

Improving the safety of food contact articles

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Food Packaging Forum

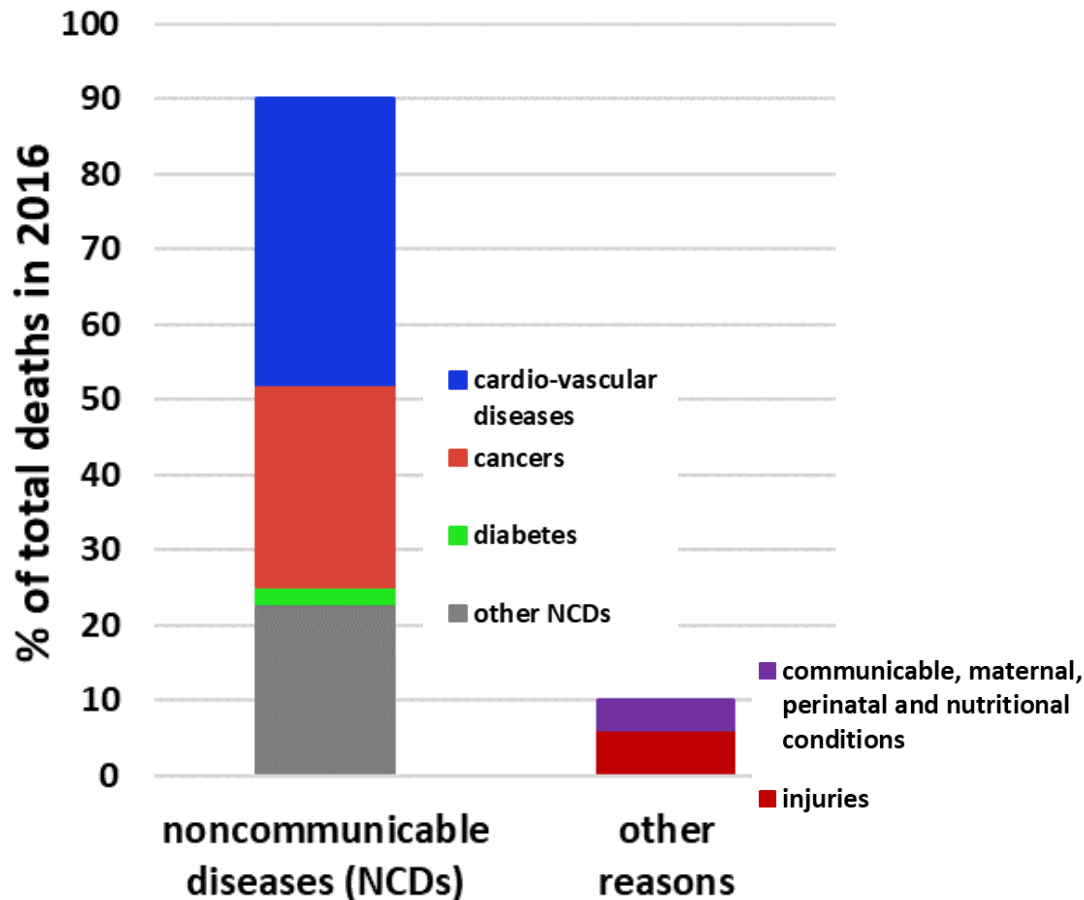
4 October 2018

Talk overview

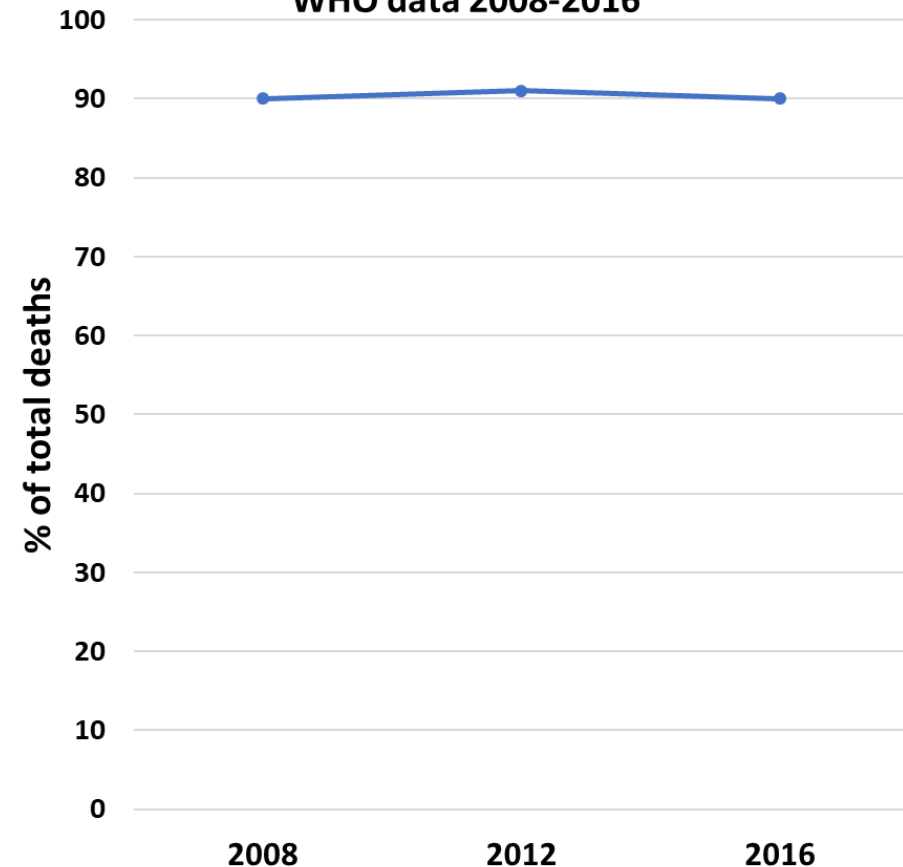
- Chemicals as a risk factor for noncommunicable diseases
- Why focus on food contact chemicals?
- FPF's work and vision for safe food contact articles

The burden of noncommunicable diseases (NCDs)

