Chemicals of concern in food contact materials

- an analysis by the FPF

Birgit Geueke, Charlotte Wagner, Jane Muncke

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Food Packaging Forum Foundation

- Charitable foundation founded in 2012
- Function: Science communication
- Topics: Food contact materials, chemicals and health
- Governed by foundation board: independent academic scientists, science communication expert
- Funding: donations, including from the packaging supply chain, charitable foundations
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Food contact substances and chemicals of concern: a comparison of inventories

Birgit Geueke*, Charlotte C. Wagner and Jane Muncke

Food Packaging Forum Foundation, Zurich, Switzerland

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Food contact materials (FCMs) are intended to be in contact with food during production, handling or storage. They are one possible source of food contamination, because chemicals may migrate from the material into the food. More than 6000 FCM substances appear on regulatory or non-regulatory lists. Some of these substances have been linked to chronic diseases, whilst many others lack (sufficient) toxicological evaluation. The aim of this study was the identification of known FCM substances that are also considered to be chemicals of concern (COCs). The investigation was based on the following three FCM lists: (1) the 2013 Pew Charitable Trusts database of direct and indirect food additives legally used in the United States (or Pew for short), (2) the current European Union-wide positive list for plastic FCMs (or Union for short), and (3) the 2011 non-plastics FCM substances database published by EFSA (or ESCO for short). These three lists of food contact substances (Pew, Union, ESCO lists) were compared with the Substitute It Now! (SIN) list 2.1, which includes chemicals fulfilling the criteria listed in article 57 of Regulation (EC) No. 1907/2006 (REACH), and the TEDX database on endocrine-disrupting chemicals. A total of 175 chemicals used in FCMs were identified as COCs. Fifty-four substances present on the SIN list 2.1 were also found on the Union and/or ESCO lists. Twenty-one of those 54 substances are candidates for Substances of Very High Concern (SVHC), and six of these 21 are listed on Annex XIV and intended for phase-out under REACH. In conclusion, COCs used in FCMs were identified and information about their applications, regulatory status and potential hazards was included.

Keywords: food contact materials; hazard identification; chemicals of concern; regulation; endocrine disruption; Substances of Very High Concern

Introduction

Chemical exposures have been linked to several chronic

referred to as FCM framework regulation), manufacturers have the responsibility to guarantee that their products 'do

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Food contact materials (FCMs)

	FCM Inventories	
	**Union list 2011**	• Annex I of Commission Regulation (EU) No. 10/2011 • EU legally binding positive list for plastics monomers and additives
 **CH & N**	**ESCO list 2011**	• Annex I of a Report by **E**FSA's **S**cientific **Co**operation (ESCO) Working Group • Compilation of lists for non-plastic FCMs • Member state and industry practice lists
	**PEW list 2013**	• Source: The PEW Charitable Trusts • Database on direct and indirect food additives in US, food contact notifications, threshold of regulation exemptions and GRAS notifications

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Chemicals of concern (COC)

	COC lists	
	**Substitute It Now! (SIN) list**	• Compiled and published by ChemSec • **S**ubstances of **V**ery **H**igh **C**oncern (SVHC) • REACH criteria applied: CMR, PBT, vPvB, equal concern/endocrine disruption (Art. 57)
	**TEDX list**	• Published by The Endocrine Disruption Exchange • Potential endocrine disruptors • Based on at least one peer-reviewed toxicity study (*in vitro* or *in vivo*)

