

Key developments on FCMs in Europe

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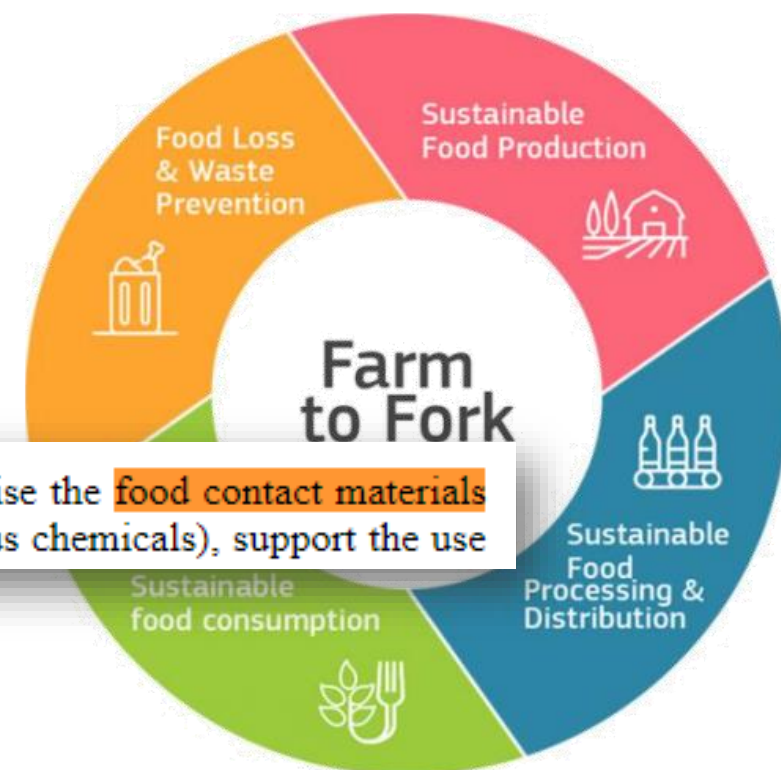


EU Chemicals Strategy for Sustainability

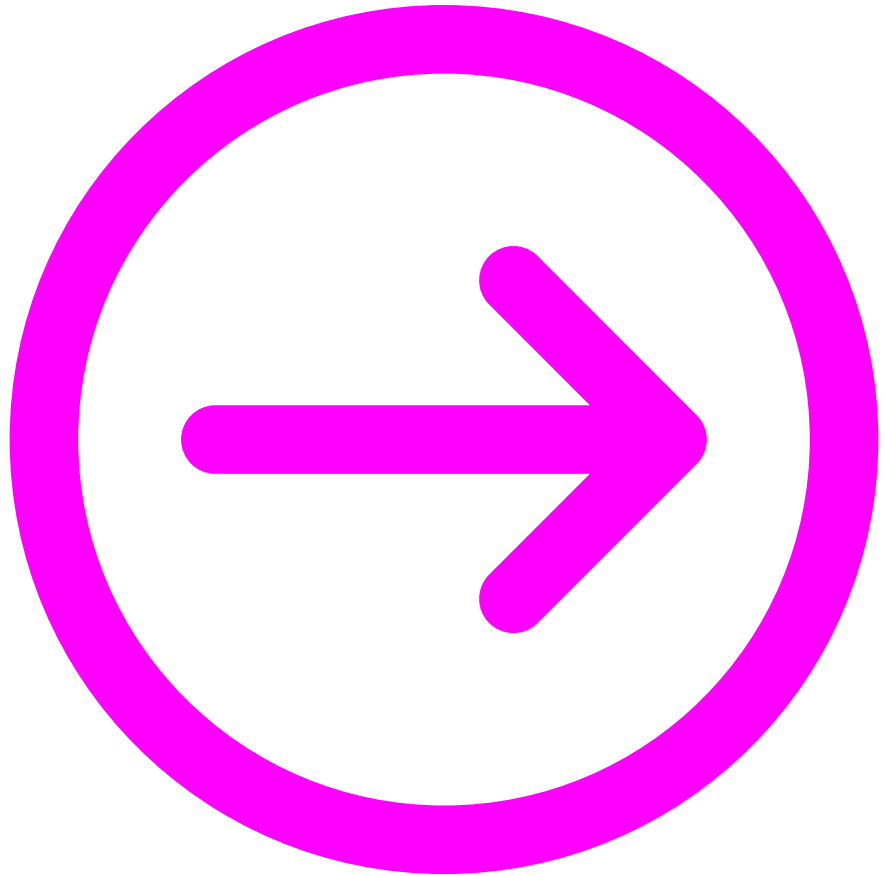
The Commission will:

- extend the generic approach to risk management to ensure that consumer products – including, among other things, **food contact materials**, toys, childcare articles, cosmetics, detergents, furniture and textiles - do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative. In

#ChemicalsStrategy
#EUGreenDeal



Food packaging plays a key role in the sustainability of food systems. The Commission will revise the **food contact materials** legislation to improve food safety and public health (in particular in reducing the use of hazardous chemicals), support the use



generic
approach to risk
management

id est hazardous
chemicals are not
allowed in FCMs.

