Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Home Affairs FDHA
Federal Food Safety and Veterinary Office FSVO
Risk Assessment Division

Bundesinstitut für Risikobewertung

Joint safety evaluation of substances in printing inks by Germany (BfR) and Switzerland (FSVO)

Stefan Merkel (BfR)
Stefan Kucsera (FSVO)

5th EFSA FIP Network FCM Meeting
Parma, 10.-11.7.2017

Overview

- History and background
- Swiss Ordinance on FCM
- Draft German Ordinance on Printing Inks
- Joint safety evaluations by Germany and Switzerland
  - Methodology
  - Results
- Conclusions

Chronology of Packaging inks regulation

1900s….	Regulations on As and Pb in inks (CH)
1990	Formation of the Ad-hoc working group at the Council of Europe
14.09.2005	Resolution **[Res AP(2005)2]** is adopted by the Council of Ministers
2005	Contamination of infant formula by photoinitiator (ITX)
07.03.2008	Publication of the regulation on packaging inks in the Swiss legislation **[RS 817.023.21]** effective as of April 2010
09.2009	Exhaustive list of substances used in production of packaging inks is delivered by EuPiA
2010	1st Draft German Ordinance on Printing Inks
2012	Questionnaire for Roadmap indicates demand of member states and industry for regulation of inks for FCM
2012	**Joint evaluation of printing inks starts**
2013	CH: 3rd revision of the list of permitted substances
01.05.2017	**Revised Swiss Ordinances on Food and Consumer products including FCM printing inks entered into force.**

Swiss Ordinance on FCM

Annex 10: Printing inks

2 categories of substances:

Toxicologically evaluated substances ***(part A)***

- Specific migration limit (SML) are given (derived from risk assessment & management)

Non-evaluated substances ***(part B)***

- No CMR classification
- Should not be detected in the food (analytical limit is **10 µg/kg**)

https://www.blv.admin.ch/blv/en/home/gebrauchsgegenstaende/materialien-in-kontakt-mit-lebensmitteln/verpackungen.html

List of permitted substances (Swiss Ordinance)

List	Substance category	Part A	Part B
I	Monomers	338	1098
II	Colorants	101	357
III	Solvents and energy curing monomers	81	184
IV	Additives	695	2412
V	Photoinitiators	28	78

Sum of substances (double entries excluded) → **1087** **3927**

Σ = **5014 substances** (includes many monomers and additives of EU Regulation 10/2011)

Notification of new substances (Swiss Ordinance)

Art. 41 Updating of Annexes

[1] The FSVO shall adjust the annexes to the state of the scientific and technical knowledge as well as to the legislation of the major trade partners of Switzerland.

[2] Transitional provisions can be defined if required.

[3] Each person is entitled to file for the inclusion of a new substance into the annexes.

[4] The petition must be accompanied by a dossier that shall in particular include the following information:

a. identity of the substance;
b. chemical and physical properties of the substance;
c. foreseen use of the substance;
d. authorization of the substance if applicable;
e. migration of substance (residual amount in food contact material, identity and concentration of substances that are expected to migrate, analytical methods);
f. toxicology of the substance as well as of its relevant degradation products and impurities.

Disclaimer: This text is an unofficial translation of a Swiss legislative text and thus is not legally binding.

Draft German Ordinance on Printing Inks *(1/2)*

- Based on List A of the Swiss positive list
- Developed in close cooperation with the FSVO including joint evaluation of substances with the aim of harmonisation of the German positive list with List A of the Swiss regulation
- Permitted substances: one category
  - *Toxicologically evaluated substances*
    - Specific migration limits (SMLs) are given (derived from risk assessment & management)
  - Non-evaluated substances
    - Should not be detected in the food

      (analytical limit is **10 µg/kg,** evaluation on case by case basis for cancerogenic / mutagenic substances)

Draft German Ordinance on Printing Inks *(2/2)*

- According to an agreement between the German Printing Ink Association and the BMEL, for the period until the Ordinance on Printing Inks comes into force, migration data need not be submitted in petitions for the addition of new substances.
- But: Information on impurities and decomposition products must be provided.

→ November 2011: first evaluation of substances for German ordinance on printing inks (photo initiators)

Cooperation between Germany and Switzerland

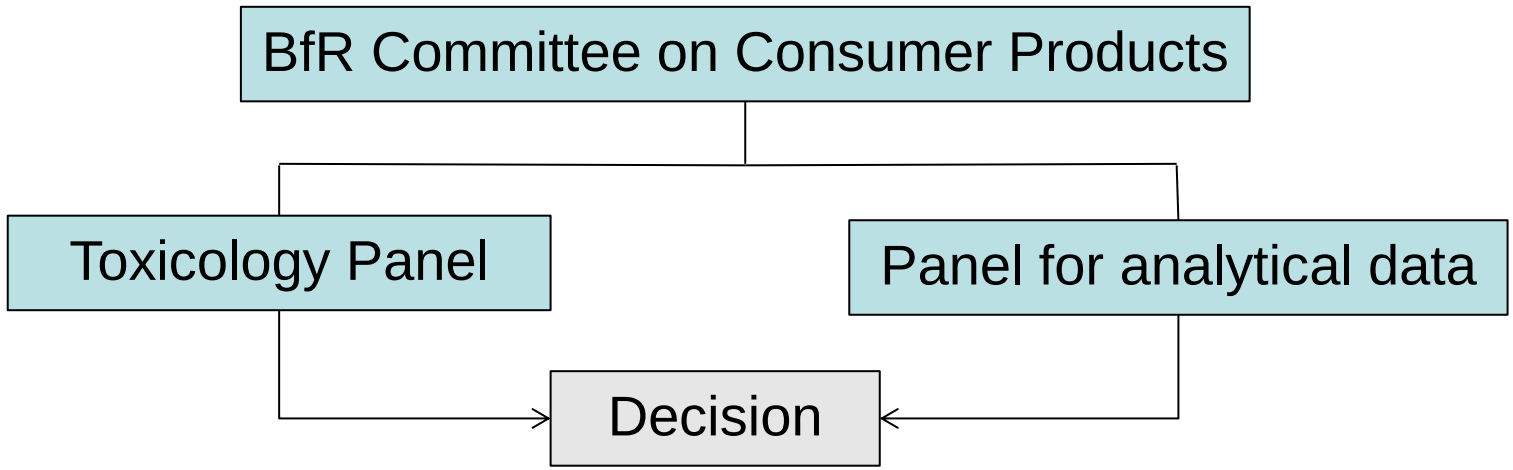
- For the evaluation of substances in printing inks, close cooperation between the Swiss FSVO with the German Federal Institute for Risk Assessment (BfR), Commission for Consumer Products, Toxicology Panel and Panel for evaluation of analytical data

