Printing inks for food packaging materials

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Current EC regulations

Regulation 2011/10

On plastic materials and articles intended to come into contact with food

- Plastic materials and articles shall not transfer their constituents to food simulants in quantities exceeding 10 milligrams of total constituents released per dm2 of food contact surface(mg/dm2).
- Refers only to plastic materials, the provisional list of additives included monomers, starting materials and additives used also in printing ink

Regulation 2011/10

Coatings, printing inks and adhesives are not yet covered by a specific EU legislation and therefore not subject to the requirement of a declaration of compliance. However, for coatings, printing inks and adhesives to be used in plastic materials and articles adequate information should be provided to the manufacturer of the final plastic article that would enable him to ensure compliance for substances for which migration limits have been established in this Regulation

Regulation 2011/10

Applies to

- (a) materials and articles and parts thereof consisting exclusively of plastics
- (b) plastic multi-layer materials and articles held together by adhesives or by other means
- (c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating
- (d) plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials
- (e) plastic layers in multi-material multi-layer materials and articles

Regulation 2011/10

Referring to printing inks

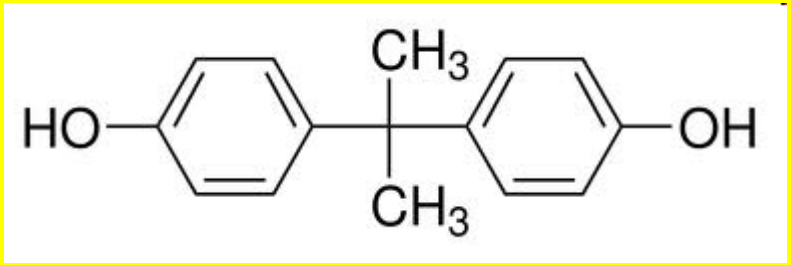
Therefore plastic materials and articles that are printed, coated or held together by adhesives should be allowed to contain in the printing, coating or adhesive layer other substances than those authorised at EU level for plastics. Those layers may be subject to other EU or national rules.

Amending Regulations

- ***2011/321, 2011/1282, 2012/1183, 2014/202, 2015/174, 2016/1416***
- **Amending and correcting Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food**
- Annex I to Regulation (EU) No 10/2011 is amended in accordance with the Annex to these Regulation

Regulations 2011/1282, 2011/321

- **Amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles**
- SML (T): 0.6 mg/Kg
- Not to be used for the manufacture of polycarbonate infant feeding bottles



Commission directive 2007/42/EC

- **Relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs**

Article 5

- Printed surfaces of regenerated cellulose film shall not come into contact with the foodstuffs.

Regulation 1935/2004 EC

- This Regulation shall apply to materials and articles, including active and intelligent food contact materials and articles, (hereinafter referred to as materials and articles) which in their finished state:

  (a) are intended to be brought into contact with food; or

  (b) are already in contact with food and were intended for that purpose; or

  (c) can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

Regulation 1935/2004 EC

FIRST REFERENCE TO PRINTING INKS

List of groups of materials and articles which may be covered by specific measures

Defines: traceability

- The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

Regulation 1935/2004 EC

ARTICLE 3

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

- (a) endanger human health; or
- (b) bring about an unacceptable change in the composition of the food; or
- (c) bring about a deterioration in the organoleptic characteristics thereof.

Regulation 2023/2006

On good manufacturing practice (GMP) for materials and articles intended to come into contact with food

No specific guidelens given to printing inks manufacturers

Regulation 2023/2006

1. Printing inks applied to the non food-contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side:

   (a) through the substrate or;

   (b) by set-off in the stack or the reel,

   in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

Regulation 2023/2006

2. Printed materials and articles shall be handled and stored in their finished and semi-finished states in such a manner that substances from the printed surface are not transferred to the food-contact side:

- (a) through the substrate or;
- (b) by set-off in the stack or reel,
- in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.
- 3. The printed surfaces shall not come into direct contact with food.

Regulation 1895/2005

Restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food:

- BADGE, Bisphenol-A DiGlycidyl Ether
- BFDGE, Bisphenol-F DiGlycidyl Ether
- NOGE, *Novolac* glycidyl ether

Council of Europe - CoE

Basic Resolutions:

- Paper & board :ResAP(2002)1
- Coatings : ResAP(2004)
- Colorants : ResAP(89)1
- Packaging inks : ResAP(2005)2

CoE, Res AP (2005)2

- **Resolution ResAP(2005)2 on packaging inks applied to the non-food contact surface of food packaging materials and articles intended to come into contact with foodstuffs**
- (*Adopted by the Committee of Ministers on 14 September 2005 at the 937th meeting of the Ministers' Deputies*)