death statistics for Switzerland, WHO data 2016

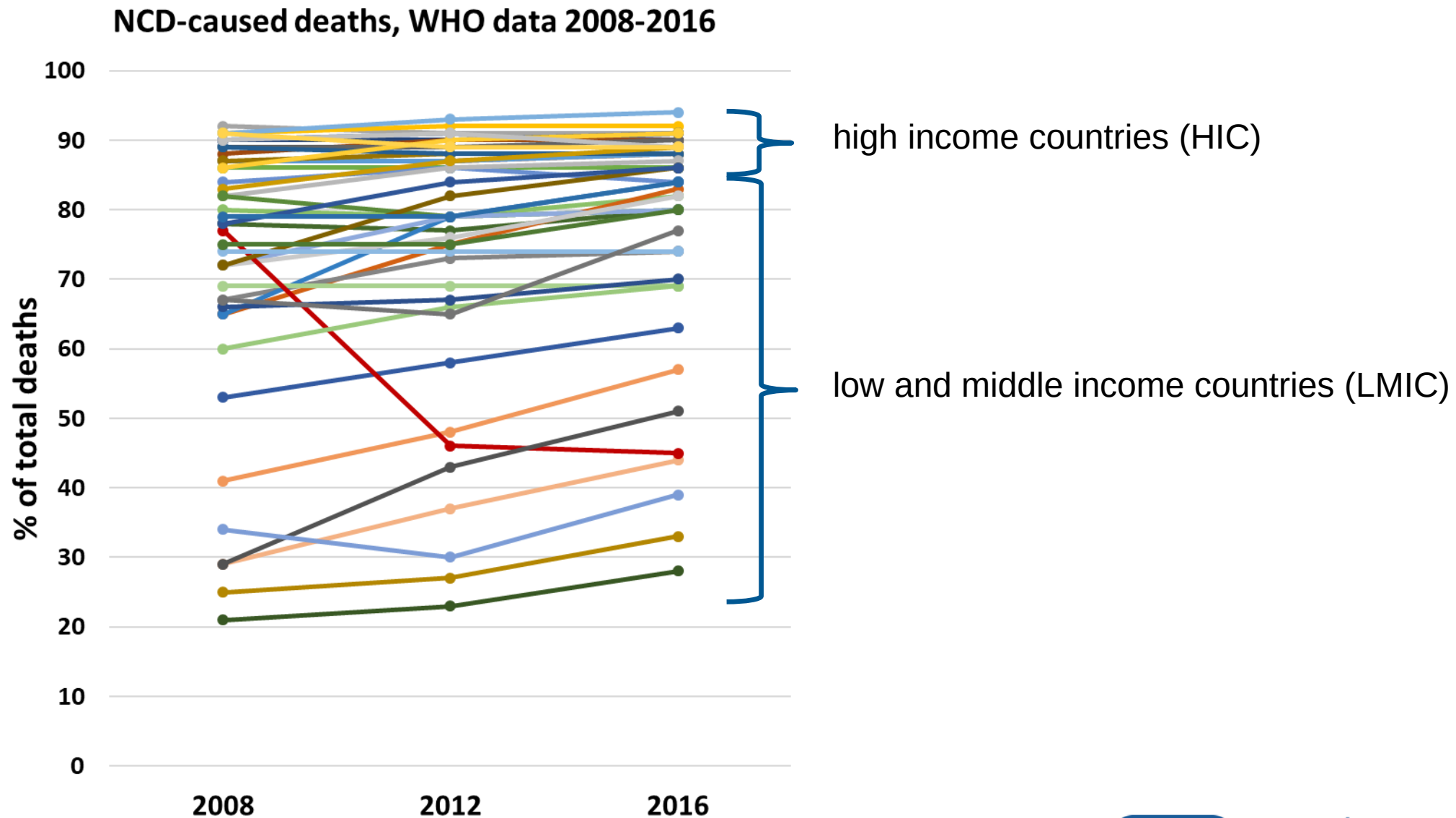


NCD-caused deaths in Switzerland, WHO data 2008-2016



<http://www.who.int/nmh/countries/en/>

NCDs gain importance worldwide



<http://www.who.int/nmh/countries/en/>

Why care about NCDs?

- high treatment costs
- high incidence of accompanying diseases and disabilities
- 'preventative' health care more efficient than 'curative' health care
- chronic condition resulting in impaired quality of life

↑ years of life → ↑ years of life in 'good health'

Prevention of NCDs: Where to look?

Factors involved in NCD etiology:

- intrinsic (=) genetics
- extrinsic (=) environmental impacts
 - lifestyle
 - diet
 - psychosocial factors
 - **chemicals**

“... environmental exposure is a major cause of disease, death, and disability in countries around the world. [...]

The adverse health consequences of exposure to environmental toxicants [...] receive insufficient attention.”