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FCMs and # COCs

FCM inventories	# of CAS entries
Union list	873
ESCO list	1577
PEW list	5802

COC inventories	# of CAS entries
SIN LIST	789
TEDX	855

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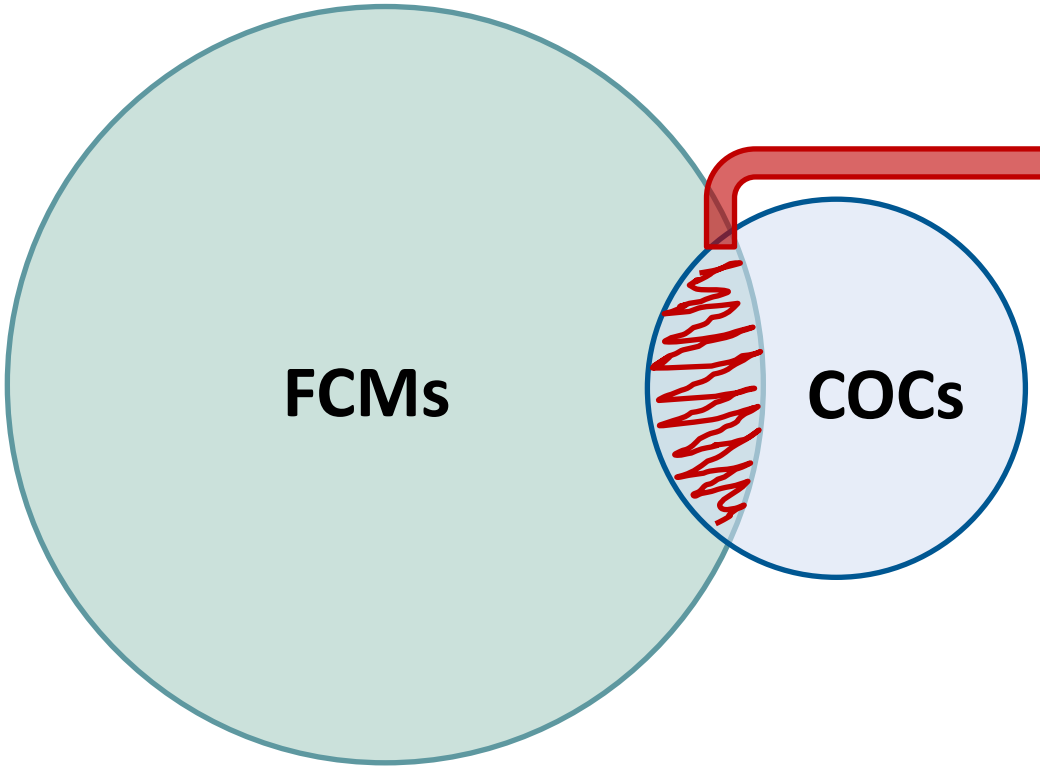
1. Comparison: COCs on FCM lists



Σ 175 chemicals identified

- 154 on PEW list
- 92 on Union and ESCO list

- 119 on TEDX list
- 96 on SIN list

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1. Comparison: Σ 175 Chemicals

Supplemental online material

Table S1. 175 chemicals present on the SIN list 2.1, the TEDX, Union, ESCO and/or Pew lists. The FDA approval for chemicals present on the Pew list were shown according to the agency's designation as listed in [1]. A truncated format was used for the CASRN $((X)_nXXX$ instead of $(X)_n$-XX-X).

CASRN	Chemical name	SIN 2.1	TEDX	Union	ESCO	Pew	FDA approval						Application of non-indirect food additives in FCM
							Direct	Indirect	Flavour	GRAS	Colour	Prior sanct.	
50000	Formaldehyde	+		+	+	+	D	I					
51036	Piperonylbutoxide		+			+		I					
56235	Carbon tetrachloride		+		+	+		I					
56359	Tributyltin oxide (TBTO)	+	+		+	+		I					
56360	Tributyltin acetate		+			+		I					
57578	Propiolactone	+				+		I					
58082	Caffeine		+			+	D		F	G			Not known.
59507	4-Chloro-3-methylphenol		+		+	+		I					
60822	Phloretin		+			+	D		F	G			Not known.
62533	Aniline	+				+		I					
64675	Diethyl sulphate	+				+		I					
65850	Benzoic acid		+	+	+	+		I	F	G			
68122	N,N-Dimethylformamide	+	+			+		I					
71432	Benzene	+	+		+	+	D	I					
71487	Cobalt acetate	+				+		I					
74317	Diphenyl-*p*-phenylenediamine		+			+		I					
75014	Chloroethylene	+		+	+	+		I					
75092	Dichloromethane		+			+	D	I			C		

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1. Comparison: 14 Chemicals on all 5 lists

CAS	Chemical
75-21-8	Ethylene oxide
80-05-7	Bisphenol A
84-74-2	Dibutyl phthalate (DBP)
85-68-7	Benzylbutyl phthalate (BBP)
94-13-3	Propylparaben
98-54-4	4-tert-Butylphenol (PTBP)
100-42-5	Styrene
106-89-8	1-Chloro-2,3-epoxypropane (Epichlorohydrin)
108-46-3	1,3-Dihydroxy-benzene (Resorcinol)
117-81-7	Bis(2-ethylhexyl) phthalate (DEHP)
119-61-9	Benzophenone
131-57-7	Benzophenone-3; Oxybenzone
10043-35-3	Boric acid
25013-16-5	tert-Butyl-hydroxyanisole (BHA)

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Monomer

Additive

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CMR and EDC

EDC

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Migration documented in scientific literature

No migration studies found

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2. Comparison:
European food contact substances on SIN list, SVHC list and Annex XIV

SIN list	• **S**ubstances of **V**ery **H**igh **C**oncern (SVHC) • REACH criteria applied (Art. 57) • Compiled and published by ChemSec • 802 entries
SVHC Candidate list	• Official candidate list of substances to be phased out from consumer products under REACH • All member states can suggest chemicals for SVHC listing • 155 entries
Annex XIV	• Authorization list under REACH • Use and placing on the market for listed substances is prohibited unless special authorization has been obtained • 31 entries

