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Draft Annex XVII Restriction on DMF Available

On 15 September 2011, the European Commission (EC) submitted to the World Trade Organisation (WTO) its draft regulation[1] on the proposed Annex XVII restriction on dimethylfumarate (DMF). The regulation is proposed to enter into force in March 2012.

The proposed restriction[2] is the permanent solution to the current temporary ban on DMF under Decision 2011/135/EU, which will end on 15 March 2012. It will become entry 61 within REACH Annex XVII.

The draft text of the restriction is presented in Table A. For a full description of the restriction procedure, visit the ECHA's website[3]. ■

Table A: Proposed Text for Entry 61 of Annex XVII

Section	Proposed text
61. Dimethylfumarate (DMF) CAS No 624-49-7 EC 210-849-0	Shall not be used in articles or any parts thereof in concentrations greater than 0.1 mg/kg. Articles or any parts thereof containing DMF in concentrations greater than 0.1 mg/kg shall not be placed on the market.

[1] See the draft regulation in full at http://ec.europa.eu/enterprise/tbt/index.cfm?fuseaction=Search.getProject&Country_ID=EEC&num=403&dspLang=en&nextpage=1&basdatedeb=&basdatefin=&baspays=eec&baspays2=&basnotifnum=403&basnotifnum2=&bastypepays=ANY&baskeywords=&fromform=viewBasic&project_type_num=1&project_type_id=1&lang_id=EN

[2] Visit ECHA's webpage on other current restrictions under consideration at http://echa.europa.eu/reach/restriction/restrictions_under_consideration_en.asp

[3] See a description of the restriction procedure at http://echa.europa.eu/reach/restriction/restriction_process_en.asp

Toys & Children Products

California Bans BPA in Bottles and Cups

The Governor of California has signed into law bill SB 1319 "The Toxin-Free Infants and Toddlers Act"[1], thus banning Bisphenol A (BPA) in bottles and cups for children age three and under. A summary of the Act is as follows:

- **Product:** Bottles or cups designed or intended to be filled with liquid, food, or beverage intended primarily for consumption from that bottle or cup by children three years of age or younger.
- **Requirement:** No person shall manufacture, sell, or distribute in commerce any bottle or cup that contains BPA at a detectable level above 0.1 part per billion (ppb).
- **Effective Date:** July 1, 2013

However, the new state ban does not apply to medical devices or to food and beverage containers for consumption by the general population.

California now joins Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, Minnesota, New York, Vermont, Washington and Wisconsin in banning BPA in baby bottles and other food or beverage containers intended for use by children. There is no federal law regulating BPA in the US at the moment.

Table B on the next page provides a glance of the BPA requirements in different states in the United States:

1 Download the California Toxin-Free Infants and Toddlers Act (Assembly Bill No. 1319) from http://www.leginfo.ca.gov/pub/11-12/bill/asm/ab_1301-1350/ab_1319_bill_20111004_chaptered.pdf

Continued on next page >>

<< From previous page

Table B: BPA Requirements in Different States in the US

State/State Law	Requirements	Effective Date
California Health and Safety Code Division 104 Part 3, Chapter 12 (Section 108940-108941)	**Banning:** Manufacture and sale of any bottle or cup that contains BPA at a detectable level above 0.1 part per billion (ppb)	1 July 2013
Connecticut Title 21a Statutes of Connecticut Chapter 416, Section 21a-12b, 21a-12c (Public Act 09-103)	**Banning:** Manufacture and sale of any reusable food or beverage container containing BPA Manufacture and sale of any infant formula or baby food stored in plastic container, jar or can that contains BPA	1 October 2011
Delaware Section 2509, Chapter 25, Title 6, Delaware Code	**Banning:** Sale of empty bottle or cup capable of being filled with food or liquid that is designed or intended by a manufacturer to be used by children under four years of age that contains BPA	31 December 2011
District of Columbia District of Columbia Official Code Division I Title 8 § 8-108.01	**Banning:** Manufacture and sale of any empty bottle/cup/container that is designed/intended to be filled with food/liquid for consumption by a child under four years of age that contains BPA	1 July 2011
Maine 06-096 Code of Maine Rules Chapter 882 (Department of Environmental Protection, Bill LD 412)	**Information Submission:** Required for Infant Formula/Baby Food and Toys/Childcare Articles/Tableware containing intentionally-added BPA **Banning:** Sales of any reusable good/beverage container that contains BPA (e.g. baby bottles, spill-proof cups, sports bottles, thermoses.)	1 January 2012
Maryland Maryland code, Health - General, Section 24-304	**Beginning 1 January 2012, banning:** Manufacture and sale of any child care articles containing BPA **Beginning 1 July 2014, banning:** 1. Infant formula in container containing more than 0.5ppb of BPA 2. Manufacture and sale of any container of infant formula containing more than 0.5ppb of BPA	1 January 2012/ 1 July 2014
Massachusetts Department of Public Health Regulation 105 CMR 650.020	**Banning:** Children's reusable food or beverage containers containing BPA that are manufactured on or after January 7, 2011, or sold at retail on or after July 1, 2011.	**For manufacturers:** Jan 7, 2011 **For retailers:** Jul 1, 2011
Minnesota Minnesota Statutes Section 325F.173	**Banning:** Manufacture and sale of any empty bottles or cups to be filled with food or liquid that is designed or intended by a manufacturer to be used by a child under three years of age that contains BPA	**For manufacturers:** 1 January 2010 **For retailers:** 1 January 2011
New York Laws of New York - Environmental Conservation Article 37 Title 5	**Banning:** Manufacture and sale of any child care products intended for use by a child under three containing BPA **Labeling Requirement:** Products that do not contain BPA may be authorized to have the label of "Bisphenol A free"/"BPA-free" Exempts Resale Products	1 December 2010
Vermont Title 18 Vermont Statues Section 1512	**Beginning 1 July 2012, prohibit:** Manufacture and sale of any reusable food or beverage container containing BPA; Manufacture and sale of any infant formula or baby food stored in plastic container or jar that contains BPA. **Beginning 1 July 2014, prohibit:** Manufacture and sale of any infant formula or baby food stored in a can that contains BPA	1 July 2012/ 1 July 2014
Washington Washington State, Chapter 70.280 RCW Law 2010, Ch 140	**Beginning 1 July 2011, banning:** Manufacture and sale of any empty containers designed/intended to be filled with liquid, food, beverage primarily for age three or younger that contains BPA **Beginning 1 July 2012, banning:** Manufacture and sale of any sport bottles that contains BPA	1 July 2011/ 1 July 2012
Wisconsin Wisconsin Statutes Chapter 100.335	**Banning:** Manufacture and sale of any empty baby bottle or spill-proof cup for children three years or younger that contains BPA	17 June 2010

