to avoid animal skin products will benefit from the new requirement. Basically any use of animal-derived materials, such as fur, will have to be stated on product labels. This should not be confused with animal-derived fibres such as wool, which already require labeling in textile garments under the *European Fibre Content Labelling Directive* and its amendments.

These new labelling rules concerning animal origin will come into force 20 days after publication in the *EU Journal*. However, there will be a two and a half year transition to allow industry time to adapt.

Country of Origin Labelling:

Although the European Parliament was strongly in favour of "Made in" labels for textile products imported from non-European Union countries, the Council did not agree. This potential legislation is controversial, with some countries seeing the label as useful for consumers and others against the idea. Those who did not approve, including some EU member countries, saw it as being a barrier to free trade and a "protectionist" measure against imports from countries outside the EU.

The result of these differences was that the EU Commission must present a study by 30 September 2013 on the feasibility of an origin labelling scheme. Essentially, this means mandatory country of origin labelling for textiles in the EU is not on the current legislative horizon. However, it should be noted that under the *European General Product Safety Directive* all products in the EU must be traceable through the supply chain back to the manufacturing source, including country, in case of product recalls.

Possible New Labelling Requirements and New Technologies:

Another result of the Session was an agreement to have an assessment made on the feasibility of harmonizing certain labeling requirements including: care labelling (currently voluntary); EU-wide uniform size labelling and labelling to indicate the presence of possible allergenic substances. Also, the EU Parliament stressed the need to evaluate innovative labelling technologies such as micro-chips or radio frequency identification as means of conveying information to EU consumers.

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May 2011, Bulletin 11B-124

New Cadmium Restrictions under REACH

On 20 May 2011, the European Commission issued a regulation (EU 494/2011) amending the restrictions on cadmium under Annex XVII of REACH regulation (EC) No.1907/2006. This regulation restricts cadmium in jewellery, brazing sticks and all plastic materials and comes into force on 10 December 2011 as per the Corrigendum of 21 May 2011.



Background

Annex XVII of the REACH regulation (EC 1907/2006) already contains several restrictions on cadmium in mixtures and articles. Now, these restrictions have been extended to jewellery, brazing sticks and all plastic materials with a limit of 100 mg/kg. For the recycling of PVC in construction products, the new legislation allows the re-use of recovered PVC containing low levels (0,1%) of cadmium.

Highlights of the Revision

Jewellery

The following jewellery articles shall not be placed on the market if their concentration in cadmium is equal or greater than 0.01% (100 mg/kg) by weight of the metal:

- Metal beads and other metal components for jewellery making,
- Metal parts of jewellery and imitation jewellery articles and hair accessories (i.e. bracelets, necklaces, rings, piercing jewellery, wrist-watches, wrist-wear, hair accessories, brooches, cufflinks).

Note: These requirements will not apply to jewellery more than 50 years old on 10 December 2011.

Mixtures and Articles

The list of specific articles that were subject to cadmium restrictions when cadmium was used as a PVC stabiliser has been removed. Instead, that concern is addressed by: Cadmium shall not be used in mixtures and articles produced from synthetic organic polymers, which extends the restriction to all plastic materials. The limit is still 0.01% (100 mg/kg) by weight of the plastic material.

Paints

Cadmium shall not be used in paints. For paints with zinc content higher than 10%, the limit is 0.1%. Painted articles shall not be placed on the market if their concentration of cadmium is equal or greater than 0,1% (1000 mg/kg) by weight of the paint on the article.

Recovered PVC

Mixtures produced from PVC waste and mixtures, and articles containing recovered PVC, can be placed on the market if their concentration of cadmium does not exceed 0,1% (1000 mg/kg) by weight of some rigid PVC applications. Examples of these articles are: profile and rigid sheets for building application, doors, windows, shutters, walls, blinds, fences, roof gutters, decks, terraces, cable ducts, and pipes for non-drinking water. **Articles and mixtures containing recovered PVC must be visibly, legibly and indelibly marked as follows:**

“Contains recovered PVC” or with a designated pictogram (shown in PDF).



Brazing Fillers

Cadmium shall not be used in brazing fillers containing equal or greater than 0.01% (100 mg/kg) cadmium.

Additional Information

View the Rapid Press Release (select language):

<http://europa.eu/rapid/pressReleasesAction.do?reference=IP/11/620&format=HTML&aged=0&language=EN&guiLanguage=en>

Contact Us

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REACH: Seven New SVHC Expand ECHA Candidate List

On 31 May 2011, the European Chemicals Agency (ECHA) announced that seven new compounds are identified as substances of very high concern (SVHC). This Candidate List will be updated soon to the ECHA website.

Once a substance is put on the candidate list, producers, importers or suppliers may have to consider communication obligations that require them to provide business clients and consumers with information on the safe use of any product containing SVHC exceeding 0.1% (w/w). Retailers have 45 days to respond to consumer inquiries regarding the presence of SVHC in the product.



Background

In February 2011, ECHA invited interested parties to public consultation which ended in April. Now the Member states have agreed to add seven new substances to the Candidate List. An eighth SVHC, cobalt dichloride, was originally included in the Candidate List in October 2008 and the purpose of its second consultation is to update its classification to "toxic to reproduction." The substances are listed below:

SEVEN NEW SUBSTANCES OF ECHA CANDIDATE LIST AND COBALT DICHLORIDE

Substance name	EC no. (CAS no.)	Reason for proposing	Remarks (examples)
2-ethoxyethyl acetate	203-839-2 (111-15-9)	CMR*	In paints, adhesives, glues, cosmetics, leather, wood stains, semi-conductors, photographic and photolithographic
Strontium chromate	232-142-6 (7789-06-2)	CMR*	In paints, varnishes and oil colors, metal conditioners or in aluminum flake coatings
1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters (DHNUP)	271-084-6 (68515-42-4)	CMR*	Plasticizer in PVC, electrical cables and adhesives
Hydrazine	206-114-9 (7803-57-8; 302-01-2)	CMR*	In metal coatings, on glass and plastics, in plastics, rubber, PU and dyes
1-methyl-2-pyrrolidone	212-828-1 (872-50-4)	CMR*	Solvent in coatings, surface treatment of textiles & resins and metal coated plastics
1,2,3-trichloropropane	202-486-1 (96-18-4)	CMR*	Solvent in degreasers, cleaning solutions, paint thinners, pesticides, resins and glues
1,2-Benzenedicarboxylic acid, di-C6-8-branched alkyl esters, C7-rich (DIHP)	276-158-1 (71888-89-6)	CMR*	Plasticizer in PVC, sealants and printing inks
Cobalt dichloride	231-589-4 (7646-79-9)	CMR*	Absorber for gases, humidity indicator, dye mordant for glass industry, invisible inks, electroplating and additive in rubber

Note: *CMR means - Carcinogenic, Mutagenic or Toxic to Reproduction

Additional Information

- ECHA Press Release: http://echa.europa.eu/news/pr/201105/pr_11_13_msc_identify_seven_new_svhc_en.asp
- ECHA will update Candidate list at:
http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp

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REACH: French Opinion on Definition of 'Articles' impacts Obligations for SVHC

In an opinion letter ("AVIS") published in the *Official Journal of the French Republic* on 8 June 2011, French authorities stated their position on the interpretation of the meaning of "articles" in regards to REACH (EC 1907/2006). Since the French opinion differs from the ECHA interpretation, this opinion impacts obligations for Article 33 (Information Obligation) and Article 7.2 (Notification of SVHC) under REACH. The French opinion is based on the concept that components of a finished product should be regarded as individual articles.



Background

Once a substance is put on the candidate list, producers, importers or suppliers have to consider information obligations (Article 33 of REACH regulation) that require them to provide business clients and consumers with information on the safe use of any product containing SVHC exceeding 0.1% (w/w). Retailers have 45 days to respond to an inquiry by consumers in regards to the presence of SVHC in the product. Furthermore, if the total amount of a SVHC is more than 1 Tonne/Year companies have to notify ECHA about the substance (Article 7.2 of REACH regulation).

Defining the Meaning of "Article"

To calculate the concentration of SVHC in an article and to check further obligations under REACH, the definition of "article" is important. Most Member States, as well as ECHA, follow the concept of considering the whole article, as noted in the ECHA *Guidance on Requirements for Substances in Articles*. However, France, Austria, Belgium, Denmark, Germany and Sweden have a different point of view. Their approach is based on the concept that an "article" might be made from different components which should be also regarded as articles. This interpretation has a major impact in regards to obligations on SVHC.

Comparative Example using Different Definitions of "Article"

Presume that an imported belt is composed of a leather strap with a metal buckle and contains an SVHC with 0.2 % (w/w) in the metal buckle and the total quantity of the SVHC is 1.5 Tonnes/Years per importer.

