
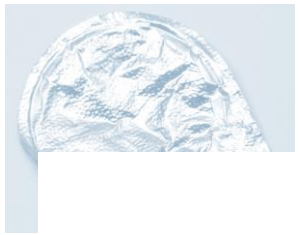








FPF scientific study

Migration of Substances of Very High Concern

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Food Packaging Forum

13 March 2017

Food Packaging Forum

Packaging Technology and Science
An International Journal

PACKAGING TECHNOLOGY AND SCIENCE
Packag. Technol. Sci. 2017;
Published online in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/pts.2288

Substances of Very High Concern in Food Contact Materials: Migration and Regulatory Background

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Food contact materials (FCMs) are needed to produce, transport, process and store our food. Although essential for handling and protecting food from farm to fork, FCMs are often not inert, and chemical components may partition into food. In Europe, FCMs are regulated under the FCM Framework Regulation 1935/2004 which covers their effects on human health. Environmental effects of FCM substances are included in the scope of the European Chemicals Regulation [Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)] which aims at substituting Substances of Very High Concern (SVHCs) by safer alternatives. In this study, we focus on 10 FCM substances that are SVHCs and already included in the authorization list of REACH (Annex XIV): We show their possible application in the manufacture of FCMs and give evidence or highlight the absence thereof for migration into food or food simulants. An overview on migration of four phthalates (diisobutyl

European legislation on FCMs

FCM Framework Regulation

FCMs shall ”not transfer their constituents to food in quantities which could endanger human health”

- Harmonized regulations
  - National regulations
    - Regulatory gaps?

REACH

covers environmental effects of FCM substances, but not their health effects

- Substances of Very High Concern

Read more:
EC JRC (2016) C. Simoneau et al. Non-harmonised food contact materials in the EU: Regulatory and market situation (Baseline study - Final report)

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REACH: Substances of Very High Concern

SVHCs have serious and often irreversible effects on human health and the environment

- Carcinogenic, mutagenic, toxic for reproduction
- Persistent, bioaccumulative and toxic; very persistent and very bioaccumulative
- Equivalent levels of concern

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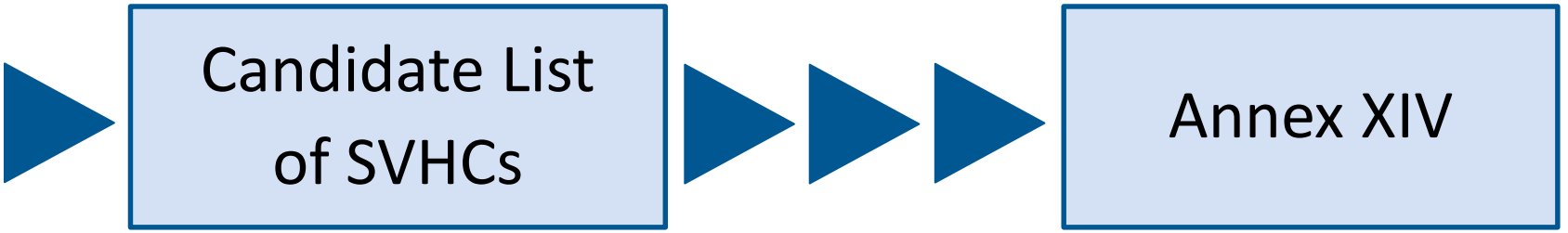
REACH: Authorization process



- Legal obligations

involves the European Chemicals Agency, Member States, the European Commission; allows public comments

- Need for authorization
- FCMs are exempted

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FCM Substances:
Subject to authorization under REACH

Chemical name		Union list (SML mg/kg)	ESCO list	FACET list
Diisobutyl phthalate	DiBP	-	+	+
Dibutyl phthalate	DBP	+ (0.3)	+	+
Benzyl butyl phthalate	BBP	+ (30)	+	+
Bis(2-ethylhexyl) phthalate	DEHP	+ (1.5)	+	+
4,4'-Methylenedianiline	MDA	-	+	+
4,4'-Methylenebis[2-chloroaniline]	MBOCA	-	+	-
Tris(2-chloroethyl)phosphate	TCEP	+ (n.d.)	+	+
Trichloroethylene	TCE	-	-	+
Hexabromocyclododecane	HBCD	-	-	+
Bis(2-methoxyethyl) ether	Diglyme	-	-	+