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ECHA votes Eight Substances into Annex XIV

In its meeting on 27-28 September 2011, the European Commission's REACH Committee voted unanimously to list in Annex XIV the eight substances recommended by the ECHA in December 2010. The regulation[1] is expected to enter into force in January 2012.

As recommended by the ECHA, the draft text contains no exemptions for any category of use for these eight substances.

Businesses operating in the European Union should take note that unless an authorisation has been granted, the use of these substances (including importing them as substances on their own or as part of mixtures) will be prohibited after the sunset date. However, authorisation does not apply to subtances of very high concern (SVHCs) already used during the production of an imported article, for example, bis(2-ethylhexyl)phthalate (DEHP) incorporated into the plastic of a cable cord.

Details of the eight substances as well as their proposed dates for the last application for authorisation[2] and the sunset dates are given in Table C. ■

[1] See at http://ec.europa.eu/transparency/regcomitology/index.cfm?do=search.documentdetail&dxoAhq6JMWarAYbSDBv22QylAM+T291cdj68xlkqK+YDftvKF0Kx2dvStAkgOOoq

[2] See a summary of the authorisation process at http://guidance.echa.europa.eu/authorisation_en.htm or find out more about the authorisation application process at http://echa.europa.eu/reach/authorisation_under_reach/authorisation_application_en.asp

Table C: Eight Substances Listed in Annex XIV

	Substance Name	CAS No. (EC No.)	Intrinsic Property(ies)	Transitional Arrangements (EIF = Date of the Regulation's Entry into Force)	
				Latest Application Date	Proposed Sunset Date
1.	**Diisobutyl phthalate (DIBP)**	84-69-5 (201-553-2)	Toxic for Reproduction Cat. 1B	EIF + 18 months or 21 August 2013 (whichever is the latest)	EIF + 36 months or 21 February 2015 (whichever is the latest)
2.	**Diarsenic trioxide**	1327-53-3 (215-481-4)	Carcinogenic Cat. 1A	EIF + 21 months or 21 November 2013 (whichever is the latest)	EIF + 39 months or 21 May 2015 (whichever is the latest)
3.	**Diarsenic pentaoxide**	1303-28-2 (215-116-9)	Carcinogenic Cat. 1A		
4.	**Lead chromate**	7758-97-6 (231-846-0)	Carcinogenic Cat. 1B Toxic for reproduction Cat. 1A		
5.	**Lead sulfochromate yellow (C.I. Pigment Yellow 34)**	1344-37-2 (215-693-7)	Carcinogenic Cat. 1B Toxic for Reproduction Cat. 1A		
6.	**Lead chromate molybdate sulfate red (C.I. Pigment Red 104)**	12656-85-8 (235-759-9)	Carcinogenic Cat. 1B Toxic for Reproduction Cat. 1A		
7.	**Tris(2-chloroethyl) phosphate (TCEP)**	115-96-8 (204-118-5)	Toxic for Reproduction Cat. 1B	EIF + 24 months or 21 February 2014 (whichever is the latest)	EIF + 42 months or 21 August 2015 (whichever is the latest)
8.	**2,4-Dinitrotoluene (2,4-DNT)**	121-14-2 (204-450-0)	Carcinogenic Cat. 1B		

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