- Following the ECHA approach (calculation for the whole belt), the concentration of SVHC in the whole belt is 0.05%. Therefore, no further obligations for Information or Notification are applicable because the whole belt contains less than 0.1% SVHC.
- Following the French approach, the belt should be regarded as two articles (leather strap and buckle). Therefore, calculation and obligations would differ. As the buckle contains 0.2% SVHC, Information Obligation applies and since more than 1.5 Tonnes /Year SVHC are imported, Notification for this substance at ECHA would be requested as well.

These different interpretations and opinions may have an impact on producers, importers, suppliers and retailers when calculating the concentration of SVHC in the article. The legal interpretation is unclear because REACH is a European Regulation which applies in all EU Member states. A final interpretation may be found in Court.

Additional Information

- ECHA guidance on requirements for substances in articles:
http://guidance.echa.europa.eu/docs/guidance_document/articles_en.pdf
- French AVIS (in French)::
<http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=?cidTexte=JORFTEXT000024144346&dateTexte=&oldAction=rechJO&categorieLien=id>

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EC Publishes Guidance Document on Plastic Chinese Kitchenware

On 14 June 2011, the European Commission (EC) published a Guidance Document relative to Commission Regulation (EU) No 284/2011 applicable on 1 July 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region.

The document provides for legal clarifications on some definitions and guidelines for implementation by business operators.



Summary of Key Points

Background

Regulation (EU) No 284/2011 aims at ensuring uniform import procedures at EU level of kitchenware made of polyamide and melamine originating in or consigned from China and Hong Kong regarding the release of primary aromatic amines (PAA) and formaldehyde.

Clarifications from Guidance Document

- **Definition of plastic kitchenware:**

Polyamide and melamine plastic kitchenware are plastic kitchenware as defined by customs Combined Nomenclature CN code 3924 10 00 (tableware and kitchenware). They may consist completely of polyamide or melamine, or consist of parts intended to come into contact with food that are made of polyamide or melamine.

- **Clarifications about consignment and first point of introduction:**

Reminder: Importers or their representatives shall notify the competent authority at the first point of introduction at least two working days in advance of the estimated date and time of physical arrival of consignments originating in, or consigned from, China and Hong Kong.

A **consignment** means a quantity of polyamide or melamine plastic kitchenware covered by the same document(s) and conveyed by the same means of transport from the same third country. A consignment can arrive at the first point of introduction in one container, in several containers, or only as part of one container together with other consignments. A consignment can consist of articles that differ in shape, size, print pattern, food contact areas and/or conditions of use.

The **first point of introduction** is the point of entry of a consignment into the EU. The EC has published the national list of first points of introduction available at this link:
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/table_1st_point_21062011.pdf

- **Clarification about declaration and laboratory report:**

Reminder: Importers shall submit to the competent authorities for each consignment a declaration, which shall be in the official language, or in one of the official languages of the Member State in which the consignment is imported, accompanied with a laboratory report demonstrating that the products meet the requirements concerning the release of primary aromatic amines and formaldehyde laid down in Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

The **declaration** can be submitted on paper or in electronic form. The model is downloadable in all EU languages at this website:
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

Where onward transportation to another Member State is allowed and the goods are intended for free circulation in that Member State, it is recommended that an additional copy of the Declaration in the language of the Member State where the products are to be released be presented to competent authorities.

Continued on next page....

The **laboratory report** must be representative of the consignment. In the case of several consignments produced with the same materials under the same production conditions, one common report is accepted but it must accompany each consignment. If the consignment consists of articles with different shapes, print patterns or contact areas or different conditions of use, then the laboratory report can be attached to all the items for which it is representative. The description must be clear and pictures should be used if necessary; the batch and/or lot number of the contained articles should be mentioned.

Technical guidelines on testing the migration of primary aromatic amines from polyamide kitchenware and of formaldehyde from melamine kitchenware can be found at the EC Institute for Health and Consumer Protection website: http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m/technical-guidelines-2011

- **Onward transportation authorization:**
Only specific circumstances such as physical/space reasons and financial reasons can lead the competent authority at the first point of introduction to authorize onward transportation.
- **Scheme for release for free circulation:**
The competent authorities at the first point of introduction are in charge of the checks. Once the consignment is “Conform,” the authority should complete the Declaration and return it to the business operator responsible for the introduction. The business operator will present the Declaration to the customs authorities when the goods are intended to be released for free circulation who will take the information provided into account when deciding to release the goods for free circulation..
- **Reaction of authorities in case of non-respect of procedure or non-compliance of goods:**
 - **The consignment has not been presented for official controls:**
The competent authority should order that it be recalled or withdrawn and placed under official detention without delay and that it be then re-dispatched.
 - **A consignment which is presented to the customs authorities for its release for free circulation is not accompanied by the declaration:**
The consignment cannot be accepted for release for free circulation and the competent authorities may grant the business operator a limited time frame to provide the declaration.
 - **The documentary checks are unsatisfactory and/or incomplete:**
The competent authorities may request further information from the business operator to be provided within a timeframe. If unsatisfactory or insufficient information is provided to the competent authority, the consignment should be considered non-compliant and appropriate measures could be taken.
 - **The results of the identity and physical checks show non-compliance of the consignment:**
The competent authority should place the consignment under official detention, and then order its destruction, re-dispatching or recycling for purposes other than for food contact. The competent authority should inform the Commission through RAPEX and notify Customs of its decision.

Additional Resources

Full Text of Guidance document:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/20110614_guidelines_china_measure_en.pdf

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Newsbytes

NEWSBYTE: European Union - Publication of EN 71-1:2011 under Revised Toy Safety Directive

The European Commission has published in the *Official Journal of the European Union* (OJEU) C178 of 18 June 2011, the first list of harmonized standards under revised *Toy Safety Directive 2009/48/EC*. This list includes the recent revision of Standard EN 71-1 "*Safety of toys - Mechanical and physical properties*," dated 2011.

The revised version of EN 71-1 that has been recently published by CEN, incorporates new safety requirements from Directive 2009/48/EC as well as amendments to the previous version (A10 to A14).

As a reminder, Directive 2009/48/EC will come into application on 20 July 2011. EN 71-1:2011 is the first toy safety standard giving a presumption of compliance to the essential safety requirements of Directive 2009/48/EC.

Additional Information

The list of harmonised standards can be viewed at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:178:0004:0005:EN:PDF>

Status of Revised EN 71-2 - Safety of Toys – Flammability

EN71-2 is currently subjected to CEN formal vote. Once a formal vote is completed (closure is the end of June), the standard is expected to be published by CEN around mid-July. The European Commission will then release a revised list of standards including EN71-2:2011.

How Can Bureau Veritas Help?

We can assist with any of your testing needs to the revised EU toy standards as well as any other toy or juvenile product requirements. If you have any questions, please contact your customer service representative or visit:

<http://www.bureauveritas.fr/> ; <http://www.bureauveritas.de/cps> ; <http://www.bureauveritas.co.uk/cps>

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11NB-037, June 2011

European Commission Publishes Revised RoHS Directive

On 1 July 2011, the European Commission (EC) published revised RoHS Directive 2011/65/EU in the *Official Journal of the European Union*. The Directive of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) will enter into force on 21 July 2011. A summary of key points follows.



Dates of Application

Directive 2002/95/EC is repealed from 3 January 2013. Member States must transpose Directive 2011/65/EU into national law by 2 January 2013.

Equipment that was outside the scope of the original Directive 2002/95/EC, and which would not be in compliance with this revised Directive, may continue to be made available on the market until 22 July 2019. This means that economic operators will be able to supply an EEE for distribution, consumption or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge.

However, the revised Directive defines shorter time periods for placing on the market of certain equipment. For example, the requirements for restricted substances will apply to medical devices and monitoring and control instruments placed on the market from 22 July 2014.

Reminder: New Key Provisions

Scope

Under the revised Directive, the scope of application has been extended to **ALL electrical and electronic equipment** (including medical devices, monitoring and control instruments).

New Definitions

Some important definitions are now included while others have been modified. Some examples:

- Definitions of economic operators: "manufacturer," "importer," "distributor" ...
- Definition of "homogeneous material": Defined as one material of uniform composition throughout. Or, a material consisting of a combination of materials that can not be mechanically disjointed into different materials. This means that the materials can not be separated by mechanical actions such as unscrewing, cutting, crushing, grinding or abrasive processes,
- New definition of "electrical and electronic equipment" (EEE): Defined as equipment that is dependent on electric currents or electromagnetic fields in order to work properly and equipment for the generation, transfer and measurement of such currents and fields; designed for use with a voltage rating not exceeding 1000 volts for alternating current and 1500 volts for direct current; where "dependent" is defined as "needing electric currents or electromagnetic fields to fulfill at least one intended function."

Note: With this new definition, the determination of the electric/electronic primary function would no longer exclude such electric products as musical plush toys from the scope of the revised Directive 2002/95/EC.