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FCM Substances:
Subject to authorization under REACH

Chemical name		Reason for inclusion
Diisobutyl phthalate	DiBP	Toxic for reproduction, human endocrine disruptor
Dibutyl phthalate	DBP	Toxic for reproduction, human endocrine disruptor
Benzyl butyl phthalate	BBP	Toxic for reproduction, human endocrine disruptor
Bis(2-ethylhexyl) phthalate	DEHP	Toxic for reproduction, human and environmental endocrine disruptor
4,4'-Methylenedianiline	MDA	Carcinogenic
4,4'-Methylenebis[2-chloroaniline]	MBOCA	Carcinogenic
Tris(2-chloroethyl)phosphate	TCEP	Toxic for reproduction
Trichloroethylene	TCE	Carcinogenic
Hexabromocyclododecane	HBCD	PBT
Bis(2-methoxyethyl) ether	Diglyme	Toxic for reproduction

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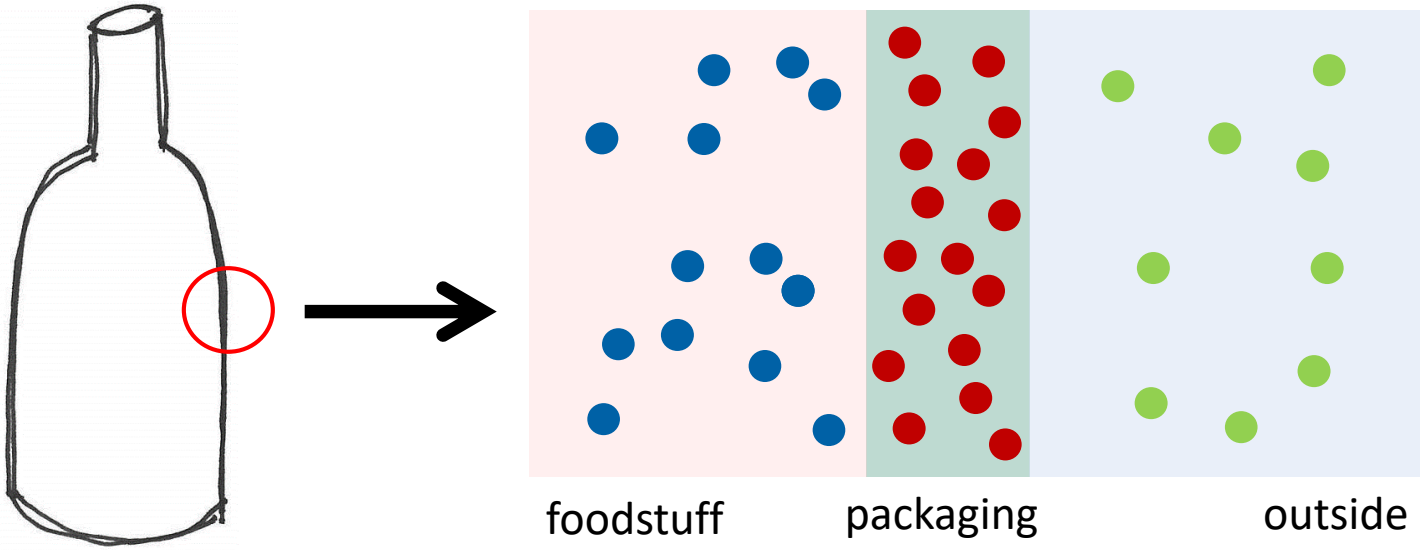
Migration



Migration

Chemical name		Migration
Diisobutyl phthalate	DiBP	plastic packaging, (recycled) paper and board, milking machines tubes and tanks, lids
Dibutyl phthalate	DBP	
Benzyl butyl phthalate	BBP	
Bis(2-ethylhexyl) phthalate	DEHP	
4,4'-Methylenedianiline	MDA	(black) polyamide cooking utensils, multilayer films
4,4'-Methylenebis[2-chloroaniline]	MBOCA	no evidence
Tris(2-chloroethyl)phosphate	TCEP	
Trichloroethylene	TCE	
Hexabromocyclododecane	HBCD	
Bis(2-methoxyethyl) ether	Diglyme	

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Ways forward?