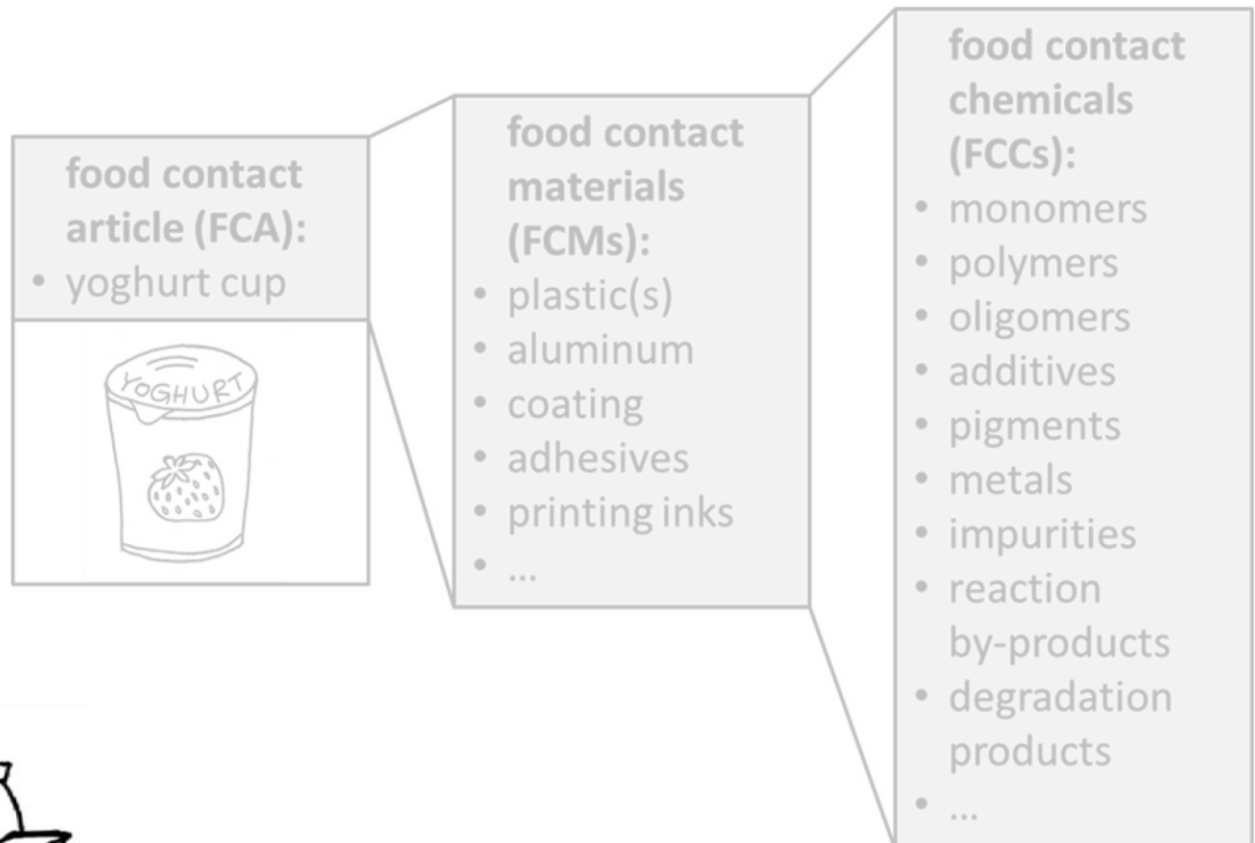
Landrigan et al., 2016. Health consequences of environmental exposures: Changing global patterns of exposure and disease. *Annals of Global Health* 82(1):10-19

WHO (2016). “The public health impact of chemicals: Knowns and unknowns.”

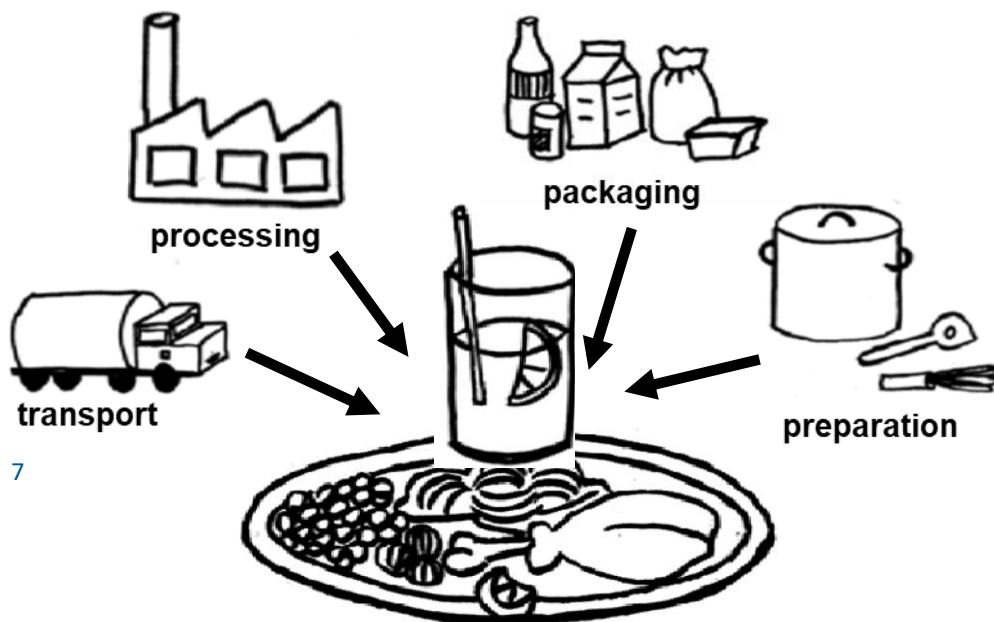
WHO (2017). “Preventing noncommunicable diseases (NCDs) by reducing environmental risk factors.”