Text continued on following page...

July 2011
Bulletin 11B-134

Key Requirements for Economic Operators

Overview of obligations of manufacturers:

- Create technical documentation that will show compliance with Article 4 Prevention (Restricted substances) and Annex II (current restrictions of cadmium, lead, mercury, chromium VI, PBB and PBDE);
- Implement an internal production control procedure; ensure procedures are in place for series production to remain in conformity; draw up an EC Declaration of Conformity and affix the **CE marking** on the EEE; and
- Mark electrical and electronic equipment (EEE) with the following: CE marking, equipment identification (type, batch or serial number or other element providing their identification), name, registered trade name or registered trade mark and address.

Overview of obligations of importers:

- Ensure that the manufacturers have complied with their obligations as listed above;
- Retain an available copy of the EC Declaration of Conformity for the market surveillance authorities and ensure that the technical documentation can be readily available to those authorities, upon request; and
- Ensure that the marking of EEE has been affixed by the manufacturer and that their name, registered trade name, or registered trade mark and address are affixed.

Presumption of Conformity

Materials, components and EEE for which tests and measurements have been performed to demonstrate their compliance with the requirements of Article 4 (Restricted substances), or which have been assessed in accordance with harmonised standards, (the references of which have been published in the *Official Journal of the European Union*), shall be presumed to comply with the requirements of this Directive.

Additional information

View the revised Directive 2011/65/EU:

<http://eur-lex.europa.eu/JOHtml.do?uri=OJ%3AL%3A2011%3A174%3ASOM%3AEN%3AHTML>

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BUREAU
VERITAS

European Union - Publication of EN 71-2: 2011 under Revised Toy Safety Directive

The European Commission published in the *Official Journal of the European Union* (OJEU) C215 of 21 July 2011, the updated list of harmonized standards under the revised *Toy Safety Directive* 2009/48/EC. This list includes the recent revision of EN71-2 "Safety of Toys – Flammability," dated July 2011.



Summary of Key Points of Revised EN71-2: 2011

Updated definitions or clarifications

Some definitions have been revised or added, particularly to consider the requirements of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP). As an example, EN 71-2 includes a new definition for flammable liquid: "liquid having a flash point $\geq 23^{\circ}\text{C}$ and $\leq 60^{\circ}\text{C}$." (In previous edition: values were 21°C and 5°C).

Clarifications about definition of materials with similar features

Toys to be worn on the head contain some elements that could become ignited without the child's knowledge; for example, when blowing candles on a birthday cake. Hair, pile or materials with similar features, would present the highest flammability hazard.

"Materials with similar features" are now defined as: "material having the ability to flow like hair, to hang closely to the head and continue to move on its own after the head is rotated then stopped." Materials with similar features can be free-hanging ribbons, paper, cloth strands or "other flowing elements." Anything protruding upwards, e.g. native Indian feathers on top of headwear, should not be regarded as falling into this category.

Hygiene requirements

Textile toys intended for use by children under 36 months must fulfil the safety requirements even after having been cleaned, according to new *Toy Safety Directive* 2009/48/CE. This means that flammability properties must be ensured after the toy is washed.

Clarifications about soft-filled toys

Soft-filled toys are not limited to soft-filled toys (animals and dolls) with a piled or textile surface. The revised standard now includes all soft-filled toys that can be cuddled or hugged by a child (eg. play mat). Soft-filled toys or soft-filled parts of toys which cannot be cuddled or hugged by a child during play, (examples: the soft-filled rim of a push-chair or a non-removable soft-filled mattress of a toy cot), continue to be excluded from the scope of requirements specifically applicable to soft-filled toys.

Some clarifications have also been made relative to the test flame application point.

Additional Information

The list of harmonised standards can be viewed at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:215:0029:0030:EN:PDF>

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France Publishes New Requirements for Placing Foam Puzzle Mats on the Market

France published on 22 July 2011 in the *Official Journal of the French Republic* (OJFR), a French Arrêté providing requirements for the placing on the market of foam toy “puzzle mats” that emit formamide. These requirements follow the results of a scientific study from the French Agency for Food Safety, Environment and Labor (ANSES) evaluating the health risks of formamide contained in foam puzzle mats.



Background

In December 2010, France issued a three-month ban on foam toy “puzzle mats” containing formamide. This ban was extended until 15 July 2011. Some “puzzle mats” with high levels of formamide (CAS No 75-12-7), which is classified as toxic to reproduction category 1B according to regulation (EC) No 1272/2008 (CLP), were found on the European market.

As a result, French authorities requested that ANSES perform a scientific study on formamide aimed at determining its different uses in consumer products and determining health risks for children. Some typical uses of formamide were identified as being for plasticisers or as blowing agents in the manufacture of foam products.

Recommendations from the Study Performed by ANSES

The ANSES study revealed that health risks from formamide are exclusively linked to inhalation. ANSES recommended avoiding exposure to formamide emissions from foam toy “puzzle mats” as much as possible for children less than three years of age.

- Emission of formamide into the air should be limited.
- The consumer should keep the “puzzle mat” unpacked for some days and away from young children so that the formamide emissions decrease.

In order to remove the use of formamide from such foam toys as puzzle mats and other products, it would be necessary to identify formamide’s uses, and to know precisely what its effect on health might be and to find some substitute substances.

ANSES also noted that not only puzzle mats, but also other articles (including toys), can be made from EVA foam which may contain formamide.

Continued on next page ...

Summary of Key Points of New French Arrêté

Importation and placing on the market of foam toy “puzzle mats” are forbidden until 20 July 2012 unless the manufacturer, the importer or the distributor can show that one of the three following conditions is met:

- “puzzle mat” does not contain formamide over 2 mg/kg (extraction method using acetone is described in part A of annex)
- “puzzle mat” does not emit more than 20 µg of formamide per m³ of air after 28 days (test chamber method according to ISO 16000-6 ⁽¹⁾ and EN ISO 16000-9 ⁽²⁾ with specific test parameters given in part B of annex)
- “puzzle mat” does not emit more than 40 µg of formamide per m³ of air after 7 days (test chamber method according to ISO 16000-6 and EN ISO 16000-9 with specific test parameters given in part B of annex).

(1) ISO 16000-6: 2004 - Indoor air - Determination of volatile organic compounds in indoor and test chamber air by active sampling on Tenax TA sorbent, thermal desorption and gas chromatography using MS/FID

(2) EN ISO 16000-9: 2006 - Indoor air - Determination of the emission of volatile organic compounds from building products and furnishing - Emission test chamber method

Additional Information

- The French Arrêté can be viewed at:

http://www.legifrance.gouv.fr/jopdf/common/jo_pdf.jsp?numJO=0&dateJO=20110722&numTexte=18&pageDebut=12563&pageFin=12564

- The report from ANSES can be viewed at:

<http://www.anses.fr/Documents/CHIM2010sa0302Ra-2.pdf>

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EU: New Nickel Release Test Methods Published

A new revision of European Standard EN 1811, and a new test method EN 16128, have been published. EN 1811 is a test method to determine the release of nickel from all post assemblies which are inserted into pierced parts of the human body and articles coming into direct and prolonged skin contact; EN 16128 is a new test method for determination of the release of nickel specific for spectacle frames and sunglasses. The scope of the former EN 1811:1998 + A1:2008 is now divided into: EN 1811:2011 and EN 16128:2011. This standard will be repealed by March 2013.



Background

Nickel is a common metal often combined with other metals to create alloys with increased hardness and resistance to corrosion. However, the presence of nickel in certain products which are intended to come into direct and prolonged skin contact may cause sensitization of humans to nickel and may lead to allergic reactions. Nickel released is regulated under EC 1907/2006 REACH Annex XVII, Item 27 with the following limits. EN 1811:2011 and EN 16128:2011 will be used to verify the conformity of the products to the regulation.