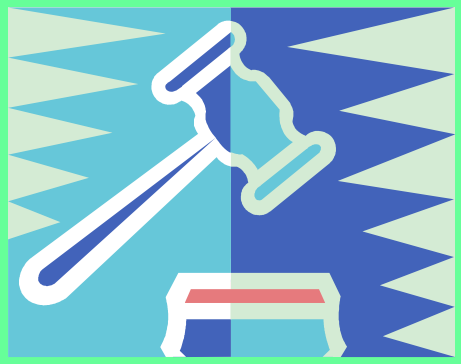
CoE, Res AP (2005)2

- Incomplete inventory list
- Non evaluated substances should not be detectable in limits above 10 ppbthe printed or overprinted varnished layer of finished printed material or article should not come into direct contact with food;
- there should be no, or only negligible, visible set-off or migration from the printed or varnished non-food contact layer to the food contact surface
- the packaging inks should be applied in accordance with converters' good manufacturing practices

Council of Europe - CoE

BUT

- Refers to substances not classified / tested in EU
- Non members of EU participating
- No legal force



(EFSA): European Food Safety Authority

- Is the EU risk assessment body for food and feed safety, provides independent scientific advice to risk management and clear communication on existing and emerging risks
- Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food
- Valid assessment in EU, provides scientific opinion

efsa
European Food Safety Authority

BfR – Guidelines

- (Bundesinstitut für Risikobewertung – German Federal Institute for Risk Assessment')
- **XXII. Polymers Based on Esters of Acrylic and Methacrylic Acids, their Copolymers, and Mixtures of these with other Polymers**
- **XLI. Linear Polyurethanes for Paper Coatings**
- **XV. Silicones**
- **……**

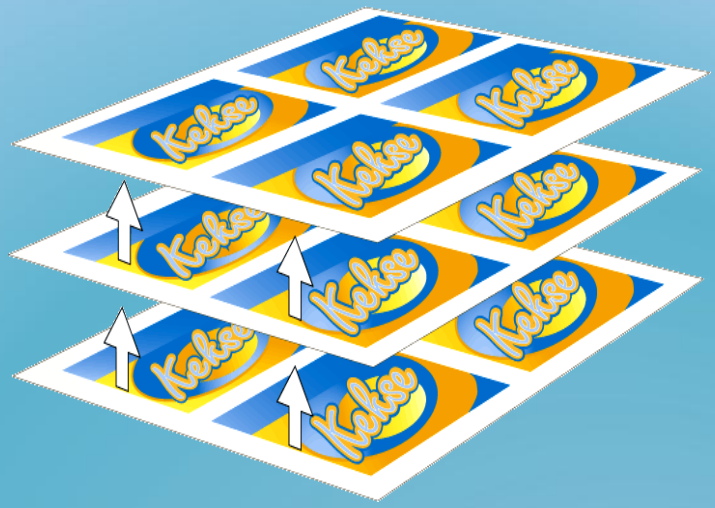
Terms and definitions

Barrier in packaging

- Materials with high barrier / (permanent barrier): glass, metal
- Materials with high – functional barrier: alum foil, nano-structures
- Materials with (marginal barrier): paper, board, PE and PP films