Our focus: Food Contact Chemicals (FCCs)



sources of FCCs:



FCCs as food contaminants

	Pesticides	FCCs
Number of substances	~1500	Possibly ~100,000
Level of food contamination	µg/kg	mg/kg
Detailed toxicological evaluation	Yes	Often no

Source: Koni Grob and Gregor McCombie,
Official Food Control Authority Zurich (adopted)

Risk assessment and risk management of FCCs

Commentary

A Section 508-conformant HTML version of this article
is available at <https://doi.org/10.1289/EHP644>.

Scientific Challenges in the Risk Assessment of Food Contact Materials

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BACKGROUND: Food contact articles (FCAs) are manufactured from food contact materials (FCMs) that include plastics, paper, metal, glass, and printing inks. Chemicals can migrate from FCAs into food during storage, processing, and transportation. Food contact materials' safety is evaluated using chemical risk assessment (RA). Several challenges to the RA of FCAs exist.

OBJECTIVES: We review regulatory requirements for RA of FCMs in the United States and Europe, identify gaps in RA, and highlight opportunities for improving the protection of public health. We intend to initiate a discussion in the wider scientific community to enhance the safety of food contact articles.

DISCUSSION: Based on our evaluation of the evidence, we conclude that current regulations are insufficient for addressing chemical exposures from FCAs. RA currently focuses on monomers and additives used in the manufacture of products, but it does not cover all substances formed in the production processes. Several factors hamper effective RA for many FCMs, including a lack of information on chemical identity, inadequate assessment of hazardous properties, and missing exposure data. Companies make decisions about the safety of some food contact chemicals (FCCs) without review by public authorities. Some chemical migration limits cannot be enforced because analytical standards are unavailable.