Products	Limit
Any post assemblies which are inserted into pierced ears and other pierced parts of the human body	0.2 $\mu\text{g}/\text{cm}^2/\text{week}$
Articles intended to come into direct and prolonged contact with the skin such as: earrings, necklaces, watch straps, and rivet buttons in garments	0.5 $\mu\text{g}/\text{cm}^2/\text{week}$

Key Changes in Test Methods

New test method EN 16128:2011

- Technically unchanged as compared to the former European Standard EN 1811:1988 + A1:2008
- Limited to spectacle frames and sunglasses in the scope

New revision of test method EN 1811:2011

- Correction factor of 0.1 was deleted from the previous version
- Measurement uncertainty must be taken into account
 - Correlation test uncertainty was found to be 46% which is given in the standard
 - Laboratories may use their own internal measurement uncertainty to evaluate the test result
 - Results within the range of uncertainties are inconclusive
 - Stricter requirement will increase failure rate

Concentration measured ($\mu\text{g}/\text{cm}^2/\text{week}$)	Limit ($\mu\text{g}/\text{cm}^2/\text{week}$)	According to EN 1811: 2011 (using 46% uncertainty for evaluation)
< 0.11	0.2	Pass
0.11 – 0.35		Inconclusive
> 0.35		Fail
< 0.28	0.5	Pass
0.28 – 0.88		Inconclusive
> 0.88		Fail
Concentration measured ($\mu\text{g}/\text{cm}^2/\text{week}$)	Limit ($\mu\text{g}/\text{cm}^2/\text{week}$)	According to EN 1811:1998 + A1:2008
≤ 2 (adjusted value: 0.2)	0.2	Pass
> 2 (adjusted value: 0.2)		Fail
≤ 5 (adjusted value: 0.2)	0.5	Pass
> 5 (adjusted value: 0.2)		Fail

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Two EU Directives Add New Fibre Name and Amend Quantitative Analysis Methods

At the end of July 2011, the European Union issued Directive 2011/73/EU that amended Annexes 1 and V of Directive 2008/121/EC, the key Directive governing the use of fibre content names. It added a new fibre name, "polypropylene/polyamide bicomponent," to the list of acceptable generic fibre names.



The addition of the new fibre required that the methods of quantitative analysis for textile fibre mixtures be amended to account for it. Therefore, the framework of Directive 96/73/EC, related to quantitative analysis, was amended by Directive 2011/74/EC and published simultaneously with 2011/73/EU.

Keypoints of Legislation

The new fibre name is "Polypropylene/Polyamide Bicomponent" and it is defined as "*a bicomponent fibre composed of between 10% and 25% by mass of polyamide fibrils embedded in polypropylene matrix.*" It becomes row No. 49 in Annex 1 of Directive 2008/121/EC. As part of the adoption of the new fibre, Annex V (list of allowed EU generic fibre names) has also been amended.

Because a new fibre type has been added to the list of allowed names, the quantitative analysis must also be addressed. Various chemical separation methods contained within Directive 96/73/EC have been amended by 2011/74/EU to take into account the new fibre. The purpose of this EU Directive is to provide the EU "official" methods for separating blends of different fibre types.

Effective Date

Since the two new amendments are Directives rather than Regulations, each member state is required to bring into force laws, regulations and administrative provisions necessary to comply with the new amendments by 30 July 2012.

Additional Information

See full details of changes in:

- Directive 2011/73/EU
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:198:0030:0031:EN:PDF>
- Directive 2011/74/EU
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:198:0032:0036:EN:PDF>

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Newsbytes

NEWSBYTE: EU Publishes List of Harmonised Standards Under the Revised Toy Safety Directive

The European Commission has published in the *Official Journal of the European Union* (OJEU) C235 of 11 August 2011, the updated list of harmonised standards under the revised *Toy Safety Directive* 2009/48/EC.

The list includes EN 62115 “Electric toys – Safety,” dated 2005 and its new amendment, EN 62115/A2, published in July 2011 by CENELEC.

As a reminder, EN71-1:2011 and EN71-2:2011 were published in OJEU C215 of 21 July 2011.

Additional Information

The list of harmonised standards can be viewed at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:235:0007:0008:EN:PDF>

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11NB-052, August 2011

REACH – Consultation on 20 New Potential SVHC

In a press release, dated 29 August 2011, the European Chemicals Agency (ECHA) invited interested parties to a public consultation on twenty new proposed Substances of Very High Concern (SVHC). Interested parties are invited to comment on these proposals by 13 October 2011. Comments will be taken into account when deciding whether the substances will be added to the actual Candidate List.



Background

Following is a list of twenty new potential SVHC candidates published by the European Chemicals Agency. After preparing dossiers for these substances, ECHA has invited interested parties to a public consultation in which they can provide comments within a timeframe of 45 days (until 13 October 2011).

After consultation, a decision will be made as to whether the substances will be added to the ECHA Candidate list. Once on the Candidate list, producers, suppliers, importers or retailers must provide business clients and consumers (upon request) information on the safe use of any product containing the SVHC that exceeds 0.1% (w/w).

Two substances (Aluminosilicate refractory ceramic fibres and Zirconia aluminosilicate refractory ceramic fibres) were already included in the ECHA candidate list and were re-evaluated to cover a wider substance definition.

List of Potential New SVHC for Consultation

Substance name	EC number (CAS number)	Proposed property	Remarks*
Dichromium tris(chromate)	246-356-2 (24613-89-6)	CMR (carcinogenic)	Main use in mixtures for metal surface treatment in aeronautic/ aerospace, steel and aluminum coating sectors.
Potassium hydroxyoctaoxodizincate di-chromate	234-329-8 (11103-86-9)	CMR (carcinogenic)	Main use in coatings in aeronautic/ aerospace, steel and aluminum coil coating and vehicle coating sectors.
Pentazinc chromate octahydroxide	256-418-0 (49663-84-5)	CMR (carcinogenic)	Main use in coatings in vehicle coating and aeronautic / aerospace sectors.
Aluminosilicate Refractory Ceramic Fibres (RCF)	-	CMR (carcinogenic)	Refractory ceramic fibres are used for high-temperature insulation, almost exclusively in industrial applications (insulation of industrial furnaces and equipment, equipment for the automotive and aircraft/aerospace industry) and in fire protection (buildings and industrial equipment).
Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)	-	CMR (carcinogenic)	
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1 (25214-70-4)	CMR (carcinogenic)	Raw material for production of other substances. Minor use as hardener for epoxy resins, e.g. in rolls, pipes and moulds, and adhesives.
Bis(2-methoxyethyl) phthalate	204-212-6 (117-82-8)	CMR (toxic for reproduction)	Main uses in the past were as plasticiser in polymeric materials and paints, lacquers and varnishes, including printing inks.
2-Methoxyaniline; o-Anisidine	201-963-1 (90-04-0)	CMR (carcinogenic)	Main use in production of dyes for tattooing and coloration of paper, polymers and aluminum foil.
4-(1,1,3,3-tetramethyl butyl)phenol, (4-tert-Octylphenol)	205-426-2 (140-66-9)	equivalent level of concern	Main use in production of polymer preparations and ethoxylates. Further use as a component in adhesives, coatings, inks and rubber articles.
1,2-Dichloroethane	203-458-1 (107-06-2)	CMR (carcinogenic)	Main use in production of other substances. Minor use as solvent in the chemical and pharmaceutical industry.

...More information on the following page...

Substance Name	EC Number (CAS Number)	Proposed property	Remarks*
Bis(2-methoxyethyl) ether	203-924-4 (111-96-6)	CMR (toxic for reproduction)	Used as solvent or process chemical in various applications. Used also as solvent for battery electrolytes and in other products (sealants, adhesives, fuels and automotive care products).
Arsenic acid	231-901-9 (7778-39-4)	CMR (carcinogenic)	Used to remove gas bubbles from ceramic glass melt and in the production of laminated printed circuit boards.
Calcium arsenate	231-904-5 (7778-44-1)	CMR (carcinogenic)	Present in complex raw materials imported for manufacture of copper, lead and other precious metals. Main use as precipitating agent in copper smelting and to manufacture diarsenic trioxide.
Trilead diarsenate	222-979-5 (3687-31-8)	CMR (carcinogenic & toxic for reproduction)	Used In complex raw materials imported for production of copper, lead and other precious metals. During metallurgical refinement process, it is transformed to calcium arsenate and diarsenic trioxide.
N,N-dimethylacetamide (DMAC)	204-826-4 (127-19-5)	CMR (toxic for reproduction)	Used as solvent in production of other substances and fibres for clothing and other applications. Also used as reagent, and in products (industrial coatings, polyimide films, paint strippers and ink removers).
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9 (101-14-4)	CMR (carcinogenic)	Used as curing agent in resins and in the production of polymer articles and production of other substances. Further use in construction and arts.
Phenolphthalein	201-004-7 (77-09-8)	CMR (carcinogenic)	Main use as pH indicator (laboratory), for the production of pH-indicator paper and in medicinal products.
Lead azide, Lead diazide	236-542-1 (13424-46-9)	CMR (toxic for reproduction)	Use as initiator or booster in detonators (civilian and military) and as initiator in pyrotechnics.
Lead styphnate	239-290-0 (15245-44-0)	CMR (toxic for reproduction)	Use as a primer for small calibre and rifle ammunition. Other common uses are in munition pyrotechnics, powder actuated devices and detonators for civilian use.
Lead dipicrate	229-335-2 (6477-64-1)	CMR (toxic for reproduction)	Explosive compound like lead diazide and lead styphnate and may be used in detonator mixtures together with the two other mentioned lead compounds.

Note: * Remarks are based on information in the Annex XV dossier by the submitting EU Member State.