Migration mechanism: set-off

Film wound in reels



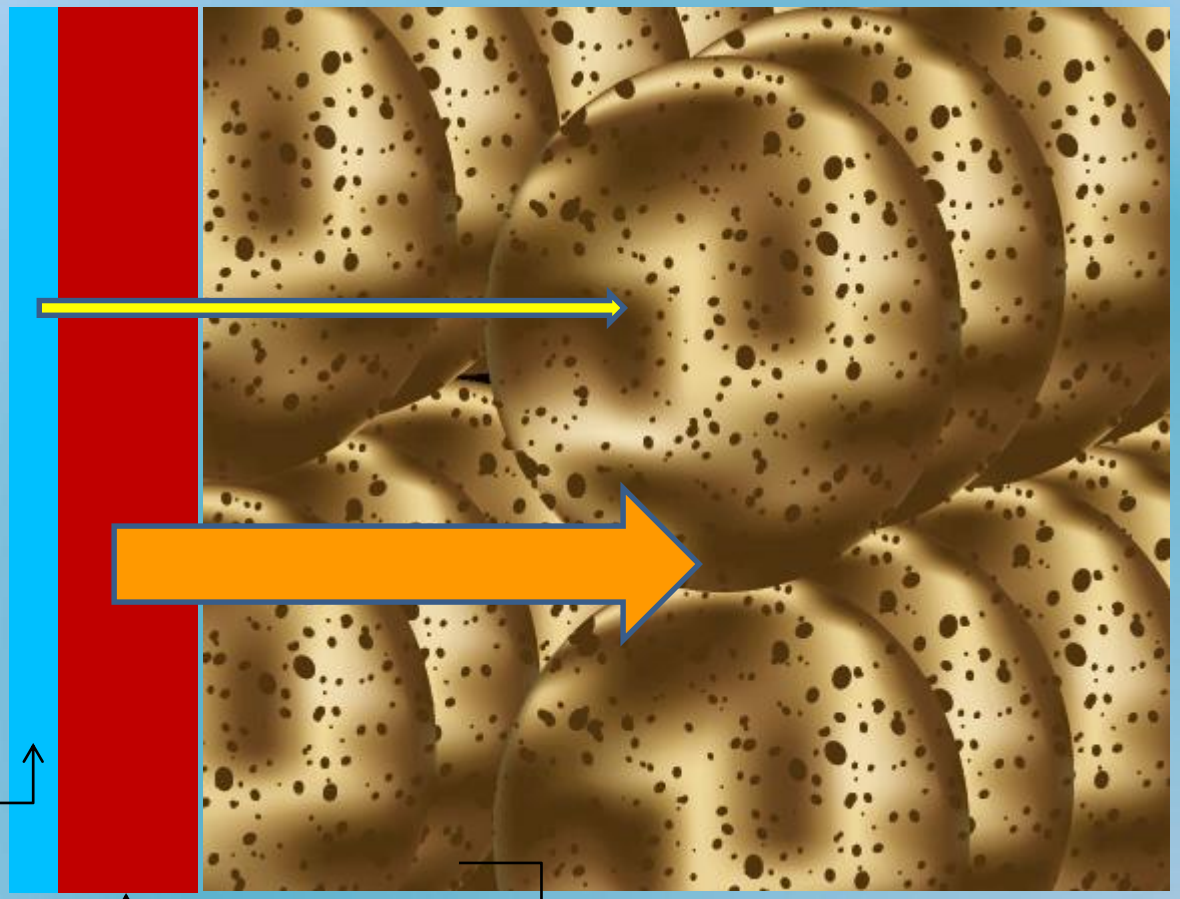
Paper staking

Invisible Set-off : non visible migration of substances from the printed side to the unprinted – food contact area

Mechanisms:
- Blocking
- Friction
- Peeling

Migration mechanism: penetration

Penetration migration: Migration of low molecular weight substances through the substrate – FCM



Migration mechanism: gas phase

Substances may migrate into the FCD and finally into the food though condensation

Relating to food processing:

- **Sterilization, pasteurization**
- **Hot filling**
- **HT heating**
- **Baking: conventional, microwaving**

EUPIA position

European Printing Inks Association

EUPIA exclusion policy

3rd version, November 2016

Raw materials excluded by the Policy, and which must therefore be avoided in the formulation of printing inks, are those substances or mixtures classified in one or more of the CLP hazard classes/categories listed in **Group A and Group B**

EUPIA exclusion policy

GROUP A	**GROUP B**
Acute Toxicity Cat. 1 & 2 [H300, H310, H330]	
Acute Toxicity Cat. 3 (inhalation) [H331]	Acute Toxicity Cat. 3 (oral, dermal) [H301, H311]
Carcinogen or Mutagen Cat. 1A & 1B [H350, H340]	
Toxic to Reproduction Cat. 1A & 1B [H360] *(non-threshold substances)*	Toxic to Reproduction Cat. 1A & 1B [H360] *(if threshold exists)*
STOT Single Exposure Cat. 1 [H370]	STOT Repeated Exposure Cat. 1 [H372]

EUPIA exclusion policy

Includes colorants:

- Auramine (Basic Yellow 2 - CI 41000), Chrysoidine (Basic Orange 2 - CI 11270), Fuchsine (Basic Violet 14 - CI 42510), Induline (Solvent Blue 7 - CI 50400) , Cresylene Brown (Basic Brown 4 - CI 21010)
- Pigment colorants based on and compounds of antimony3, arsenic, cadmium, chromium (VI), lead, mercury, selenium.
- Other soluble azo dyes which can decompose in the body to bio-available carcinogenic aromatic amines of Category 1A and 1B according to the CLP Regulation (EC) No. 1272/2008.