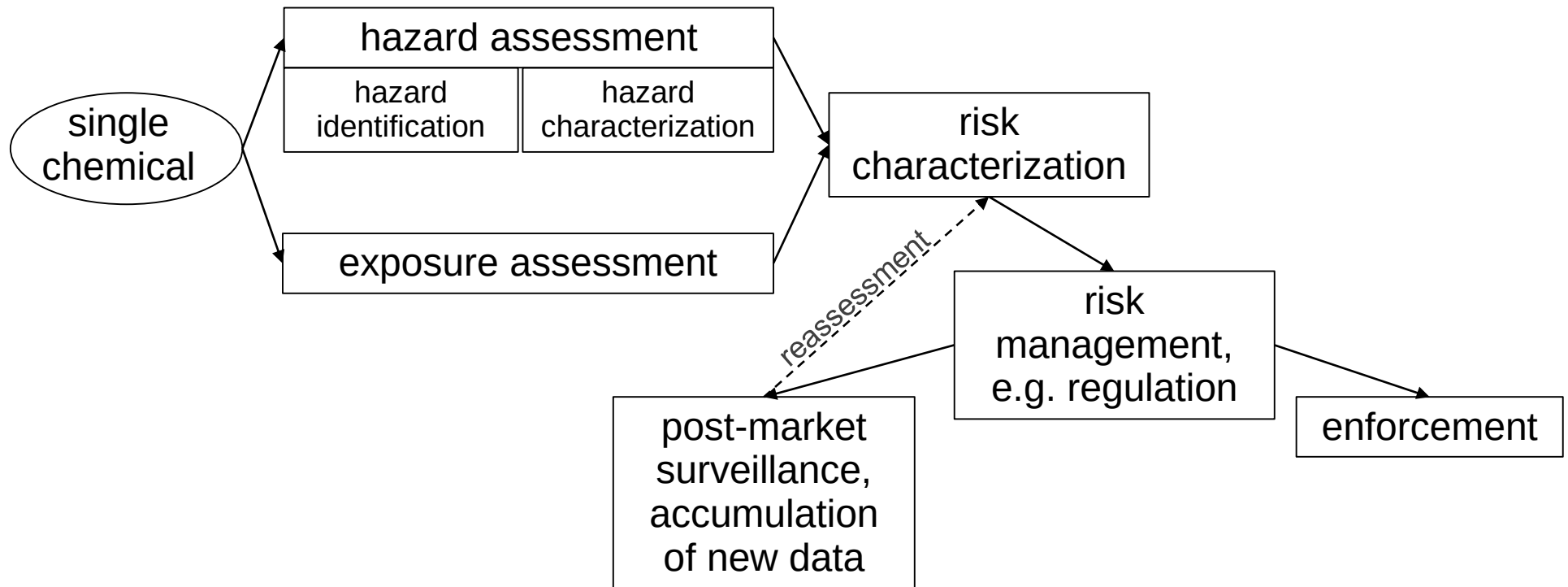
CONCLUSION: We think that exposures to hazardous substances migrating from FCAs require more attention. We recommend *a*) limiting the number and types of chemicals authorized for manufacture and *b*) developing novel approaches for assessing the safety of chemicals in FCAs, including unidentified chemicals that form during or after production. <https://doi.org/10.1289/EHP644>

Environmental Health Perspectives

095001-1



Risk assessment and risk management of FCCs



Identification: Too many chemicals

huge diversity of FCAs, FCMs, and FCCs

- 17 FCM types in the EU
- at least 8030 intentionally added or intentionally formed substances (IAS)
(JRC 2016. Non-harmonized food contact materials in the EU: Regulatory and market situation: Baseline study.
[en_jrc104198_fcm_baseline_final_report_2017-01-16_all.pdf](#))
- up to 100 000 non-intentionally added substances (NIAS)
 - analytical challenge for identification and quantification
 - chemical identity often remains unknown

Dossier – Non-intentionally added substances (NIAS)



June 2018, 2nd edition

DOI: 10.5281/zenodo.1265331

Birgit Geueke

auch in Deutsch! DOI: 10.5281/zenodo.1280986

- reference substances often unavailable
for both IAS and NIAS



Identification: Limited data on chemicals in products

“Hazardous chemicals in plastic packaging:
State of the art, prioritization, and assessment”
(HCPP project): multi-partner research project led by FPF, 2017-2019

Overview of known plastic packaging-associated chemicals and their hazards

Ksenia Groh, Thomas Backhaus, Bethanie Carney-Almroth, Birgit Geueke, Pedro Inostroza, Anna Lennquist, Maricel Maffini, Heather Leslie, Daniel Slunge, Leonardo Trasande, Michael Warhurst, Jane Muncke

Science of the Total Environment (accepted)

- Database of Chemicals associated with Plastic Packaging (CPPdb)
 - ca. 900 substances likely associated
 - ca. 3350 substances possibly associated
- significant lack of publicly accessible information on the exact chemical composition of plastic packaging

Hazard assessment: Official hazard classifications

- HCPP project delivered a list of 148 known hazardous chemicals likely associated with plastic packaging
- Prioritization case studies: 5 phthalates prioritized for further assessment of risks for human health or the environment



September 2018

Prioritization approaches for hazardous chemicals associated with plastic packaging

Birgit Geueke¹, Pedro A. Inostroza², Maricel Maffini³, Thomas Backhaus², Bethanie Carney-Almroth², Ksenia J. Groh¹, and Jane Muncke¹