Additional Information

- Consultation: http://echa.europa.eu/consultations/authorisation/svhc/svhc_cons_en.asp
- Press Release: http://echa.europa.eu/news/pr/201108/pr_11_20_svhc_consultation_20110829_en.asp

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Sweden Proposes Restriction on Nonylphenol and Nonylphenol Ethoxylates in the European Union

The Swedish Chemicals Agency has announced its intention to propose the restriction of 4-nonylphenol (CAS no. 84852-15-3), branched Nonylphenol (CAS no. 25154-52-3) and Nonylphenol ethoxylates on textile and leather articles on September 2, 2011. According to the ECHA restriction process, the restriction dossiers with information on hazards and risk, alternatives and justification for restrictions at the EU level should be submitted by August 3, 2012. Once they are restricted, articles containing these hazardous substances also will be controlled and eliminated from the EU market. The proposed restrictions come as a result of two recent reports published by Greenpeace which profile the problem of toxic water pollution resulting from the release of toxic chemicals by the textile industry. Sweden is the first country to propose restrictions for these two chemicals on articles in the EU.

Recent Greenpeace Reports

On July 13, Greenpeace released its first report "Dirty Laundry," which found hazardous chemicals including nonylphenol (NP) in samples of wastewater discharged from two Chinese textile processing facilities with links to a number of well-known global clothing brands, to start its "Detox" campaign to call on major brands to remove toxic chemicals from their supply chain.

On August 23, Greenpeace released its second report "Dirty Laundry 2: Hung Out to Dry." According to this report, nonylphenol ethoxylates (NPEs) were found in two thirds of 78 clothing and fabric-based shoes sold internationally. It reveals strong evidence that NPEs were applied as surfactants or other functions during the production of these textile products. Greenpeace once again urged industry and governments to take actions and make policies to eliminate hazardous chemicals such as NPEs or NP for a toxic-free future.

Toxicity and usage of Nonylphenol (NP) and Nonylphenol Ethoxylates (NPEs)

Substance	Toxicity	Usage
Nonylphenol (NP)	<ul style="list-style-type: none"> • persistent in the aquatic environment • moderately bioaccumulative • extremely toxic to aquatic organisms 	Used in the textiles industry in cleaning and dyeing processes and manufacture of NPEs
Nonylphenol ethoxylates (NPEs)	<ul style="list-style-type: none"> • highly toxic to aquatic organisms • can degrade into NP in the environment 	Used as surfactants, emulsifiers, dispersants and wetting agents in a variety of industrial and consumer applications including textile manufacture and industrial detergents

Current EU Regulation

Currently in the EU, there are no requirements restricting NPEs content on articles. The REACH regulation only restricts the use of NP and NPEs in textiles and leather processing as a substance or in mixtures in concentrations equal to or greater than 0.1% by weight (1000ppm).

Other Information

ECHA intention list for restriction:

http://echa.europa.eu/chem_data/reg_int_tables/reg_int_en.asp?substance_type=Restriction&substance_stat e=current

Greenpeace report: <http://www.greenpeace.org/international/en/publications/reports/>

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REACH: Danish Proposal for New Phthalates Restrictions

On 19 September 2011, the European Chemicals Agency (ECHA) published a proposal made by Denmark that would amend the REACH Regulation. The proposal would restrict four phthalates in articles intended for indoor use and articles that may come into direct contact with the skin or mucous membranes. Interested parties are invited to provide comments during the public consultation period.



Background

Currently, the use of phthalates DEHP (bis(2-ethylhexyl) phthalate), DBP (dibutyl phthalate) and BBP (benzyl butyl phthalate) is restricted in toys and childcare articles under the REACH Regulation Annex XVII, entry 51. Denmark's proposal would add restrictions for the phthalate DIBP (diisobutyl phthalate) and widen the restrictions for DEHP, DBP and BBP to articles intended for indoor use and articles that may come into direct contact with the skin or mucous membranes.

ECHA has invited stakeholders to publicly comment on the restriction report prepared by Denmark. The consultation period will end on 16 March 2012. The Committee's final opinions are scheduled to be available by 16 September 2012.

Proposed Restriction

The draft restriction would prohibit the placing on the market of articles intended for use indoors and articles that may come into direct contact with the skin or mucous membranes containing one or more of the phthalates DEHP, DBP, BBP and DIBP in a concentration greater than 0.1 % by weight of any plasticised material.

Note: The term "use" is defined as meaning any placing, keeping, storing, hanging, laying, applying, mounting, fixing or other application indoors of articles.

The draft restriction includes a transition period allowing depletion of stocks (e.g., 12 months from the date of entry into force of the restriction).

To accommodate existing legislation, the restriction report recommends the following exemptions:

- The ban should not apply to toys. Toys containing DEHP, DBP and BBP are already covered by an existing restriction (REACH Annex XVII, entry 51) and Directive 2009/48/EC on the Safety of Toys will ban the use of CMR (carcinogenic, mutagenic or toxic for reproduction) substances of category 1A, 1B or 2 in toys from 20 July 2013.
- The ban should not apply to childcare articles containing DEHP, DBP and BBP as they also are covered by REACH restriction of Annex XVII, entry 51.
- The ban should not apply to articles intended to come into contact with food covered by Regulation (EC) No 1935/2004 and specific measures under this regulation, e.g. Commission Regulation (EU) No 10/2011.

Continued on next page

The report contains a non-exhaustive list of examples of articles that are covered and of articles that are not covered by the proposal.

Non-exhaustive list of articles to be covered by the proposal:

- Childcare articles (for DIBP)
- Interiors of cars, trains, ships, boats, aircrafts, etc.
- Wall covering and flooring
- Insulation on wires used indoors
- Insulation on cables used indoors in unsealed applications
- Coated fabric and film/sheets used for furniture
- Coated fabric and film/sheets used for bags and briefcases/suitcases and similar items
- Coated fabrics and film/sheets used for tablecloths, curtains, shower curtains and similar items
- Carpet tiles/squares produced with foam as back cover
- Water mattresses and air mattresses
- Wallpaper/tapestry
- Footwear
- Textiles
- Bathing equipment (swim jackets, wings, belts and pools - inflatable and others)
- Erasers
- Balance balls for playing (not toys) and physical exercises
- Sex toys

Non-exhaustive list of articles not to be covered by the proposal:

- Insulation on wires and cables used outdoors
- Large-scale stationary industrial tools
- Roofing material
- Car undercoating
- Garden tools which only have phthalates contained in other parts than the handle

Justifications for the Restriction

DEHP, DBP, BBP and DIBP are classified as toxic to reproduction (Repr. 1B) and are considered to be endocrine disruptors. Phthalates are found primarily in PVC as softeners but also can be found in other plastics in low concentrations. Phthalates also can be used in several different applications (e.g., dispersions, paints and varnishes, as emulsifiers, repellents and carrier fluids in biocides, in cosmetics and perfumes). Due to their widespread use in these applications, combined exposure may occur through inhalation (indoor air), ingestion (via food, toddlers suckling on plastic materials, etc.) and mucous membranes and dermal contact.

Additional Information

ECHA press release:

http://echa.europa.eu/news/na/201109/na_11_39_phthalates_en.asp

Information note on restriction report:

http://echa.europa.eu/doc/restrictions/information_note_dk4phthalates.pdf

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Newsbytes

NEWSBYTE: European Commission Proposes Draft Regulation amending Regulation (EU) No 10/2011

The European Commission has proposed a new Regulation amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

This draft regulation, notified under number SPS-EEC-410-11, will be subjected to comments by members of the WTO (World Trade Organization) until 15 October 2011.

It will update Annex I to Regulation (EU) No 10/2011 by:

- including 15 new substances,
- amending the restrictions and specifications of six authorised substances (**Note: The specific migration limit for Melamine is lowered from 30 mg/kg to 2.5 mg/kg.**), and
- correcting mistakes in the listing of two substances.

It should be applicable on 2 January 2012. However, in order to limit burden to business operators, authorities have introduced a disposition allowing exhaustion of stocks for non-compliant products placed on the market until 1 January 2013.

Additional Information

The draft regulation can be viewed at:

http://www.google.fr/url?sa=t&source=web&cd=2&ved=0CCQQFjAB&url=http%3A%2F%2Fmembers.wto.org%2Fattachments%2F2011%2Fsps%2FEEC%2F11_2726_00_e.pdf&ei=SaxgTqaRDszDswa324zeDQ&usq=AFQjCNGb7p13y0RRr17RWNSitmVptzx-kA

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11NB-055, September 2011

NEWSBYTE: Two New RoHS Exemptions Added by European Commission

The Decision 2011/534/EU of the European Commission amending the list of exemptions for the RoHS Directive (2002/95/EC) on the restriction of the use of certain hazardous substances in electrical and electronic equipment was published in the *Official Journal of the European Union* L234 of 10 September 2011.