Legal
definition of
food
packaging
safety in the
EU today

[EU 1935/2004, Art. 3.1.\(a\)](#)

“Materials and articles, [...], shall be manufactured [...] so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health”



So...

will Art. 3, 1935/2004 be revised?

EU COM is currently working on Impact Assessment for FCM regulatory revision.

Expected Q1.2022(?)



3 additional reasons:

1. BPA
2. NMDR
3. Mixtures

Reason 1: Bisphenol A (BPA; CAS 80-05-7)



draft scientific opinion EFSA
Dec. 2021



New Tolerable Daily Intake
(TDI) is 100'000 times below
current TDI due to BPA's
impacts on human health



New SML(BPA) is $>2,4$ ng/kg
food (to account for other,
non-FCM sources of
exposure to BPA)



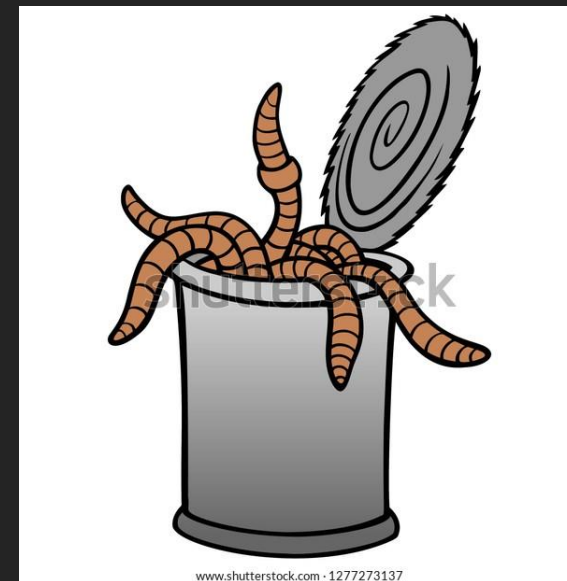
Migration limit 2 ppt:
too low to enforce?

Reason 2: Non-monotonic dose response

- EFSA new “Opinion on the impact of non-monotonic dose responses on EFSA’s human health risk assessments”
- “The Dose Makes the Poison” cannot be applied universally: for substances with NMDR in low-dose range, more detailed assessment is required:

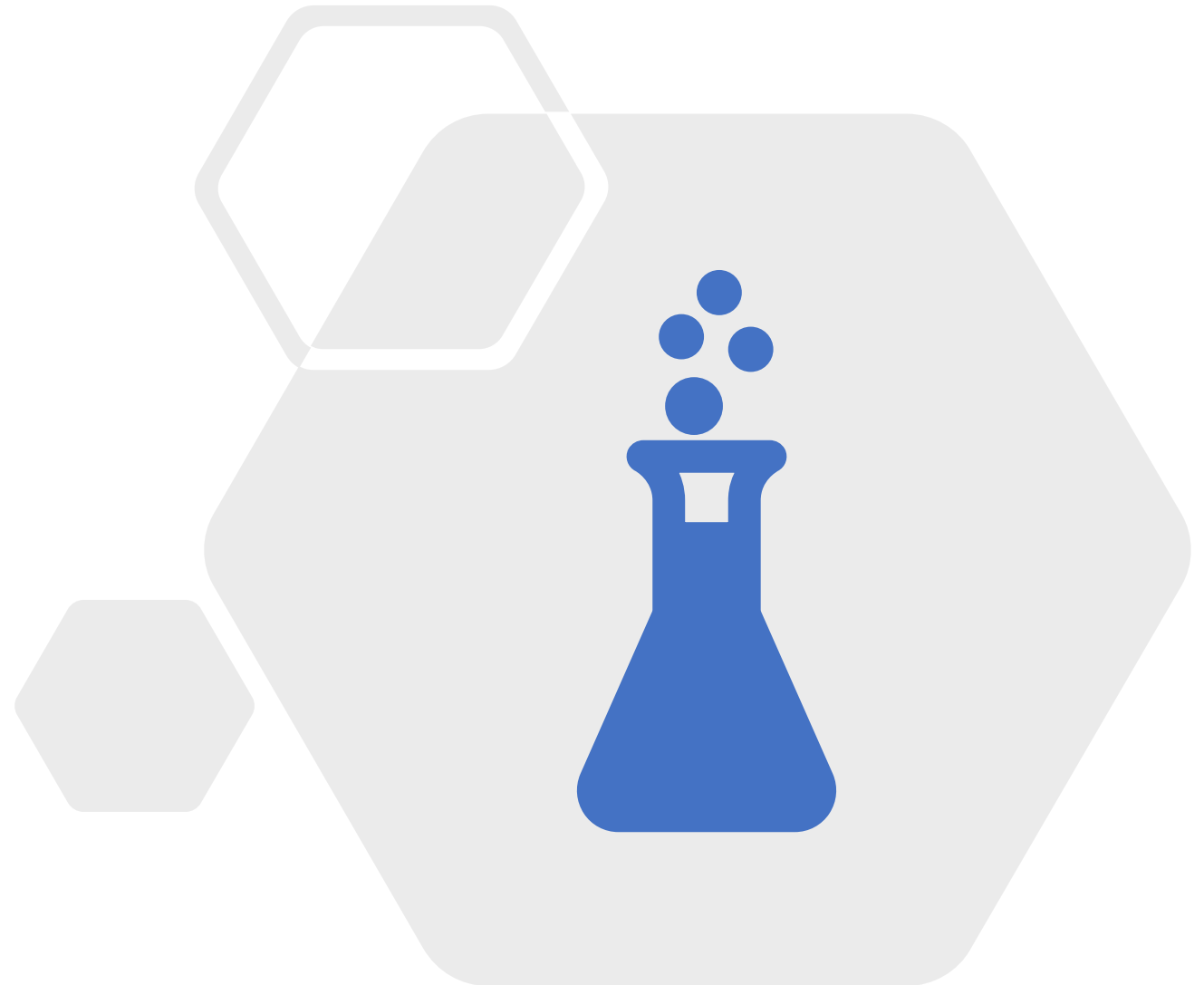
“If an NMDR is observed for an apical effect, the understanding of the underlying mechanism(s) is necessary to assess its biological plausibility and to consider the consequences for the risk assessment process”