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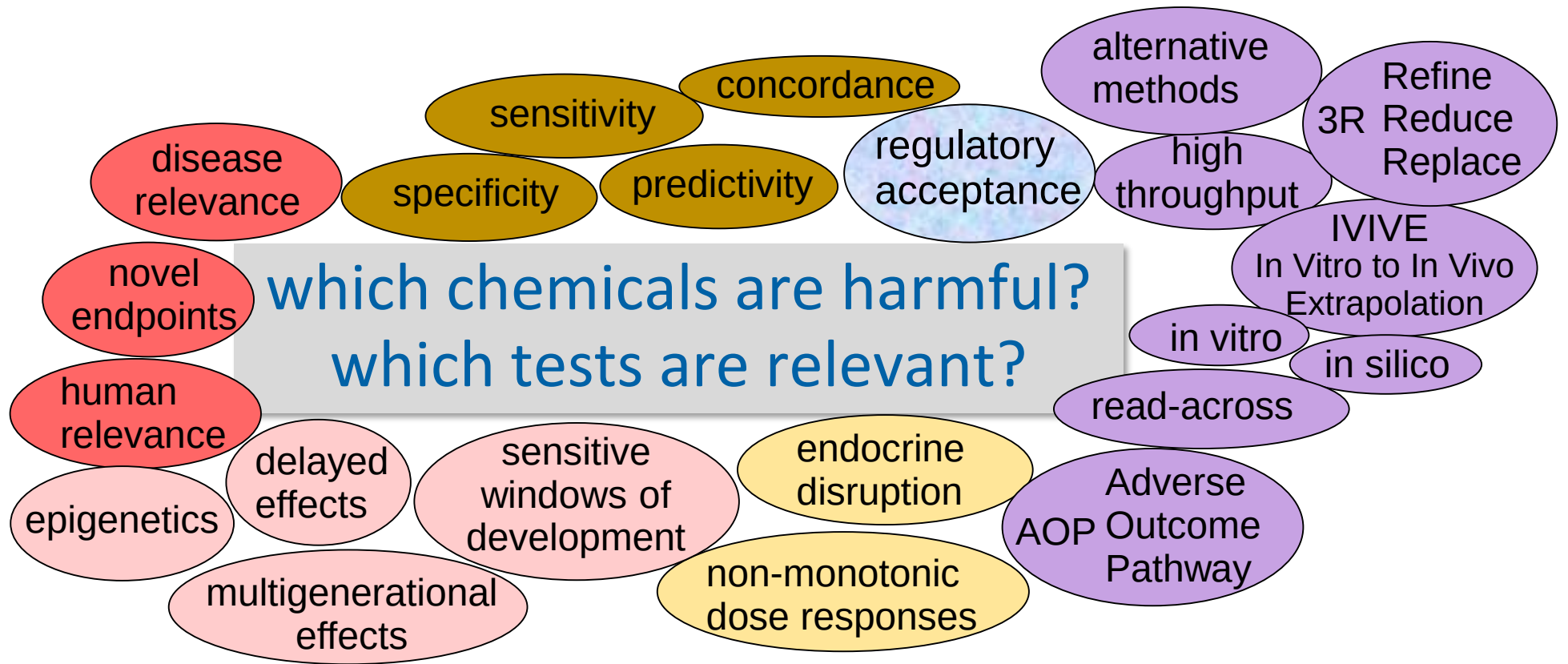
DOI: 10.5281/zenodo.1436442



Hazard assessment: Little data for many chemicals

- For many chemicals, both IAS and NIAS, hazard information often uncertain or unavailable
- For both IAS and NIAS, absence of reference substances hampers 'classical' toxicity assessment
- Would computational tools offer a solution for dealing with the large numbers of unassessed chemicals?

Hazard assessment: Further challenges



Risk management: Conflicting regulatory landscape (1)

Some Food Contact Chemicals are Substances of Very High Concern

Food Additives & Contaminants: Part A, 2014
<http://dx.doi.org/10.1080/19440049.2014.931600>



Taylor & Francis
Taylor & Francis Group

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

(Received 10 February 2014; accepted 2 June 2014)

~170 chemicals of concern identified within FCC lists, of them >20 SVHCs

But what about migration?