The RoHS Directive bans the placing on the EU market of new electrical and electronic equipment containing more than the permitted levels of lead, cadmium, mercury, chromium VI, PBB and PBDE. Some exemptions are granted for technical reasons. For the purposes of adapting to technical progress, two exemptions for applications containing lead or cadmium were added.

The Annex to Directive 2002/95/EC is amended as follows:

(a) the following point 7(c)-IV is inserted:

7(c)-IV	Lead in PZT based dielectric ceramic materials for capacitors being part of integrated circuits or discrete semiconductors	
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(b) the following point 40 is added:

40	Cadmium in photoresistors for analogue optocouplers applied in professional audio equipment	Expires on 31 December 2013
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Additional Information

The Commission Decision can be viewed at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:234:0044:0045:EN:PDF>

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11NB-059, September 2011



Newsbytes

NEWSBYTE: EU Announces Ban of Dimethylfumarate under EC 1907/2006

In September 2011, the European Commission notified the World Trade Organization on an amendment of the Regulation EC 1907/2006 Annex XVII for Dimethylfumarate (CAS 624-49-7) which will come into force in March 2012. The amendment will make permanent the current temporary prohibition 2009/251/EC for Dimethylfumarate.

Dimethylfumarate (DMFu) is a biocide and has antifungal properties. It can be used to prevent mould growth and has been found to cause skin sensations (contact dermatitis) even at very low concentrations. As a result, several reports were published in the EU's Rapid Alert System for dangerous consumer products (RAPEX). Therefore in 2009, the EU temporarily banned all types of consumer articles containing DMFu. The limit is set as 0.1 mg/kg which applies for each component part of the article. No transition period has been deemed necessary to the permanent ban since the temporary ban on DMFu already has existed since 2009.

Text of the draft Commission Decision:

http://ec.europa.eu/enterprise/tbt/index.cfm?fuseaction=Search.getProject&Country_ID=EEC&num=403&dspLang=EN&nextpage=1&basdatedeb=&basdatefin=&bas Pays=&bas Pays2=EEC&basnotifnum=400&basnotifnum2=405&bastype Pays=ANY&baskeywords=&fromform=viewKeyword&project_type_num=1&project_type_id=1&lang_id=EN

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11NB-065, October 2011

GS Mark - List of PAHs Expands by Two Substances

During the 67th meeting of the German Central Experience Exchange Circle (ZEK), the PAH-substance list was expanded from 16 to 18 PAHs. The addition of these two PAHs to the substance list completes the German recommendation to restrict the eight polycyclic aromatic hydrocarbons (PAH) in consumer goods. Therefore, in the future there will be requirements for 18 PAHs to fulfill in order to receive the German GS mark.



Background

During the manufacturing process of plastics, mineral oils are used that often contain polycyclic aromatic hydrocarbons (PAHs) as contaminants. PAHs also can be part of carbon black which is used as a colouring and filling agent for plastics and rubber.

Apart from other requirements, there are currently requirements for 16 PAHs which have to be fulfilled for the GS mark to be granted. During the 67th meeting of the ZEK on September 28th and 29th, an expansion of the PAH-substance list suggested by the Commission for Technical Work Equipment and Consumer Goods (AtAV) was accepted, increasing the list of PAHs from 16 to 18 substances. The two new substances are Benzo[j]fluoranthene and Benzo[e]pyrene. These substances are, among others, named for regulation under REACH, but have not been regarded so far in the context of the GS mark.

After the official publishing of this expansion by the Central Department of the Federal States for Safety Features (ZLS), there will be a transition period of six months after which the two new substances will have to be taken into account during the granting of the GS mark.

Note: In addition, Germany also sent a recommendation to the European Commission about the restriction of the eight PAHs through REACH in June 2010. However, the list of the 16 PAHs and those suggested by Germany were not identical and are still under consideration.

UPDATED PAH-SUBSTANCE LIST

Name of the substance	CAS-number	Part of the German Recommendation	EPA PAH	New PAH (Part of the German GS mark)
Benzo[a]pyrene (BaP)	50-32-8	X	X	X
Benzo[a]anthracene	56-55-3	X	X	X
Chrysene	218-01-9	X	X	X
Benzo[b]fluoranthene	205-99-2	X	X	X
Benzo[k]fluoranthene	207-08-9	X	X	X
Dibenzo[a,h]anthracene	53-70-3	X	X	X
Benzo[j]fluoranthene	205-82-3	X		X
Benzo[e]pyrene	192-97-2	X		X
Naphthalene	91-20-3		X	X
Acenaphthylene	208-96-8		X	X
Acenaphthene	83-32-9		X	X
Fluorene	86-73-7		X	X
Phenanthrene	85-01-8		X	X
Anthracene	120-12-7		X	X
Fluoranthene	206-44-0		X	X
Pyrene	129-00-0		X	X
Indeno(1,2,3-c,d)pyrene	193-39-5		X	X
Benzo(g,h,i)perylene	191-24-2		X	X

Bureau Veritas Solutions and Services

Bureau Veritas offers a wide range of chemical management solutions to assist you in complying with the 18 PAH restriction. Any comments and/or questions, please contact your local customer service representative or email to: marketingmail@hk.bureauveritas.com

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REMINDER: The New Version of the Norms of Transformers, EN 61558:2009 will Replace EN 61558:1997 on 1 July 2012

In 2012, the new version of the Norms of Transformers, EN 61558:2009 will replace the old one, EN 61558:1997. The DOW (Date of Withdrawal) for the old version is 1 July 2012.

IMPORTANT: These standard modifications will become compulsory from the date of withdrawal and the new versions will apply.

CATEGORY	STANDARDS	PRODUCTS	CURRENT VERSION	DOW CURRENT VERSION	
			NEW VERSION		
Lighting	EN 61558-2-6	Transformer	EN 61558-2-6:1997	July 1	2012
			EN 61558-2-6: 2009		

Standards: Old version: EN 61558-2-6:1997 New version: EN 61558-2-6:2009

Summary of Differences between the Two Versions:

- Clause 8 Marking and other information – sub clause 8.11**

1. The symbol of Class III construction: old one:



new one:



2. The symbol of indoor use only is determined:



- Clause 9 Protection against contact with hazardous live parts**

New requirement by new version: For transformers with a primary supply plug, the pins of the plug shall not be hazardous live measured 1s after withdrawal of the plug. For transformers without a primary supply plug, the terminals provided for connecting the transformer to the supply source shall not be hazardous live measured 5s after disconnection of the supply source.

- Clause 18 Insulation resistance, dielectric strength and leakage current**

New version: Adds sub clause 18.5: Touch current and protective earth conductor current; the touch current and protective earth conductor current should be measured.

Affects and solutions:

- The valid standard checked should be EN 61558-2-6:2009 and EN 61558-1:2005+A1:2009.
- The history test report or license checked by the old version can be updated to the new one by examining relevant additional clauses, like construction check and temperature rise, etc.

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Xiamen: 86-592-2964266

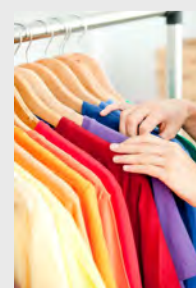
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European Union Publishes a New Regulation for Fibre Content Labelling and Testing

The European Union published a new regulation in its Official Journal on the 18th of October 2011 that combines fibre content labelling and fibre content testing into one single piece of legislation. There are several new implications involved both for fibre content labelling and testing of items falling within the scope of this new legislation. The new legislation is Regulation (EU) No. 1007/2011.

One of the most significant issues is that this legislation is now a **regulation**, which means that it will apply to all members of the European Union without the need for member states to create their own national legislation to enact the new requirements. The regulation becomes effective on 8 May 2012. Please see details below.



Background

Since both the Fibre Composition Labelling and Fibre Composition Directives have been amended a number of times, the new regulation combines all the amendments and framework legislation into a single document. As a result of this new legislation, Directives 73/44/EEC (Ternary Fibre Mixtures), 96/73/EC (Binary Fibre Mixtures) and 2008/121/EC (labelling) are repealed. The new Regulation comes into effect on 8 May 2012. Any textile products coming onto the market after 8 May 2012 will have to comply with the new regulation. Goods on the market before 8 May 2012 and not compliant with the new regulation may continue to be made available on the market until 9 November 2014.

Summary of Requirements

Non-textile parts of animal origin: Article 12 in the new regulation includes a significant change with regard to labelling of textile products containing non-textile parts of animal origin. The presence of these parts is required to be marked as "*Contains non-textile parts of animal origin*" on the labelling or marking of products containing such parts whenever they are made available on the market. Obvious items falling under this remit are leather and real fur. The reasoning behind this change is that consumers will then know, for example, if items contain real fur or faux fur.

