Improving the safety of food contact articles

Ksenia Groh
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

- % of total deaths in 2016
  - cardio-vascular diseases
  - cancers
  - diabetes
  - other NCDs
  - communicable, maternal, perinatal and nutritional conditions
  - injuries

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

% of total deaths

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

FPF workshop 2018 | 4 October 2018
NCDs gain importance worldwide

NCD-caused deaths, WHO data 2008-2016

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

\[ \uparrow \text{years of life} \rightarrow \uparrow \text{years of life in ‘good health’} \]
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.”


WHO (2017). “Preventing noncommunicable diseases (NCDs) by reducing environmental risk factors.”
Our focus: Food Contact Chemicals (FCCs)

sources of FCCs:

- food contact article (FCA): yogurt cup
- food contact materials (FCMs):
  - plastic(s)
  - aluminum
  - coating
  - adhesives
  - printing inks
  - ...

food contact chemicals (FCCs):
- monomers
- polymers
- oligomers
- additives
- pigments
- metals
- impurities
- reaction by-products
- degradation products
- ...

processing
packaging
transport
preparation

Food Packaging Forum
### FCCs as food contaminants

<table>
<thead>
<tr>
<th></th>
<th>Pesticides</th>
<th>FCCs</th>
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<tbody>
<tr>
<td>Number of substances</td>
<td>~1500</td>
<td>Possibly ~100,000</td>
</tr>
<tr>
<td>Level of food contamination</td>
<td>µg/kg</td>
<td>mg/kg</td>
</tr>
<tr>
<td>Detailed toxicological evaluation</td>
<td>Yes</td>
<td>Often no</td>
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Source: Koni Grob and Gregor McCombie, Official Food Control Authority Zurich (adopted)
Commentary

Scientific Challenges in the Risk Assessment of Food Contact Materials

Jane Muncke,1 Thomas Backhaus,2 Birgit Geneke,1 Maricel V. Maffini,3 Olwenn Viviane Martin,4 John Peterson Myers,5,6 Ana M. Soto,7 Leonardo Trasande,8 Xenia Trier,9 and Martin Scheringer10,11

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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

- **Single chemical**
  - hazard assessment
    - hazard identification
    - hazard characterization
  - exposure assessment
  - post-market surveillance, accumulation of new data
  - risk characterization
  - risk management, e.g. regulation
  - enforcement

Reassessment
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)

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

Prioritization approaches for hazardous chemicals associated with plastic packaging

Birgit Geueke¹, Pedro A. Inostroza², Maricel Maffini³, Thomas Backhaus³, 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

which chemicals are harmful?
which tests are relevant?
Risk management: Conflicting regulatory landscape (1)

Some Food Contact Chemicals are Substances of Very High Concern

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

But what about migration?

No migration = No exposure = No risk
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
European Parliament
2014-2019

P8_TA(2016)0384

Implementation of the Food Contact Materials Regulation

“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

<table>
<thead>
<tr>
<th>Current approach</th>
<th>Reality</th>
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<tr>
<td>Single chemicals (mostly IAS) assessed one-at-a-time</td>
<td>Multiple FCCs, including often unknown NIAS, are present simultaneously; mixture effects remain unaddressed</td>
</tr>
<tr>
<td>Toxicity tests prescribed from a rigid and limited set of possibilities</td>
<td>Multiple effects possible, including contribution to chronic diseases, largely not covered by currently prescribed tests</td>
</tr>
<tr>
<td>The depth of required toxicological assessment depends on the anticipated exposure levels</td>
<td>Large uncertainties in estimation of migration and exposure due to lack of information and multiple assumptions</td>
</tr>
<tr>
<td>Single chemicals assessed and managed separately within each regulatory silo</td>
<td>Combined exposures (both aggregate and cumulative) ubiquitous</td>
</tr>
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HUMAN HEALTH-RELEVANT EXPOSURE ASSESSMENT
• Test finished food contact articles to capture mixture toxicity of all migrating substances

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

*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

• recycling should not compromise FCMs’ safety

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

Journal of Cleaner Production
journal homepage: www.elsevier.com/locate/jclepro

Contents lists available at ScienceDirect

Journal of Cleaner Production 193 (2018) 491–565
Conclusions


• 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

Thank you for your attention!