Review of guidance documents

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- 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
The EuPIA Guideline is unique. 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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