Scientific Challenges in the Risk Assessment of Food Contact Materials – 2017 Workshop of the Food Packaging Forum Foundation

Zürich, October 5, 2017

www.foodpackagingforum.org

Food Packaging Forum

Welcome

- FPF‘s mandate
- Donations
- FPF‘s perspective
- Practical issues
  - Coffee breaks and lunch: next door
  - Filming
  - Next year‘s workshop: October 4, 2018, in Zürich
  - Questionnaire

Food Packaging Forum

Scientific Challenges in the Risk Assessment of Food Contact Materials – Work by the FPF's Scientific Advisory Board

Prof. Dr. Martin Scheringer

Food Packaging Forum Foundation, Zurich

www.foodpackagingforum.org

scheringer@chem.ethz.ch

Food Packaging Forum

SAB Members

- Anna-Maria Andersson, Rijkshospitalet Copenhagen
- Tamara Galloway, Exeter University
- David Gee, Brunel University
- Russ Hauser, Harvard University
- Jerrold J. Heindel, Commonweal
- Maricel Maffini, independent consultant
- Olwenn Martin, Brunel University
- Ana Soto, Tufts University
- Leonardo Trasande, New York University
- R. Thomas Zoeller, University of Massachusetts

Food Packaging Forum

Recent Publication by FPF's Scientific Advisory Board

ehp ENVIRONMENTAL HEALTH PERSPECTIVES

Current Issue | Articles | Collections | Authors | EHP 中文版 | Career Opportunities | E-Ma

COMMENTARY SEPTEMBER 2017 I VOLUME 125 I ISSUE 9

Altmetric 35

Environ Health Perspect; DOI:10.1289/EHP644

Scientific Challenges in the Risk Assessment of Food Contact Materials

Jane Muncke,[1] Thomas Backhaus,[2] Birgit Geueke,[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 Scheringer[10,11]

