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



# Cooperation on safety evaluation of substances in printing inks between Germany (BfR) and Switzerland (FSVO)

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# Overview

- History and background
- Swiss Ordinance on FCM
  - Permitted substances
  - Notification of substances
- Draft German Ordinance on Printing Inks
- Cooperation between Germany and Switzerland
- Organisation and meetings
- Important points and conclusions

# Chronology of Packaging inks regulation

<b>1900s....</b>	Regulations on As and Pb in inks (CH)
<b>1990</b>	Formation of the Ad-hoc working group at the Council of Europe
<b>14.09.2005</b>	Resolution [ <b>Res AP(2005)2</b> ] is adopted by the Council of Ministers
<b>2005</b>	Contamination of infant formula by photoinitiator (ITX)
<b>07.03.2008</b>	Publication of the regulation on packaging inks in the Swiss legislation [ <b>RS 817.023.21</b> ] effective as of April 2010
<b>09.2009</b>	Exhaustive list of substances used in production of packaging inks is delivered by EuPiA
<b>2010</b>	1 <sup>st</sup> Draft German Ordinance on Printing Inks
<b>2012</b>	Questionnaire for Roadmap indicates demand of member states and industry for regulation of inks for FCM
<b>2012</b>	Joint evaluation of printing inks starts
<b>2013</b>	CH: 3 <sup>rd</sup> revision of the list of permitted substances
<b>2017</b>	LARGO: Revised Swiss Ordinances on Food and Consumer products including FCM printing inks will come into force. Switch from notification to full authorization system

# Roadmap

## Questionnaire of the European Commission on non-harmonised FCM (2012)

Types of materials which should be regulated on EU level:

➤ **Member states**

- ✓ **Printing inks**
- ✓ Varnishes and coatings
- ✓ Paper and board
- ✓ Metals and alloys
- ✓ Adhesives
- ✓ Silicones
- ✓ Rubber and elastomers
- ✓ Ceramic materials

➤ **Industry**

- ✓ **Printing inks**
- ✓ Varnishes and coatings
- ✓ Paper and board

# Swiss Ordinance on FCM

## Annex 6: 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)

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

<http://www.blv.admin.ch/themen/04678/04887/04891/index.html?lang=en>

# List of permitted substances (Swiss Ordinance)

List	Substance category	Part A	Part B
I	Monomers	328	1102
II	Colorants	100	358
III	Solvents and energy curing monomers	77	189
IV	Additives	693	2468
V	Photoinitiators	27	71

*Sum of substances (double entries excluded)* → **1074** **3995**

**Σ = 5069 substances** (includes many monomers and additives of EU Regulation 10/2011)

# Notification of new substances (Swiss Ordinance)

## Art. 26h Duty of disclosure of additional substances

<sup>1</sup> The use of any additional substances that are not included in Lists I and II in Annex 1 and in Annex 6 must be reported by the person responsible to the FSVO.

<sup>2</sup> The report must be accompanied by a dossier that shall in particular include the following information:

- a. the toxicology of the substance;
- b. the nature and the concentration of the substances migrating to the foodstuffs or to the food simulants;
- c. the trace analysis methods used in relation to the substances;
- d. the technical necessity for using the substances.

<sup>3</sup> The FSVO shall stipulate the conditions for using the reported substances and notify the implementation authorities of the report of each new substance.

# 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**)



# 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 must not be submitted in petitions for the addition of new substances.
- But: Information on impurities and decomposition products must be provided.

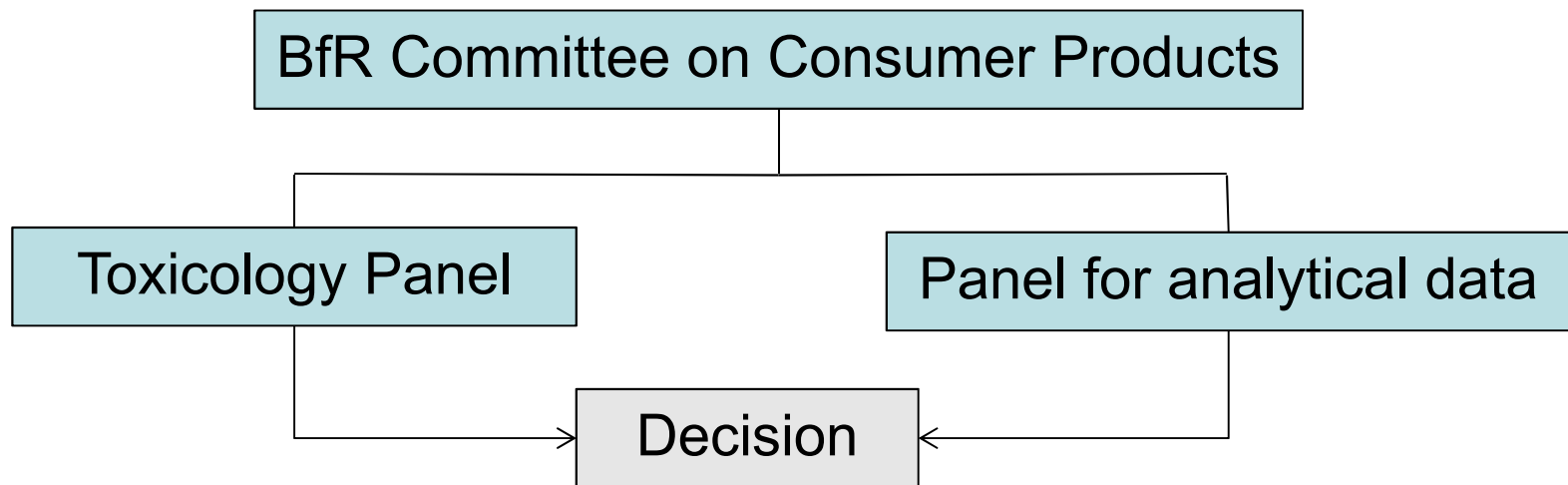
→ November 2011: first evaluation of substances for German ordinance on printing inks (photo initiators)

# 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 (at present in most cases toxicological data, only)

# Number of evaluations / re-evaluations within the last 5 years

- Since spring 2012, coordinated evaluation between FSVO and BfR
- 60 petitions received since 2011
- Detailed evaluations (approx. 30 since 2011):
  - Photoinitiators: on-going evaluations
  - Acrylates
  - Additives
  - Glycoethers: on-going evaluations
  - Hydrocarbon solvents: on-going evaluations
- In addition, specific evaluations of 170 substances from other regulatory context for use in printing inks (BfR recommendations, food additives, Synoptic Document, EFSA opinions)
- Evaluation includes NIAS, e.g. decomposition products of photoinitiators

# Important points

- Petitioners submit dossiers to BfR and FSVO at the same time
- Questions during the review process are discussed unbureaucratically and effectively in form of direct contact
- For discussions German is common language (petitions are filed in German or in English)
- Joint panel for discussion and decision
- Aim: harmonized regulation (part A only)
  - Separate evaluation, joint discussion
  - Joint result

# Conclusions

- The joint evaluation has proven to work in practice.
- Consensus could be achieved in all evaluated dossiers so far between BfR and FSVO.
- The joint evaluation works out to be efficient and effective and to be well accepted by petitioners.
  
- BfR: Joint evaluation as a basis for an European Regulation for printing inks (?)
- Successful cooperation could serve as an example for a joint regulation of other non-harmonized FCMs

# Thanks for your attention

