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U.S. President Signs CPSIA Amendment into Law after Approval by Congress

On 12 August 2011, the US President signed into law H.R. 2715[1], a bill reforming the CPSC and amending some of the requirements in CPSIA. The text of this bill is summarised below:

Section 1. Limitation on Lead in Children's Products

- 100ppm Lead Content Limit (effective 14 August 2011) will only apply to products manufactured after the effective date. Products manufactured before that date, which complies with 300ppm limit, can still be sold in the market.
- Sets up requirements and procedures for the application of Exception from Lead Content requirement.
- Excluding Off-Highway Vehicles, while including All-Terrain Vehicles, snowmobiles, and other vehicles not primarily used on public road, from Lead Content requirement.
- Requires Metal Component Part of Bicycles to meet 300ppm Lead Content Limit after 31 December 2011.
- Excludes used children's products (but not including children's metal jewelry) from Lead Content requirement.

Section 2. Application of Third Party Testing Requirements

- Requires "representative" sample instead of "random" sample for Third Party Testing.
- Orders the CPSC to reduce redundant Third Party Testing.
- For small batch manufacturers, the CPSC might consider alternative testing requirements or exempt them from third party testing.
- Exempts ordinary books and paper-based printed materials from third party testing (does not include books with nonpaper-based components, books with inherent play value or books for children under 3).
- Exempts Metal Component Parts of Bicycles from third party testing for Lead Content test.

Section 3. Application of and Process for Updating Durable Nursery Products Standards

- If an organisation revises a standard that has been adopted by the CPSC, it shall notify the CPSC.
- The revised version will be adopted 180 days after the notification unless the CPSC, within 90 days, rejects the changes.

Section 4. Application of Section 106 to FDA-Regulated Products

- Clarifies the exception of any provision in ASTM F963 that promulgates FDA regulations from being mandated.

Section 5. Application of Phthalates Limit

- Phthalates requirement should only apply to accessible plasticised component part of a toy or child care article.

Section 6. Authority to Modify Tracking Labels Requirement

- Gives the CPSC authority to exempt a specific product from the tracking labels requirement.

Section 7. Improved Product Identification For Public Database

- If the CPSC receives a notice claiming the report is inaccurate, the CPSC can stay the publication of such report for no more than 5 additional days.
- Requires the CPSC to obtain product identification information (e.g. model, serial number or a photograph of the final product)

Section 8. Subpoena Authority

- Authorising the CPSC to issue subpoenas.

Section 9. Deadline for Rule by CPSC on Standards for ATV

- Requiring the CPSC to issue standards for All Terrain Vehicles within a year.

Section 10. Technical Amendments

Section 11. Effective Date

- Effective upon Enactment (12 August 2011)

[1] See the H.R. 2715 bill as approved by the U.S. Congress at http://www.gpo.gov/fdsys/pkg/BILLS-112hr2715enr/pdf/BILLS-112hr2715enr.pdf

Electricals & Electronics

European Union Publishes New RoHS Directive – 2011/65/EU

On 1 July 2011 the EU published a new RoHS directive in its official journal – 2011/65/EU, which came into effect 20 days after its publication. EU Member States have to incorporate the directive into their respective national laws before 2 January 2013 (within 18 months). The previous directive, 2002/95/EC and its amendments will be repealed as of 3 January 2013.

The main changes implemented in 2011/65/EU are as follows:

1. Expanded product scope: the scope of the directive will cover all electrical and electronic products (including cables and spare parts). However, a transition period is given to the newly included Category 8 medical devices, and Category 9 monitoring and control instruments (including industrial monitoring and control instruments). In addition, over 20 exemptions have been given for these two categories of products (listed in Annex IV). The new Category 11 includes electrical and electronic equipment outside the 10 categories of Annex I, but has an 8 year transition period and will be effective on 22 July 2019. Other effective dates are:
    - Medical devices, as well as monitoring and control instruments will be effective on 22 July 2014.
    - In vitro diagnostic medical devices will be effective on 22 July 2016.
    - Industrial monitoring and control instruments will be effective on 22 July 2017.
2. The list of restricted substances has not expanded. However, the review process will ensure that the harmful substances listed in the directive will take priority during assessment, setting a clear direction for the future expansion of the list of restricted substances.
3. To increase coherence with REACH (Regulation 1907/2006) by clarifying definitions such as the removal of the definition of "producers", while including definitions for "manufacturer", "authorised representative", "importer", and "distributor", and their respective legal oligations.
4. RoHS will become a CE marking directive. The product must be labelled with the CE mark and related procedures have to adhere to Annex II, Module A of Decision 768/2008/EC.
5. To provide a legal definition for homogenous materials. The definition is: one material of uniform composition throughout or a material, consisting of a combination of materials that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes.