Environmental Health Perspectives (2017), doi: 10.1289/EHP644

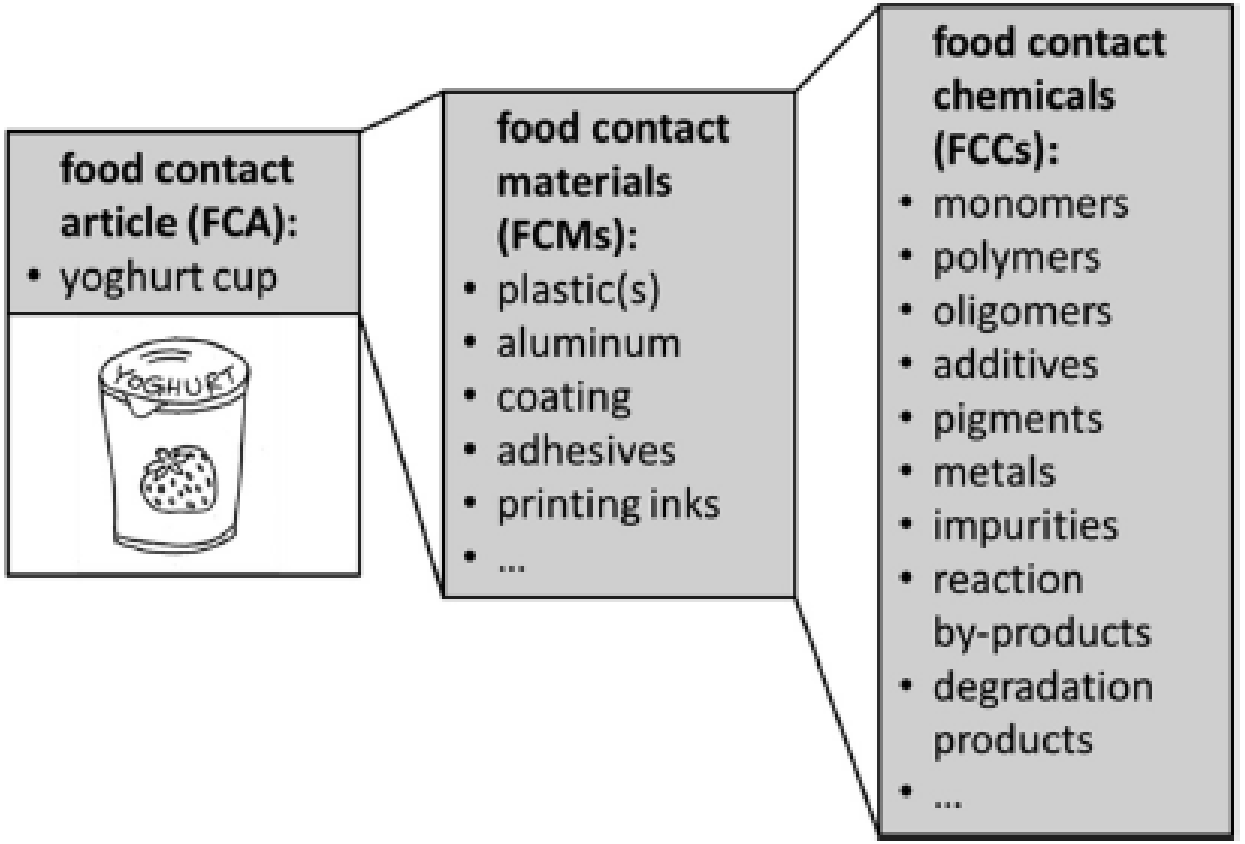
Overview

- Regulatory context
- Scientific challenges
- Possible solutions
- Conclusions

Food Packaging Forum

Food Concact Chemicals, Food Contact Materials, and Food Contact Articles

- FCAs
- FCMs
- FCCs



Muncke et al. (2017) *Environmental Health Perspectives*, Figure 1

Food Packaging Forum

Regulations in the EU and in the US

- SAB paper: Overview of legal requirements and testing procedures
- FCMs and FCAs "shall be manufactured [. . .] so that they do not transfer their constituents to food in quantities which could endanger human health."[1]
- FCMs are considered safe if there is "reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use."[2]

1 EU FCM Framework Regulation (1935/2004)
2 U.S. Code of Federal Regulations Title 21, part 170.3 (i)

Food Packaging Forum

Regulations in the EU and in the US

- Practical implications
  - Testing requires **detailed knowledge** about the chemicals present in FCMs: identity, properties, exposure, effect thresholds
  - Risk assessments primarily performed for **individual substances** used **intentionally** – as starting substances or additives – in FCM manufacture

Food Packaging Forum

Regulations in the EU and in the US

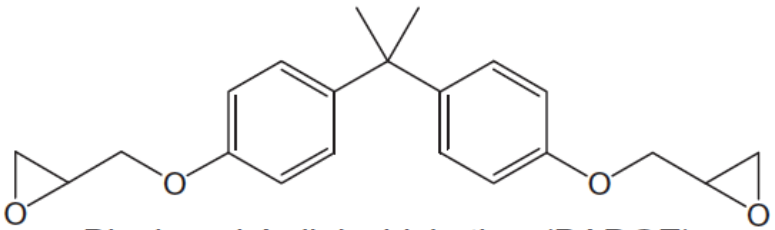
- Practical implications
  - Testing requires **detailed knowledge** about the chemicals present in FCMs: identity, properties, exposure, effect thresholds
  - Risk assessments primarily performed for **individual substances** used **intentionally** – as starting substances or additives – in FCM manufacture
- Testing requirements depend on extent of migration

Food Packaging Forum

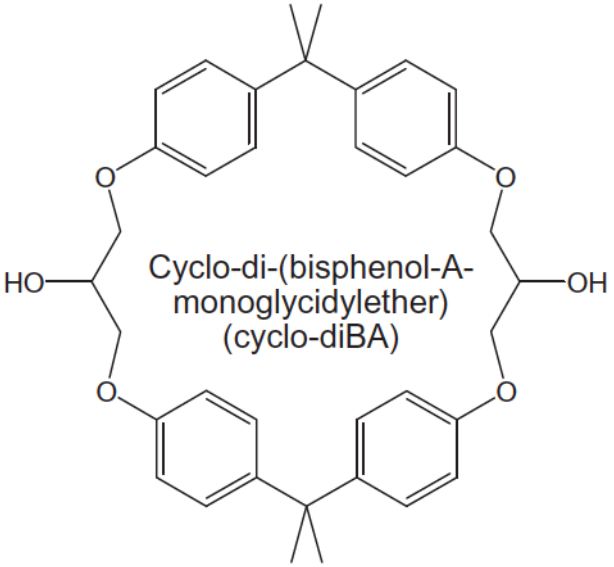
Challenges (I)