A substance is banned under REACH and…

… authorized and used in FCMs (e.g. phthalates in plastic FCMs)	→	re-assessment?
… neither allowed, but found in FCMs (e.g. MDA in plastic FCMs)	→	stricter enforcement?
… actual use in FCMs is unknown (e.g. HBCD)	→	filling of data gaps?

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Supplementary material

⇩ Download

Table S1. 180 Chemicals of concern (COCs) listed on the Union list, ESCO list and/or the FACET database. The hazard criteria that led to the inclusion of FCM substances on the SIN list, SVHC list and Annex XIV are specified.

CAS	Name	Union list (additive)	Union list (monomer)	ESCO list	FACET	Reason for inclusion on SIN list	Reason for inclusion on SVHC list	Reason for inclusion on Annex XIV
50-00-0	Formaldehyde	+	+	+	+	Formaldehyde is classified as a possible carcinogen (C3), also reported to be mutagenic and toxic for reproduction. It is has been detected in both humans and the environment.		
56-35-9	Tributyltin oxide (TBTO)			+		Substance is concluded to be PBT by European Chemicals Bureau, PBT working group.	PBT (Art. 57d)	
57-14-7	*N,N*-Dimethylhydrazine				+	Classified CMR (Class I & II) according to Annex 1 of Directive 67/548/EEC.		
62-53-3	Aniline				+	Aniline is classified as a possible carcinogen (C3) and as a possible mutagenic substance (M3). Aniline is very toxic and has been found in both humans and environmental samples.		
68-12-2	*N,N*-Dimethylformamide (DMF)				+	Classified CMR (Class I & II) according to Annex 1 of Directive 67/548/EEC.	PBT (Art. 57d)	
71-43-2	Benzene			+		Classified CMR (Class I & II) according to Annex 1 of Directive 67/548/EEC.		
71-48-7	Cobalt acetate				+	Classified CMR according to Annex VI of Regulation 1272/2008.	Carcinogenic and toxic for repro-duction (Art. 57a and c)	
75-01-4	Chloroethylene		+	+	+	Classified CMR (Class I & II) according to Annex 1 of Directive 67/548/EEC.		
75-12-7	Formamide				+	Classified CMR (Class I & II) according to Annex 1 of Directive 67/548/EEC.	Toxic for reproduction (Art. 57 c)	
75-21-8	Ethylene oxide		+	+	+	Classified CMR (Class I & II) according to Annex 1 of Directive 67/548/EEC.		
75-55-8	2-Methylaziridine				+	Classified CMR (Class I & II) according to Annex 1 of Directive 67/548/EEC.		
75-56-9	Methyloxirane		+	+	+	Classified CMR (Class I & II) according to Annex 1 of Directive 67/548/EEC.	Carcinogenic (Art. 57a); mutagenic (Art. 57b)	
77-58-7						DBT compounds are potential endocrine disruptors, showing also [illegible] toxic effects and are highly toxic to aquatic species. DBT is [illegible] DBT has been widely found in the		

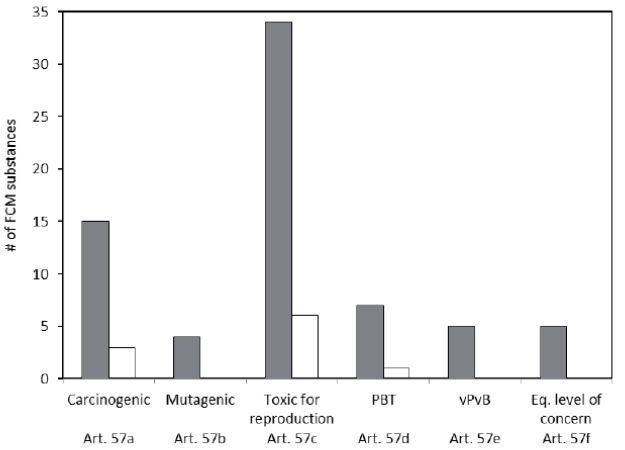

Figure S1. Number of FCM substances on the SVHC list (grey) and on Annex XIV (white) categorized by their hazard properties according to Article 57 of REACH.

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Thank you!

Please send questions to:

events@fp-forum.org