Language for labelling or marking: Article 16 Paragraph 3 underlines the fact that unless a member state provides otherwise: "*The labelling or marking shall be provided in the official language or languages of the Member State of the territory of which the products are made available to the consumer.*"

Visibility of labelling: Also in Article 16 regarding the use of textile fibre names, the new regulation recognises that the information regarding labelling must be clearly visible where the product is made available on the market. This has always been the case, but the new regulation now includes purchasing by electronic means, such as via the internet, so the fibre content must be visible in these circumstances.

Other points of note are as follows:

- **Fibre content labelling:** The new labelling legislation has removed a reference from the previous directive requiring mandatory labelling for fibre composition of warm linings of gloves, mitts, and mittens that comprise 80% by weight of the complete article.
- **New fibre names:** A new procedure has been added into the new regulation regarding the process for adding a new fibre name into the list of allowed designations in Annex 1 of the new regulation.

Continued on next page

- **Mandatory labelling or marking exemptions:** There are changes to the list of textile products that cannot be made subject to mandatory labelling or marking. In particular, felts and felt hats have been removed from the list of items not subject to mandatory labelling, so they now require to be labelled with regard to fibre content.
- **Modified descriptions:** Some other products in Annex 111 of the old legislation regarding this issue of exemption (now Annex V in the new legislation) have their descriptions modified, e.g. what was “*Containers which are soft and without foundation – Saddlery of Textile Materials*” has now changed to “*Fancy goods and saddlery of Textile Materials.*”
- **Expansion of items in Annex VII:** The new regulation contains an Annex VII that tabulates components of products that do not need to be taken into account for the determination of fibre composition. Although there was a similar piece of information in the text of the old labelling directive, the new regulation, in addition to the tabulation aspect, now has been expanded to include items not contained within the previous directive.

Note: New items listed under Annex VII include both socks and tights. For socks, under the new regulation, additional elastic yarns used in the cuff, and stiffening and reinforcing yarns used in the toe and heel can be excluded from fibre content determination. In the case of tights, additional elastic yarns used in the belt, and stiffening yarns and reinforcement yarns used in the toe and heel also can be excluded from the determination of fibre composition.

- **Items to be addressed:** There is also a requirement in Article 24 of the new regulation for the EU Commission to report to the EU Parliament by the 30th of September 2013 on the following issues:
 - Origin Marking
 - A harmonised EU wide care-code labelling system
 - An EU wide uniform code for sizing of garments
 - An indication of allergenic substances
 - Electronic labelling and other new technologies, and the use of language independent symbols or codes for the identification of fibres.

Please note: The above information is only a high-level summary of 64 pages of European legislation. Full detail can only be found by an in-depth examination of the new regulation.

Additional Information:

Full text of the legislation from the *Official Journal of the European Union*

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:272:0001:0064:EN:PDF>

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Denmark Announces Dossier regarding Hexavalent Chromium in Leather

The European Chemicals Agency (ECHA) received a notice of intention by Denmark to submit a dossier regarding the restriction of Chromium VI in leather with skin contact based on its allergic effects. The dossier according to Annex XV of the REACH-directive is expected to be submitted in January 2012. If approved by the ECHA, Chromium VI could become regulated under Annex XVII in the future for products placed on the European market.



Background

Denmark has notified ECHA of its intentions to submit a dossier according to Annex XV of REACH (EC 1907/2006) regarding restrictions of Chromium VI in leather with skin contact. According to the proposal, Chromium VI would be included to Annex XVII of the Regulation EC 1907/2006. The dossier includes suggestions for limits as well as field of application and is expected to be submitted by 19 January 2012 according to the ECHA "Registry of intentions."

The proposal comes as the result of a survey conducted by the Danish Ministry of the Environment which analyzed the contents and the sensitization potential of Chromium in leather shoes. Both Chromium III and Chromium VI were taken into account by the study. The results indicated that 50 of 60 reviewed shoes contained Chromium. Migration studies of 18 shoes determined that 44% of the reviewed shoes emitted Chromium VI. The Chromium VI-release of three of the 18 samples was more than 10 mg/kg. Furthermore, sandals seemed to be over-represented in the group of Chromium VI-containing shoes. The study also outlined that Chromium VI has a sensitizing effect and can cause skin reactions with allergic people.

No conclusion could be drawn on the influence of Chromium III on sensitization. Chromium III is used during the tanning process of 80% of the world's leather production. Under certain production and storage circumstances, Chromium III can transform to Chromium VI. The content of Chromium VI in leather with skin contact is already prohibited in concentrations above limits of detection in leather products with skin contact in Germany according to the Consumer Goods Ordinance, Annex 5, Nr.2 (Bedarfsgegenständeverordnung). However, currently there is no such regulation concerning the whole of the EU.

Additional information:

Danish survey and health assessment of Chromium in leather shoes
<http://www2.mst.dk/udgiv/publications/2011/08/978-87-92779-22-9.pdf>

ECHA "Registry of intentions"

http://echa.europa.eu/chem_data/reg_int_tables/reg_int_en.asp?substance_type=Restriction&substance_state=current

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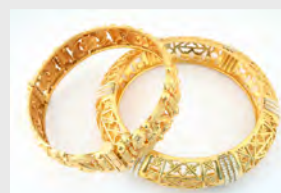
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Proposed EU Restriction on Lead in Jewellery – RAC and SEAC Finalize Opinions

In 2010, France proposed a restriction of lead in jewellery under REACH Annex XVII (EC 1907/2006). As part of this process, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) have finalized their opinions on the proposed restriction, so that the EU Commission can now prepare a decision on restricting lead in jewellery. Proposed limits are 0.05% total content and/or 0.05 µg/cm²/hour.



Background: Due to several serious incidents that have occurred with lead-containing children's products, France proposed a restriction on lead and lead compounds in jewellery under REACH Annex XVII and issued an Annex XV Dossier which was subject to a public consultation which ended in December 2010. Following the official process of implementing a new restriction, the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) issued a report with their opinions on the Annex XV dossier.

Proposal: Both, RAC as well as SEAC agreed on the need to restrict lead under REACH Annex XVII. Even so, both committees have different proposals for the restriction:

RAC proposal:

Lead and its compounds shall not be used or placed on the market in:

- i) Metallic and non-metallic parts of jewellery articles if the lead concentration is equal to or greater than 0.05% by weight of the part;
- ii) The paragraph above does not apply when it can be demonstrated that the rate of lead release from the jewellery article or any part thereof does not exceed 0.05 µg/cm²/hr (0.05 µg/g per hr).

SEAC proposal:

Lead and its compounds:

1. Shall not be used or placed on the market if the concentration of lead is equal to or greater than 0.05% by weight of any individual part of the jewellery articles and hair accessories, including:
 - bracelets, necklaces and rings, piercing jewellery, wrist watches and wrist-wear, brooches and cufflinks.
2. Paragraph 1 shall not apply to:
 - i) "Full Lead Crystal" and "Lead Crystal" as defined in Annex I in Council Directive 69/493/EEC;
 - ii) internal components of watch timepieces inaccessible to consumers;
 - iii) non-synthetic or reconstructed precious and semiprecious stones (CN code 7103) unless they have been treated with lead or its compounds or mixtures contain these substances;
 - iv) enamels defined as vitrifiable products resulting from the fusion, vitrification or sintering of minerals melted at a temperature of at least 500 °C.
3. Paragraph 1 shall not apply to jewellery articles placed on the market before 12 months after the entry into force and jewellery articles produced before 10 December 1961.

The European Chemical Agency (ECHA) will send these two opinions to the European Commission which will make the decision as whether to introduce the suggested restriction in Annex XVII of the REACH regulation.

Additional Information

- Background document of RAC and SEAC
http://echa.europa.eu/doc/reach/restrictions/background_doc_lead_and_its_compounds.pdf

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REACH – 20 New Substances of Very High Concern (SVHC)

In a press release, dated 19 December 2011, the European Chemicals Agency (ECHA) introduced 20 new Substances of Very High Concern (SVHC). Two substances (refractory ceramic fibres) were already included in the ECHA Candidate List and were re-evaluated to cover a wider substance definition. Therefore, the ECHA Candidate List is extended to 73 substances.



Background

After inviting interested parties to comment on the addition of the 20 new SVHC, the Member States Committee agreed on including the proposed substances to the ECHA Candidate List. Two substances (Aluminosilicate refractory ceramic fibres and Zirconia aluminosilicate refractory ceramic fibres) were already included in the ECHA Candidate List and were re-evaluated to cover a wider substance definition.

Once on the Candidate List, producers, suppliers, importers or retailers are required to provide business clients and consumers (on request) information on the safe use of any product containing the SVHC that exceeds 0.1% (w/w).