The new RoHS directive includes the following 11 categories of EEE:

- Large household appliances;
- Small household appliances;
- IT and telecommunication equipment;
- Consumer equipment;
- Lighting equipment;
- Electrical and electronic tools;
- Toys, leisure and sports equipment;
- Medical devices;
- Monitoring and control instruments including industrial monitoring and control instruments;
- Automatic dispensers;
- Other EEE not covered by any of the categories above.

The new RoHS directive does not apply to products from the following 10 categories:

- Equipment which is necessary for the protection of the essential interests of the security of Member States, including arms, munitions and war material intended for specifically military purposes;
- Equipment designed to be sent into space;
- Equipment which is specifically designed, and is to be installed, as part of another type of equipment that is excluded or does not fall within the scope of this Directive, which can fulfill its function only if it is part of that equipment, and which can be replaced only by the same specifically designed equipment;
- Large-scale stationary industrial tools;
- Large-scale fixed installations;
- Means of transport for persons or goods, excluding electric two-wheel vehicles which are not type-approved;
- Non-road mobile machinery made available exclusively for professional use;
- Active implantable medical devices;
- Photovoltaic panels intended to be used in a system that is designed, assembled and installed by professionals for permanent use at a defined location to produce energy from solar light for public, commercial, industrial and residential applications;
- Equipment specifically designed solely for the purposes of research and development only made available on a business-to-business basis.

The new directive also includes new Annexes[1] which cover the scope of products, exempted usage of certain materials, and details of the Declaration of Conformity format as follows:

- Annex I – Categories of EEE covered by Directive 2011/65/EU
- Annex II – Restricted Substances and their maximum concentration values tolerated by weight in homogeneous materials
- Annex III – Exempted applications
- Annex IV – Exempted applications specific to medical devices and monitoring and control instruments
- Annex V – Applications for granting, renewing and revoking exemptions
- Annex VI – EU Declaration of Conformity
- Annex VII – Details of the repealed Directive 2002/95/EC
- Annex VIII – Correlation table between Directives 2002/95/EC and 2011/65/EU

[1] Details of the Annexes can be found in 2011/65/EU at http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF

Toys & Children's Products

France Further Extends Temporary Ban on Foam Puzzle Mats

On 22 July 2011, France published in its Official Gazette the extension[1] on its temporary ban on foam puzzle mats containing formamide (CAS: 75-12-7) for a period of one year until 20 July 2012. It has done so since the initial ban[2] was first announced on 16 December 2010 following a similar measure taken by the Belgian government.

The National Agency for Food Safety, Environment and Labour (ANSES) was asked by the French authority to carry out an expert assessment of the hazards associated with formamide. Following the preliminary report issued in March 2011, ANSES published another scientific report in July 2011 on the uses of this substance in common consumer goods. The report[3] stated that inhalation is the main source of exposure to the presence of formamide in foam puzzle mats.

ANSES emphasises that other consumer goods, including toys, are likely to contain formamide as a plasticiser or blowing agent, particularly those made from Ethylene-Vinyl Acetate (EVA) foam. The Agency also recommends that consumers should unpack new puzzle mats and keep them for several days in a room away from the child before using them. This is to avoid the exposure of young children (especially children under the age of three) to formamide emissions that are at their highest just after unpacking.

Foam puzzle mats can only be placed on the market if the manufacturer, importer or distributor has fulfilled one of the following three conditions:

1. The puzzle mat does not contain formamide greater than 2 mg/kg by extraction method (see Annex Part A of legal text);
2. The puzzle mat emits formamide no more than 20 µg/m^3 in indoor air after 28-day chamber test according to ISO 16000-6 and EN ISO 16000-9 (see Annex Part B of legal text);
3. The puzzle mat emits formamide no more than 40 µg/m^3 in indoor air after 7-day chamber test according to ISO 16000-6 and EN ISO 16000-9 (see Annex Part B of the legal text).

Titles of ISO standards mentioned:

- *ISO 16000-6: 2004 - Indoor air - Determination of volatile organic compounds in indoor and test chamber air by acetone extraction and analysis by GCMS*
- *EN ISO 16000-9: 2006 - Indoor air - Determination of the emission of volatile organic compounds from building products and furnishing - Emission test chamber method*

[1] Read the legal text for this extension (in French) at http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=DC0F253206C1BA521F8F712BD1FE5F04.tpdjo14v_2?cidTexte=JORFTEXT000024386056&dateTexte=&oldAction=rechJO&categorieLien=id and for the previous extension at http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=DC0F253206C1BA521F8F712BD1FE5F04.tpdjo14v_2?cidTexte=JORFTEXT000024386056&dateTexte=&oldAction=rechJO&categorieLien=id

[2] Read the legal text for the original ban (in French) at http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023233609&dateTexte=&categorieLien=id

[3] Download the ANSES formamide report (in French) from http://www.anses.fr/Documents/CHIM2010sa0302Ra-2.pdf

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