2. Comparison:
European food contact substances on SIN list, SVHC list and Annex XIV

SIN list	Criteria for listing (Art. 57, EC/1907/2006 REACH): • Carcinogenic, mutagenic, toxic for reproduction (CMR) • Persistent, bioaccumulative and toxic (PBT) • Very persistent and very bioaccumulative (vPvB) • "Equivalent concern": endocrine disruption, other hazards
SVHC Candidate list	
Annex XIV	

No legal consequences

SIN list ⇨ SVHC list ⇨ Annex XIV

All 3 lists are based on the hazards specified in Art. 57 of REACH

Speeding up legislative processes

Giving guidance to companies on which chemicals to avoid

Duty to inform comes into effect after listing

Phase out and substitute

Authorization possible

Number of substances expected to rise!

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Food contact legislation and REACH

Art. 3 of the FCM Framework Regulation (EC) No 1935/2004

«Materials and articles […] shall be manufactured […] so that, under normal and foreseeable conditions of use, they do not transfer their constituents to food in quantities that (a) endanger human health.»

Union list: Chemicals are risk assessed and authorized

ESCO list: no or only national risk assessment

REACH

- SVHC list, Annex XIV - societal and scientific consensus on hazardous substances
- REACH covers environmental aspects of FCMs, but not human health effects

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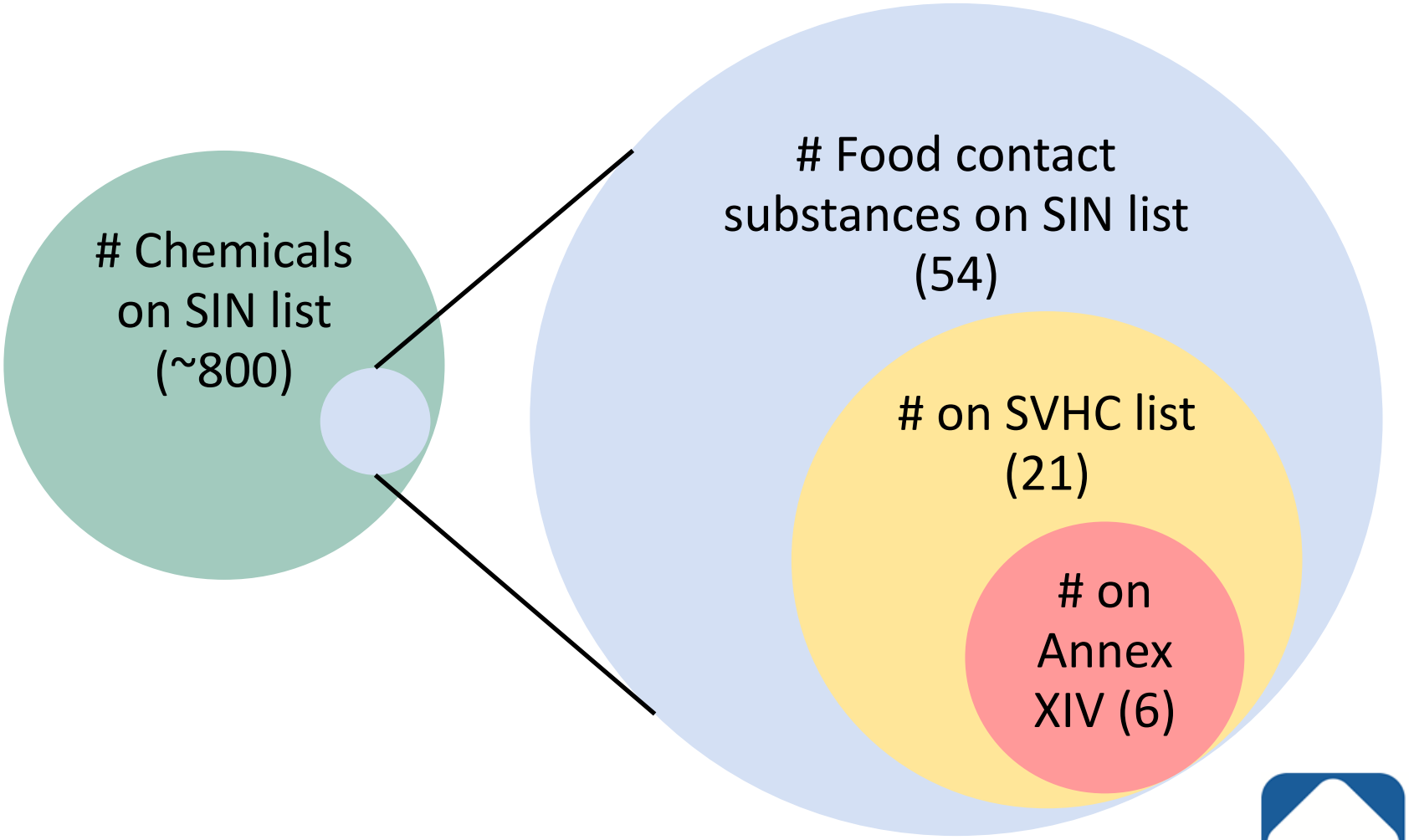
2. Comparison:
European food contact substances on SIN list, SVHC list and Annex XIV