- FCMs contain **more chemicals** than the ones known from the manufacture of FCMs: Non-Intentionally Added Substances, NIAS (100s to 1000s)
  - Impurities, by-products, oligomers, degradation products

in epoxy resins



Bisphenol A diglycidyl ether (BADGE)



Cyclo-di-(bisphenol-A-monoglycidylether) (cyclo-diBA)

Food Packaging Forum

Biedermann et al. (2013) *Food and Chemical Toxicology* **58**, 107–115

Challenges (I)

- FCMs contain **more chemicals** than the ones known from the manufacture of FCMs: Non-Intentionally Added Substances, NIAS (100s to 1000s)
  - Impurities, by-products, oligomers, degradation products
  - Many NIAS: **identity not known**.
  - Implication: many NIAS cannot be assessed (as individual substances)

Food Packaging Forum

Challenges (I)

- FCMs contain **more chemicals** than the ones known from the manufacture of FCMs: Non-Intentionally Added Substances, NIAS (100s to 1000s)
  - Impurities, by-products, oligomers, degradation products
  - Many NIAS: **identity not known**.
  - Implication: many NIAS cannot be assessed (as individual substances)
- FCCs occur not as single substances, but **in combinations**
  - Cumulative exposure
  - Mixture toxicity

Food Packaging Forum

Challenges (II)

- Limitations and unrealistic assumptions

Food Packaging Forum

Challenges (II)

- Limitations and unrealistic assumptions
  - Focus on starting substances of FCM manufacture[1]
  - Assessment of individual chemicals (one-by-one)

Food Packaging Forum

1 but: Regulation (EU) No. 10/2011 (“Plastics Regulation”)

Challenges (II)

- Limitations and unrealistic assumptions
  - Focus on starting substances of FCM manufacture[1]
  - Assessment of individual chemicals (one-by-one)
  - Generic toxicological thresholds may be used in the absence of toxicological data
  - No uptake of chemicals above 1000 Da (Dalton)

Food Packaging Forum

1 but: Regulation (EU) No. 10/2011 (“Plastics Regulation”)

Challenges (II)

- Limitations and unrealistic assumptions
  - Focus on starting substances of FCM manufacture[1]
  - Assessment of individual chemicals (one-by-one)
  - Generic toxicological thresholds may be used in the absence of toxicological data
  - No uptake of chemicals above 1000 Da (Dalton)
  - Hazard assessment focuses on certain effects, e.g. genotoxicity, but not captured are: **cardiovascular** diseases, **metabolic** diseases, diseases mediated by **endocrine disruptors**

Food Packaging Forum

1 but: Regulation (EU) No. 10/2011 (“Plastics Regulation”)

Challenges (III)

- Regulation of FCMs not consistent with other chemical regulations:
  - Some substances authorized under the European FCM Framework Regulation (1935/2004) were listed as Substances of Very High Concern (SVHCs) under REACH[1]
  - Examples: four phthalates, one primary aromatic amine
  - Problem: Use in FCM is exempted under REACH because FCM Framework Regulation is assumed to cover human health risks from use in FCMs
  - Result: relevant migration of these SVHCs into food is possible.

1 Geueke & Muncke (2017) *Packaging Technology and Science*

Food Packaging Forum

Challenges (III)

- Regulation of FCMs not consistent with other chemical regulations:
  - Some substances authorized under the European FCM Framework Regulation (1935/2004) were listed as Substances of Very High Concern (SVHCs) under REACH

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

Geueke & Muncke (2017) doi: 10.1002/pts.228

Possible Solutions (I)

- Test FCMs as endproducts and use **overall migrate** in toxicological tests
- Use bioassays of overall migrate and subsequent chemical analysis

