

Review of guidance documents

Stefan Merkel

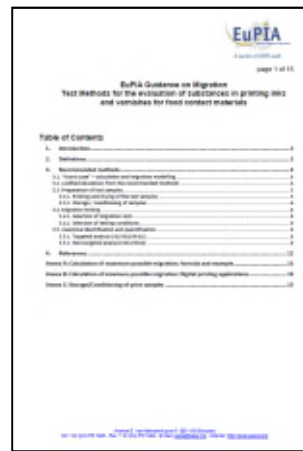
Germany

- BfR is preparing a guideline for the application of adding new substances to the German Ordinance on Printing Inks
- German Ordinance is still a draft
 - Guideline is in preparation and not public

BfR Guideline

- Application for the Safety Assessment of a Substance for the German Ordinance for Printing Inks the EFSA Note for Guidance is used
- BfR guideline contains additional explanations especially for parts that have not been answered sufficiently in the past (e.g. oligomer analytic, data quality)
- EFSA Note for Guidance is mainly used for plastic FCMs
 - Different information is required in some points when making an application for printing inks

EuPIA Guideline



EuPIA
Association

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BfR & Guideline on Migration
Test Methods for the evaluation of substances in printing inks
and varnishes for food contact materials

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Some parts of the guideline are similar to the BfR guideline (as industry contributed also to the BfR guideline)

→ Use of expertise of European Printing Ink Association

e.g. technical information for printing

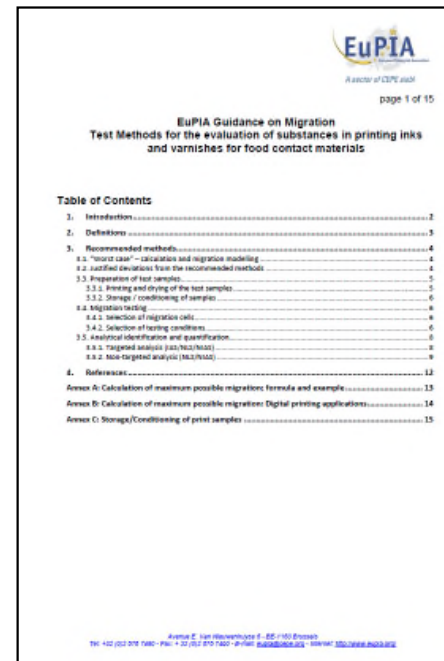
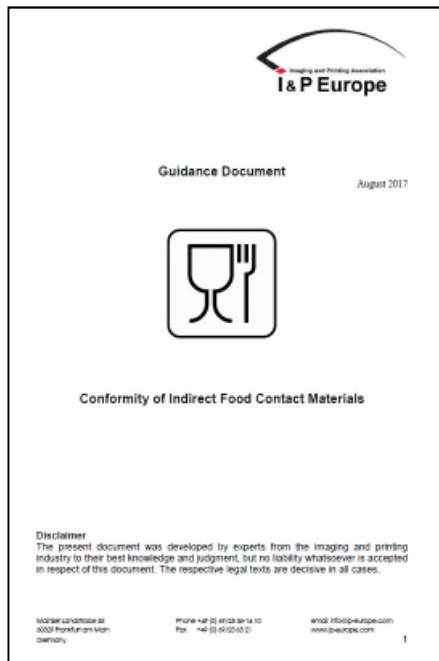
→ Critical review of the information adopted from industry

→ Comparison of new EuPIA Guideline to information at BfR – discussion with industry on differences

EuPIA Guideline and I & P Guideline

Comments

- No comments on these two guidelines
- Guidelines are for conformity work – BfR is not responsible for conformity work

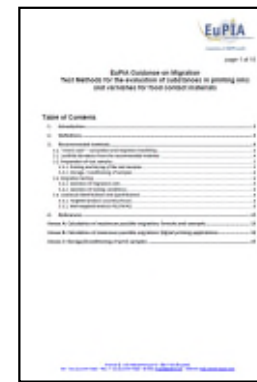




I & P Guideline

Content

- **Overview of legislation on Food Contact Materials in EU**
 - The Framework Regulation, Good Manufacturing Practice (GMP), Specific directives/regulations
- **Problem of Migration**
 - Transfer Principles, Migration Limits, Functional barrier concept, Assessment of potential migration / migration testing, Problems in packaging production, Worst case calculation
- **GMP – Good Manufacturing Practice**



EuPIA Guideline

Content

- Recommended methods

- “Worst case” – calculation and migration modelling
- Justified deviations from the recommended methods
- Preparation of test samples
- Printing and drying of the test samples
- Storage / conditioning of samples
- Migration testing
- Selection of migration cells
- Selection of testing conditions
- Analytical identification and quantification
- Targeted analysis (IAS/NLS/NIAS)
- Non-targeted analysis (NLS/NIAS)

Thank you for your attention

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