- Aim: Harmonization of the authorized substances and the SML values between Switzerland and Germany (part A only)

- Harmonized procedure in the evaluation of new submitted substances between FSVO and BfR

Organisation and meetings

- Twice per year meeting, April and November at which the submitted dossiers are discussed and approved



- Sometimes, demand for supplementary data
- Evaluation by toxicologists and chemists of BfR and FSVO

Key points for joint evaluations of printing inks

- 64 petitions received since 2011
  - 29 petitions could not be finished yet
  - 6 new petitions in 2016 and 2017
- approx. 5 substances are evaluated per year
- separate evaluations are carried out by BfR and FSVO
- discussion twice a year: subgroup toxicology of commission for FCM at the BfR
- 1 evaluator for toxicology and non-toxicology each at FSVO and at the BfR

Printing inks

- **Substances**
  - Photoinitiators
    - Substance and reaction products
  - Solvents
    - Pure substance
    - Isomeric mixtures
    - Subtance mixtures
  - Monomers
    - Acrylates (acrylate-functionalized monomers)
  - Polymerisation-Stabilizers
    - Substance and reaction products

Methodology for substance evaluations according to SCF guidelines

- characterization of substance, its impurities and reaction/degradation products
- evaluation of exposure through migration into food (simulants), alternatively worst-case calculation of maximal possible migration (solvents)
  - assumption for food consumption: 1 kg/person day
- definition of minimum data sets for toxicity data (tiered approach):
  - 1. ≤ 0.05 mg/kg (ppm) food: 2 studies covering genotoxicity
  - 2. between >0.05 and 5 ppm: additionally to above studies: subchronic repeated dose, ADME-study
  - 3. between >5 and 60 ppm: additionally to above studies: chronic repeated dose, studies covering reprotoxicity
- safety assessment
  - margin of safety to lowest NOAEL has to grant safety (default MoS: 100, additional safety factors possible)

Printing inks vs. BfR Recommendations/EFSA

- Analytical data is usually not discussed in BfR Panel for analytical data
  - Discussion when necessary

- Analytical data for characterization of substances, impurities, decomposition and reaction products (IAS and NIAS) must be submitted in accordance to Note for Guidance

- Migration data is not necessary (at the moment)

Data on migration

- Worst case calculation
- Migration data from process / quality control of the manufacturer
  - Not worst case but realistic
  - No raw data (only table of data)
  - Mostly data from different sources (different companies / laboratories)
- Migration data in accordance with Note for Guidance

Guideline for Printing Ink Petitions

Guideline (in preparation) is for analytical data for characterization of the substance and for migration

- For “Printing Ink petitions” the Note for Guidance has to be used!
- 1st part: Guideline: Explanation “How to fill in the Note for Guidance”
- 2nd part:
  - Description of printed samples for migration testing
  - Testing conditions for different printing techniques
  - Migration testing conditions (off-set consideration),
  - Typical composition of different ink systems

Methodology for joint BfR-FSVO safety evaluations

- Data requirements for application dossiers must follow SCF guidelines:
  - characterization of substance and NIAS
  - (data on migration) / worst-case calculations
  - tiered data on toxicology
- safety assessment of substance:
  - evaluation of toxicity studies according to common practices
  - genotoxicity has to be ruled out (or genotoxic carcinogenicity)
  - MoS between lowest NOAEL and exposure estimate (migration into food; consumption of 1 kg food / person day) has to be sufficient
- safety assessment of NIAS:
  - usually migration < 50 ppb → genotoxicity could be of concern
  - different methodology can be applied: read-across to “lead”-substance, QSAR-predictions, hydrolysis data

Results of joint BfR-FSVO safety evaluations

- BfR:
  - risk assessment report on evaluated substance (not publically available)
  - letter to petitioner laying down SMLs for substance (and NIAS) and purity requirements (endorsed by the FSVO)

- FSVO:
  - risk assessment report on evaluated substance (in German, not publically available)
  - inclusion of SML and remarks (e.g. concerning purity requirements) for evaluated substance in Annex 10, part A of Swiss ordinance on FCM

Important points

- Petitioners submit dossiers to BfR and FSVO at the same time
- For petitions the Note for Guidance has to be used
  - Analytcial data for migration is not needed at present
- Joint panel for discussion and decision
  - Analytical data is discussed in the panel on demand

Conclusions

- SCF guidelines and practices of EFSA CEF panel are followed in safety evaluations.
- The joint safety evaluation works out to be efficient and effective and to be well accepted by petitioners.
- Results of safety evaluation (SML) are published in Annex 10, part A of Swiss ordinance on FCM.

Thank you for your attention