Comprehensive REVIEWS in Food Science and Food Safety

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

Ksenia J. Groh and Jane Muncke

Groh & Muncke (2017)
doi: 10.1111/1541-4337.12280

Abstract: Currently, toxicological testing of food contact materials (FCMs) is focused on single substances and their genotoxicity. However, people are exposed to mixtures of chemicals migrating from food contact articles (FCAs) into food, and toxic effects other than genotoxic damage may also be relevant. Since FCMs can be made of more than 8 thousand substances, assessing them one-by-one is very resource-consuming. Moreover, finished FCAs usually contain non-intentionally added substances (NIAS). NIAS toxicity can only be tested if a substance's chemical identity is known and if it is available as a pure chemical. Often, this is not the case. Nonetheless, regulations require safety assessments for all substances migrating from FCAs, including NIAS, hence new approaches to meet this legal obligation are needed.

Possible Solutions (I)

- Test FCMs as endproducts and use **overall migrate** in toxicological tests
- Use bioassays of overall migrate and subsequent chemical analysis

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

Ksenia J. Groh and Jane Muncke

Groh & Muncke (2017)
doi: 10.1111/1541-4337.12280

- In-vitro testing of FCMs with bioassays is in principle **feasible**
- Sample preparation needs to be optimized and standardized
- In-vitro bioassays need to have relevance to human health

Possible Solutions (II)

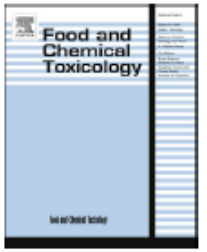
- Avoid chemicals with unknown toxicity
- Avoid SVHCs, use fewer chemicals
- Review critically – and revise – the assumptions underlying chemical risk assessment
  - Example: uptake of substances above 1000 Da

Food and Chemical Toxicology 109 (2017) 1–18

Contents lists available at ScienceDirect

Food and Chemical Toxicology

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



Review

Food contact materials and gut health: Implications for toxicity assessment and relevance of high molecular weight migrants

Ksenia J. Groh*, Birgit Geueke, Jane Muncke

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

Possible Solutions (III)

- Develop testing methods that cover important diseases: cardiovascular, metabolic, EDC mediated
- Long-term goal
- Topic of ongoing work by FPF‘s SAB

Food Packaging Forum

Conclusions

- Common denominator of many challenges: high complexity, lack of knowledge
- Therefore:
  - Fewer substances
  - Simpler chemistry

Food Packaging Forum

Today's Program (I)

09:30 **Measuring migration from FCMs: Scientific and practical challenges**
Dr. Eddo Hoekstra, EU Joint Research Centre, Italy

10:00 **Printed paper and board: Priority setting strategy for toxicological assessment**
Melissa Van Bossuyt, Scientific Institute of Public Health and Vrije Universiteit Brussel, Belgium

10:30 *Coffee break*

11:00 **Recent advances in accumulation and effects of MOSH in rats - an overview**
Dr. Jean-Pierre Cravedi, INRA, France, and EFSA CEF Panel

11:30 **Application of bioassays for packaging safety evaluation**
Dr. Benoit Schilter, Nestlé Research Center, Switzerland

12:00 **Why good science is not value-free**
Dr. Karim Bschir, ETH Zurich, Switzerland

13:30 **The reform of Chinese legislation for FCMs and the challenges for compliance**
Dr. Marco Zhong, National reference laboratory for food contact materials, China

What (and how much) migrates?

Relevant toxicological endpoints?

Cumulative exposure?

Mixture toxicity?

Food Packaging Forum

Today's Program (II)

	Podium: Ensuring the safety of FCMs in a global economy
14:00	**Packaging safety challenges: Supply chain communication** James Huang, The Coca-Cola Company, USA
14:15	**Communication in the supply chain and the influence on compliance assessment** Kris Callaert, Viaware, the Netherlands
14:30	**Independent third-party testing labs: What role can and should they play in enforcing FCM regulations?** Dr. Thomas Gude, SQTS, Switzerland
14:45	**Using new scientific knowledge to update regulations in the U.S.** Dr. Maricel Maffini, independent consultant, USA

Communication between raw material suppliers, converters, packaging manufacturers, food industry, regulators, testing labs, consumers,…

Food Packaging Forum

Acknowledgment

- Thanks to Dr. Birgit Geueke and Dr. Jane Muncke

Food Packaging Forum