No migration = No exposure = No risk

Risk management: Conflicting regulatory landscape (2)

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

By Birgit Geueke * and Jane Muncke 

Food Packaging Forum Foundation, Staffelstrasse 8, 8045, Zurich, Switzerland

Evidence of migration into food or food simulant available for
5 out of 10 FCM substances found on the Annex XIV of REACH
in 2015; for other substances, there were no (open) data



Responses from government and industry

European Parliament

2014-2019

P8_TA(2016)0384

Implementation of the Food Contact Materials Regulation

European Parliament resolution of 6 October 2016 on the implementation of the Food Contact Materials Regulation (EC) No 1935/2004 (2015/2259(INI))



“European Parliament [...] calls on the Commission to ensure better coordination and a **more coherent approach between the REACH and FCM legislation**, in particular as regards substances classified as CMRs (categories 1A, 1B and 2) or SVHCs under REACH, and to **ensure that harmful substances phased out under REACH are also phased out in FCMs**. [...]”



Food Packaging Product Stewardship Considerations:

“This is a voluntary set of considerations [...] for [...] eliminating chemicals of concern from food packaging. This document may go beyond regulatory requirements. [...]”

Problems with the current risk assessment paradigm

Current approach	Reality
Single chemicals (mostly IAS) assessed one-at-a-time	Multiple FCCs, including often unknown NIAS, are present simultaneously; mixture effects remain unaddressed
Toxicity tests prescribed from a rigid and limited set of possibilities	Multiple effects possible, including contribution to chronic diseases, largely not covered by currently prescribed tests
The depth of required toxicological assessment depends on the anticipated exposure levels	Large uncertainties in estimation of migration and exposure due to lack of information and multiple assumptions
Single chemicals assessed and managed separately within each regulatory silo	Combined exposures (both aggregate and cumulative) ubiquitous

A vision for safer food packaging: Exposure

HUMAN HEALTH-RELEVANT EXPOSURE ASSESSMENT

- Test finished food contact articles to capture mixture toxicity of all migrating substances



**Comprehensive
REVIEWS**
in Food Science and Food Safety

2017; Vol. 16, pp. 1123-1150

In Vitro Toxicity Testing of Food Contact Materials: State-of-the-Art and Future Challenges

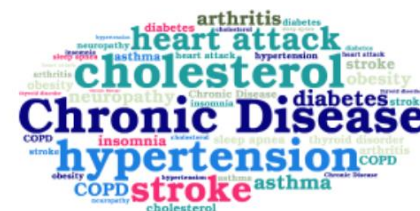
Ksenia J. Groh  and Jane Muncke 

- feasibility and usefulness demonstrated
- further research needs:
 - sample preparation
 - assay selection and interpretation

A vision for safer food packaging: Hazard

HUMAN HEALTH-RELEVANT HAZARD ASSESSMENT

- Focus on endpoints/tests relevant for prediction of chronic diseases prevalent in population



use public health concerns as drivers for improved testing



- example of novel aspects to consider in both hazard and exposure assessment

A vision for safer food packaging: Risk management

HUMAN HEALTH-CONSCIOUS RISK MANAGEMENT

- Ensure harmonized regulation and equal treatment of all potential exposure sources; ensure proper enforcement



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

Review

Food packaging in the circular economy: Overview of chemical safety aspects for commonly used materials

Birgit Geueke*, Ksenia Groh, Jane Muncke

Food Packaging Forum Foundation, Staffelstrasse 8, 8045 Zurich, Switzerland





- recycling should not compromise FCMs' safety

Conclusions

“... the current paradigm for evaluation of safety of FCMs is insufficient ...”
(European Parliament, 2016. Implementation of the food contact materials regulation. Report P8_TA(2016)0384)

- Way forward:
 - limit the number of food contact chemicals
 - test finished food contact articles in addition to single substances
 - select and use bioassays relevant for NCDs of concern

Muncke J. et al. (2017). “Scientific challenges in the risk assessment of food contact materials.” *Environmental Health Perspectives* 125: 095001.

Thank you for your attention!