- IMPLICATION: Re-assess all authorized chemicals and identify mechanisms of action for those with NMDR?
- Or: New approach to chemical risk assessment and management?



Reason 3: Mixtures

- many different chemicals in FCMs migrate simultaneously
- many other exposure routes to chemicals
- setting “safe” exposure levels for individual chemicals is not sufficiently protective for public health





low levels \neq safe levels

PROPOSAL FOR A REVISED

Legal definition of food packaging safety

“Materials and articles, [...], shall be manufactured [...] so that they do not contain constituents which could endanger human health.”

Some other developments

Recycled plastics for food contact

Printed FCMs

Styrene

Prioritization of authorized chemicals for reassessment

Recycled plastics for food contact



Recycled plastics draft regulation published Dec. 2021
public consultation ended 18 Jan. 2022
discussion and vote (?) in the Standing Committee
on 24 March 2022



Open letter sent to Commissioner Dr. Kyriakides
from by environmental and health NGOs, 21 Feb.
Concerns about safety



Systematic review article on chemicals in
(recycled) PET, levels of migration by Food
Packaging Forum and colleagues, published 4
March 2022



| Open letter

**Hazardous Chemicals and Food Safety –
recycled plastic in food packaging (updated rules)**



Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

Journal of Hazardous Materials

journal homepage: www.elsevier.com/locate/jhazmat



Review

Unpacking the complexity of the PET drink bottles value chain: A chemicals perspective

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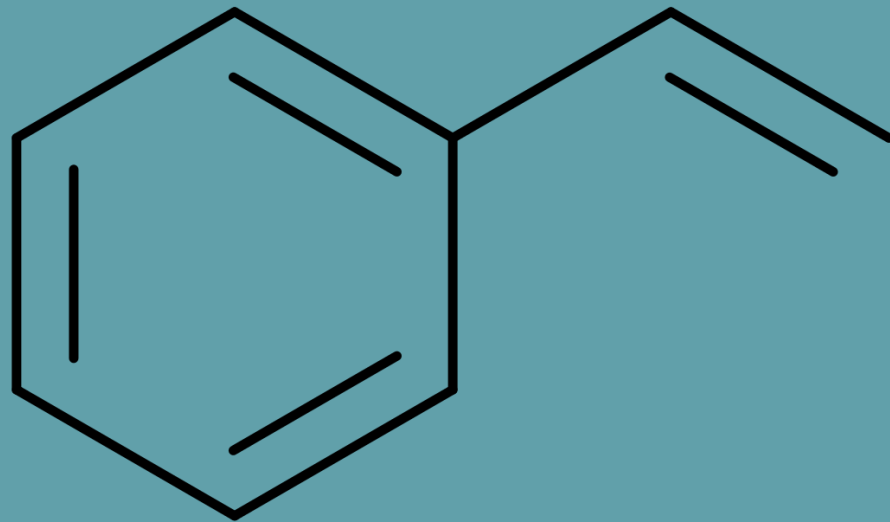


Printed FCMs: New German Ordinance

- Germany revises ordinance on printed FCMs, 2 December 2021
- Positive list of substances for inks and varnishes, some specific migration limits (for substances and groups)



Styrene



- Styrene survey published by EU Commission on 28 February 2022– open until 11 April
Input requested on use and migration levels from FCMs
- EFSA requested to work on styrene
- Food Packaging Forum webinar on styrene planned for April/May 2022, date tbc

Prioritization of authorized substances for reassessment: plasticizers

- EFSA published draft opinion on prioritization of plasticizers Nov 2021
- Proposes prioritization approach for assessing phthalate-alternative plasticizers
- Comments: Methodological shortcomings of prioritization approach; Unclear why scope only on plasticizers and not ALL authorized substances



Outlook



Prioritization of food contact chemicals with hazard properties under CSS



Systematic evidence map of chemicals migrating from/present in FCMs



Better integration of *sustainable packaging* and *chemicals*: for example Understanding Packaging Scorecard