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2. Comparison: 54 substances on SIN list

Table S2. 54 Chemicals from the SIN list 2.1 that were present on the Union and/or ESCO lists. Chemicals on the SIN list 2.1 were classified as carcinogenic, mutagenic or toxic for reproduction (CMR), as endocrine disrupters (ED) or according to further criteria referring to article 57 of REACH. The presence on the SVHC list and Annex XIV is shown. Any restrictions, specifications, specific migration limits (SMLs) of all food contact substances and applications of non-plastic food contact substances were shown. A truncated format was used for the CASRN ($(X)_nXXX$ instead of $(X)_n$-XX-X).

CASRN	Chemical name	SIN list 2.1			REACH		Union list			ESCO list			
		CMR	ED	Art. 57 REACH	SVHC list	Annex XIV		Restrictions and specifications	SML [mg/kg] Group SML (T) [mg/kg]		Application	Restrictions and specifications	SML [mg/kg] Group SML (T) [mg/kg]
50000	Formaldehyde			+[4]			+		(T) 15	+	Cork and wood, paper and board, printing inks, rubber		(T) 15
56359	Tributyltin oxide (TBTO)			+[4]	+					+	Cork and wood		0.01
71432	Benzene	+[1]								+	Coatings		0.05
75014	Chloroethylene	+[1]					+	1 mg/kg in final product	ND	+	Printing inks, rubber	1 mg/kg in final product	ND (DL = 0.01)
75218	Ethylene oxide	+[1]					+	1 mg/kg in final product	ND	+	Printing inks, rubber	1 mg/kg in final product	
75569	Methyloxirane	+[1]			+		+	1 mg/kg in final product	ND	+	Printing inks, rubber	1 mg/kg in final product	
77587	Dibutyltin (dilaurate)	+[2]								+	Coatings, silicones		0.1 for Sn; (T) 0.05
78795	Isoprene	+[1]					+	1 mg/kg in final product	ND	+	Printing inks, rubber	1 mg/kg in final product	ND (DL = 0.02)
79061	Acrylamide	+[1]			+		+		ND	+	Paper and board, printing inks, rubber		ND (DL = 0.01); 12
80057	Bisphenol A			+[4]			+	Not to be used for infant feeding bottles.	0.6	+	Printing inks		0.6
84617	Dicyclohexyl phthalate (DCHP)		+[3]							+	Coatings, paper and board, printing inks, rubber		6; 30
84662	Diethyl phthalate (DEP)		+[3]							+	Rubber		
84695	Diisobutyl phthalate	+[2]			+	+				+	Coatings, paper and board		(T) 1
84742	Dibutyl phthalate (DBP)	+[1]			+	+	+	Restricted use[5]	0.3; (T) 60	+	Paper and board, printing inks, rubber		1; 3; 15
85687	Benzyl butyl phthalate (BBP)	+[1]			+	+	+	Restricted use[6]	30; (T) 60	+	Paper and board, printing inks, rubber		6

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2. Comparison:
6 FCM substances on Annex XIV

CAS	Chemical
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Intended for phase-out from non-FCM consumer products

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CMR

Intended for phase-out from non-FCM consumer products

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Additives

Intended for phase-out from non-FCM consumer products

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Only ESCO list

Union and ESCO list

Intended for phase-out from non-FCM consumer products

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Migration documented in scientific literature

No migration study found

Intended for phase-out from non-FCM consumer products

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Concluding remarks…

- 175 Chemicals of concern found in FCM inventories, including CMRs, endocrine disruptors and persistent and bioaccumulative substances
- 21 Food contact substances identified as SVHC under REACH, 6 of them already intended for phase out (numbers expected to rise)

…and questions

- Are we as society willing to accept chemicals in FCMs that are going to be phased out under REACH?
- How to comply with Article 3 of the Framework Regulation if no EFSA risk assessment has been carried out?

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Thank you!

birgit.geueke@fp-forum.org
www.foodpackagingforum.org

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