FPF scientific study
Migration of Substances of Very High Concern

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13 March 2017
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”

REACH

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

- Harmonized regulations
- National regulations
- Substances of Very High Concern
- Regulatory gaps?

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)
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
REACH: Authorization process

- Candidate List of SVHCs
  - Legal obligations

- Annex XIV
  - Need for authorization
  - FCMs are exempted

Involves the European Chemicals Agency, Member States, the European Commission; allows public comments.
## FCM Substances:
Subject to authorization under REACH

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Union list (SML mg/kg)</th>
<th>ESCO list</th>
<th>FACET list</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diisobutyl phthalate</td>
<td>DiBP</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Dibutyl phthalate</td>
<td>DBP</td>
<td>+ (0.3)</td>
<td>+</td>
</tr>
<tr>
<td>Benzyl butyl phthalate</td>
<td>BBP</td>
<td>+ (30)</td>
<td>+</td>
</tr>
<tr>
<td>Bis(2-ethylhexyl) phthalate</td>
<td>DEHP</td>
<td>+ (1.5)</td>
<td>+</td>
</tr>
<tr>
<td>4,4’-Methylenedianiline</td>
<td>MDA</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>4,4’-Methylenebis[2-chloroaniline]</td>
<td>MBOCA</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Tris(2-chloroethyl)phosphate</td>
<td>TCEP</td>
<td>+ (n.d.)</td>
<td>+</td>
</tr>
<tr>
<td>Trichloroethylene</td>
<td>TCE</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hexabromocyclododecane</td>
<td>HBCD</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bis(2-methoxyethyl) ether</td>
<td>Diglyme</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
FCM Substances:
Subject to authorization under REACH

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<thead>
<tr>
<th>Chemical name</th>
<th>Reason for inclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diisobutyl phthalate</td>
<td>Toxic for reproduction, human endocrine disruptor</td>
</tr>
<tr>
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<td>Toxic for reproduction, human endocrine disruptor</td>
</tr>
<tr>
<td>Benzyl butyl phthalate</td>
<td>Toxic for reproduction, human endocrine disruptor</td>
</tr>
<tr>
<td>Bis(2-ethylhexyl) phthalate</td>
<td>Toxic for reproduction, human and environmental endocrine disruptor</td>
</tr>
<tr>
<td>4,4’-Methylenedianiline</td>
<td>Carcinogenic</td>
</tr>
<tr>
<td>4,4’-Methylenebis[2-chloroaniline]</td>
<td>Carcinogenic</td>
</tr>
<tr>
<td>Tris(2-chloroethyl)phosphate</td>
<td>Toxic for reproduction</td>
</tr>
<tr>
<td>Trichloroethylene</td>
<td>Carcinogenic</td>
</tr>
<tr>
<td>Hexabromocyclododecane</td>
<td>PBT</td>
</tr>
<tr>
<td>Bis(2-methoxyethyl) ether</td>
<td>Toxic for reproduction</td>
</tr>
</tbody>
</table>
Migration

foodstuff  packaging  outside
### Migration

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<thead>
<tr>
<th>Chemical name</th>
<th>Migration</th>
</tr>
</thead>
<tbody>
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<td>Diisobutyl phthalate</td>
<td>DiBP</td>
</tr>
<tr>
<td>Dibutyl phthalate</td>
<td>DBP</td>
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<tr>
<td>Benzyl butyl phthalate</td>
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<tr>
<td>Bis(2-methoxyethyl) ether</td>
<td>Diglyme</td>
</tr>
</tbody>
</table>

- Plastic packaging, (recycled) paper and board, milking machines tubes and tanks, lids
- (black) polyamide cooking utensils, multilayer films
- No evidence
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?
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.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Name</th>
<th>Reason for inclusion on SIN list</th>
<th>Reason for inclusion on SVHC list</th>
<th>Reason for inclusion on Annex XIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-06-6</td>
<td>Formaldehyde</td>
<td>+</td>
<td>+</td>
<td></td>
</tr>
<tr>
<td>50-17-9</td>
<td>Tributyltin oxide</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>62-14-7</td>
<td>1,2-dimethylhydrazine</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>52-33-5</td>
<td>Airline</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>68-12-2</td>
<td>N,N-Dimethylformamide</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>71-43-2</td>
<td>Benzene</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>75-48-7</td>
<td>Cobalt acetate</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>75-01-4</td>
<td>Chloroethylene</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>75-32-7</td>
<td>Formamide</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<tr>
<td>75-81-8</td>
<td>Ethylene oxide</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>75-06-9</td>
<td>Methylamine</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

Figure S3. Number of FCM substances on the SVHC list (grey) and on Annex XIV (white) categorized by their hazard properties according to Articles 57 of REACH.
Thank you!

Please send questions to:

events@fp-forum.org