List of New SVHC

Substance name	EC number (CAS number)	Proposed property	Remarks*
Dichromium tris(chromate)	246-356-2 (24613-89-6)	CMR (carcinogenic)	Main use in mixtures for metal surface treatment in aeronautic/ aerospace, steel and aluminum coating sectors.
Potassium hydroxyoctaoxo dizincatedichromate	234-329-8 (11103-86-9)	CMR (carcinogenic)	Main use in coatings in aeronautic/ aerospace, steel and aluminum coil coating and vehicle coating sectors.
Pentazinc chromate octahydroxide	256-418-0 (49663-84-5)	CMR (carcinogenic)	Main use in coatings in vehicle coating and aeronautic / aerospace sectors.
Aluminosilicate Refractory Ceramic Fibres (RCF)**	<i>index number</i> 650-017-00-8	CMR (carcinogenic)	Refractory ceramic fibres are used for high-temperature insulation, almost exclusively in industrial applications (insulation of industrial furnaces and equipment, equipment for the automotive and aircraft/aerospace industry) and in fire protection (buildings and industrial equipment).
Zirconia Aluminosilicate Refractory Ceramic Fibres (Zr-RCF)**	<i>index number</i> 650-017-00-8	CMR (carcinogenic)	
Formaldehyde, oligomeric reaction products with aniline (technical MDA)	500-036-1 (25214-70-4)	CMR (carcinogenic)	Raw material for production of other substances. Minor uses as hardener for epoxy resins, e.g., in rolls, pipes and moulds, and adhesives.
Bis(2-methoxyethyl) phthalate	204-212-6 (117-82-8)	CMR (toxic for reproduction)	Main uses in the past were as plasticiser in polymeric materials and paints, lacquers and varnishes, including printing inks.
2-Methoxyaniline; o-Anisidine	201-963-1 (90-04-0)	CMR (carcinogenic)	Main use in production of dyes for tattooing and coloration of paper, polymers and aluminum foil.
4-(1,1,3,3-tetramethyl butyl)phenol	205-426-2 (140-66-9)	equivalent level of concern	Main use in production of polymer preparations and ethoxylates. Further use as a component in adhesives, coatings, inks and rubber articles.
1,2-Dichloroethane	203-458-1 (107-06-2)	CMR (carcinogenic)	Main use in production of other substances. Minor use as solvent in the chemical and pharmaceutical industry.

Notes:

* Remarks are based on information provided in the Annex XV dossier by the submitting EU Member State.

**For details, please refer to <http://echa.europa.eu/web/guest/candidate-list-table>.

Substance Name	EC Number (CAS Number)	Proposed property	Remarks*
Bis(2-methoxyethyl) ether	203-924-4 (111-96-6)	CMR (toxic for reproduction)	Used as solvent or process chemical in various applications. Used also as solvent for battery electrolytes, and in other products (sealants, adhesives, fuels and automotive care products).
Arsenic acid	231-901-9 (7778-39-4)	CMR (carcinogenic)	Use to remove gas bubbles from ceramic glass melt and in the production of laminated printed circuit boards.
Calcium arsenate	231-904-5 (7778-44-1)	CMR (carcinogenic)	Present in complex raw materials imported for manufacture of copper, lead and other precious metals. Main use as precipitating agent in copper smelting and to manufacture diarsenic trioxide.
Trilead diarsenate	222-979-5 (3687-31-8)	CMR (carcinogenic & toxic for reproduction)	In complex raw materials imported for production of copper, lead and other precious metals. During metallurgical refinement process it is transformed to calcium arsenate and diarsenic trioxide.
N,N-dimethylacetamide (DMAC)	204-826-4 (127-19-5)	CMR (toxic for reproduction)	Used as solvent in production of other substances and fibres for clothing and other applications. Also used as reagent, and in products (industrial coatings, polyimide films, paint strippers and ink removers).
2,2'-dichloro-4,4'-methylenedianiline (MOCA)	202-918-9 (101-14-4)	CMR (carcinogenic)	Used as curing agent in resins and in the production of polymer articles and production of other substances. Further use in construction and arts.
Phenolphthalein	201-004-7 (77-09-8)	CMR (carcinogenic)	Main use as pH indicator (laboratory), for the production of pH-indicator paper and in medicinal products.
Lead azide, Lead diazide	236-542-1 (13424-46-9)	CMR (toxic for reproduction)	Use as initiator or booster in detonators (civilian & military) and as initiator in pyrotechnics.
Lead styphnate	239-290-0 (15245-44-0)	CMR (toxic for reproduction)	Use as a primer for small calibre and rifle ammunition. Other common uses are in munition pyrotechnics, powder actuated devices and detonators for civilian use.
Lead dipicrate	229-335-2 (6477-64-1)	CMR (toxic for reproduction)	Explosive compound like lead diazide and lead styphnate and may be used in detonator mixtures together with the two other mentioned lead compounds.

Note: * Remarks are based on information provided in the Annex XV dossier by the submitting EU Member State.

Additional Information

Press Release:

http://echa.europa.eu/web/guest/view-article/-/journal_content/a5533137-4976-4054-b8e8-da4a5b3dd623

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Newsbytes

NEWSBYTE: French National Assembly Passes Ban of Bisphenol A in All Food Contact Packaging

On 12 October 2011, the French National Assembly passed a bill by 348 votes to two that would ban all food contact packaging, containers or utensils containing bisphenol A (BPA) effective 1 January 2014. This is the first step of the French prohibition procedure. Before the ban becomes final law, it will need to be passed by the French Senate. A date has not yet been set for the French Senate to vote on the ban.

The bill would amend French law No 2010-729 of 30 June 2010 relative to the ban of baby bottles made from BPA and expand the scope of the ban to include all food packaging containers and utensils.

For food contact packaging, containers or utensils which are intended for children under three years of age, the ban would start one year earlier on 1 January 2013. The Assembly would also require the usage of health warning labels on all food packaging containing BPA to discourage use of these products by pregnant women and children under three.

The French Agency for Food Safety, Environment and Labor (ANSES) is expected to issue a report on potential substitutes for BPA. The French Government will forward this report to the French Parliament by 31 October 2012 at the latest.

Additional Information

The notice can be viewed at (in French): <http://www.assemblee-nationale.fr/13/pdf/ta/ta0747.pdf>

Reports from ANSES dated September 2011: Health effects of bisphenol A – Uses of bisphenol A (in French): <http://www.anses.fr/Documents/CHIM-Ra-BisphenolA.pdf>

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If you have any questions, please contact your customer service representative or visit: www.bureauveritas.fr, www.bureauveritas.co.uk/cps or www.bureauveritas.de/cps

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11NB-069, December 2011

NEWSBYTE: GS Mark – PAHs List Officially Expanded

On 29 November 2011, the Central Department of the Federal States for Safety Features (ZLS) officially announced the list of polycyclic aromatic hydrocarbons (PAHs) expanded from 16 to 18 PAHs for GS Mark Certification. The two newly added PAHs are Benzo[j]fluoranthene and Benzo[e]pyrene. Although the number of PAHs has increased, the total PAHs limit remains the same (see Table 1).

Table 1: Limits for PAHs levels in three different risk categories:

Parameter	Category 1: Materials intended to be in contact with the mouth or materials of a toy intended to be in contact with skin for children under 36 months	Category 2: Materials not included in Category 1 but with long-term skin contact (skin contact for more than 30 seconds)	Category 3: Materials not included in Category 1 or 2 but with short-term skin contact (skin contact up to 30 seconds)
Benzo[a]pyrene, mg/kg	Not detectable (<0.2)	1	20
Total PAHs (18 PAHs), mg/kg	Not detectable (<0.2)	10	200

To comply with the PAHs requirements under GS Mark Certification, the new standard, ZEK 01.4-08, has to be followed. Effective immediately, ZEK 01.4-08 replaces previous ZEK 01.2-08 and 01.3-08. However, there is a half-year transition period from now until July 2012.

Additional Information

To view the related announcement in the Central Department of the Federal States for Safety Features (ZLS) website (in German):

<http://www.zls-muenchen.de/de/left/aktuell/aktuell-ix.htm>

To view the ZEK 01.4-08 (in German):

http://www.zls-muenchen.de/de/left/erfahrungsaustausch/doku_pdf/01_4-08_pak.pdf

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Newsbytes

NEWSBYTE: European Commission Publishes New Regulation Amending Regulation (EU) No 10/2011

A new Regulation (EU) No 1282/2011 amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food was published on 10 December, 2011 in the *Official Journal of the European Union*.

Below are the major amendments in Annex I of the Regulation (EU) No 10/2011:

- Includes 15 new substances in Table 1
- Amends eight existing authorized substances in Table 1
 - Specific migration limit for melamine is lowered from 30 mg/kg to 2.5 mg/kg

The new Regulation will enter into force on 30 December 2011. Plastic materials and articles which have been lawfully placed on the market before 1 January 2012 and which do not comply with this Regulation may continue to be placed on the market until 1 January 2013.

Additional Information

The regulation can be viewed at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:328:0022:0029:EN:PDF>

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