EUPIA exclusion policy

Includes solvents

- 2-Methoxyethanol
- 2-Ethoxyethanol
- 2-Methoxyethyl acetate
- 2-Ethoxyethyl acetate
- Monochlorobenzene
- Dichlorobenzene
- Volatile chlorinated hydrocarbons: (trichloroethylene, perchlorethylene, methylene chloride…)
- Volatile fluorochlorinated hydrocarbons
- 2-Nitropropane
- Methanol

EUPIA exclusion policy

Includes plasticizers:

- Chlorinated naphthalenes
- Chlorinated paraffins
- Monocresyl phosphate
- Tricresyl phosphate
- Monocresyl diphenyl phosphate

EUPIA exclusion policy

Includes various compounds:

- Diaminostilbene and derivatives
- 2,4-Dimethyl-6-tertiary-butylphenol
- 4,4 Tetramethyldiaminobenzophenone (Michler's Ketone)
- Hexachlorocyclohexane

EUPIA GMP

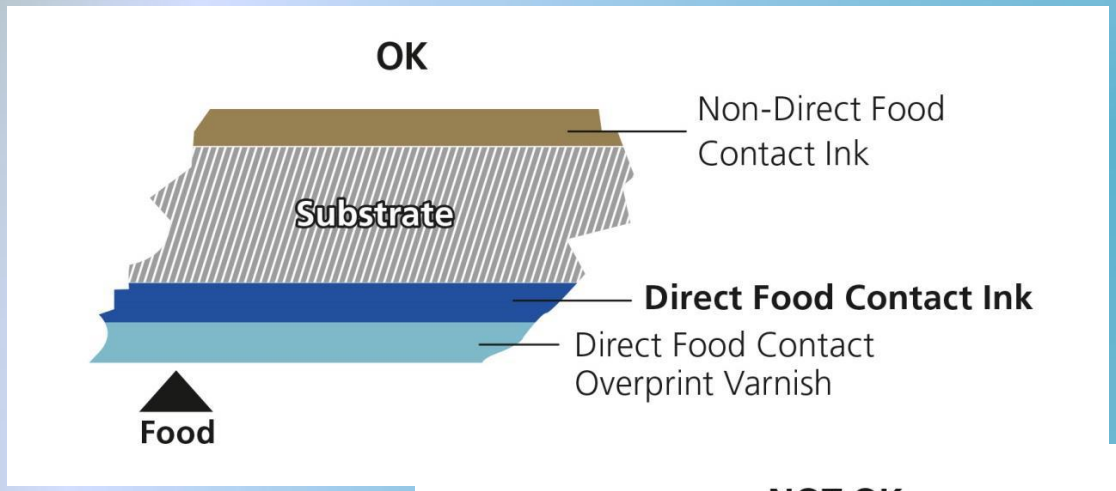
4th completely revised version

March 2016

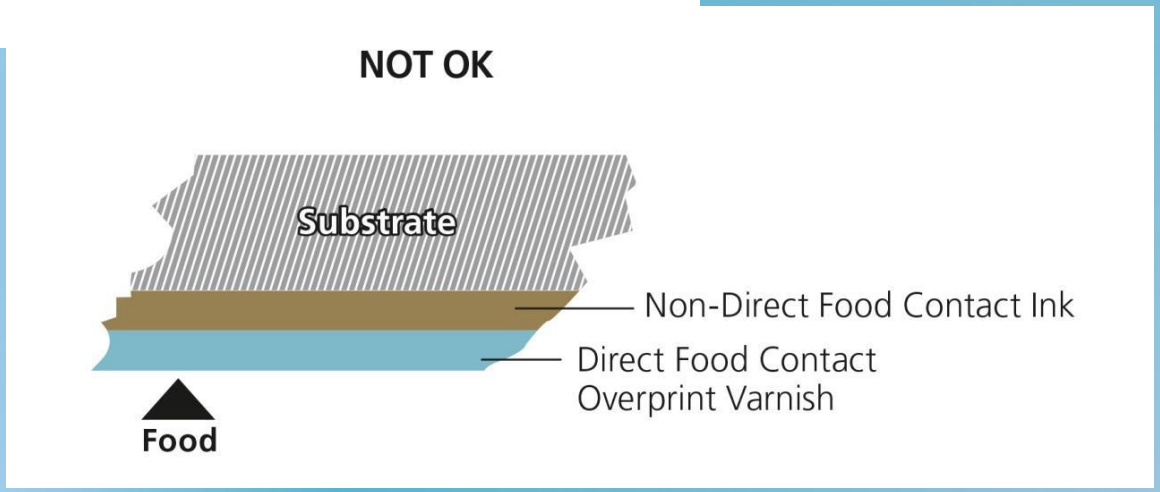
EUPIA GMP

Differences	GMP March 2009	GMP March 2015
Scope	Non-DFC surfaces of food packaging only	Both DFC and non-DFC surfaces of FCM's
Level of detail	Overview	Greater level of detail, includes flow-charts & worked examples
Risk Assessment	Not explicitly mentioned	FMEA process, including guidelines for scoring
Demonstrating compliance	Not explicitly mentioned	Evidence based, example analytical result validating cleaning process
Auditing	Internal audit using checklist	External audit by customers, in addition to internal audits
Updating	Last updated 2009	Will be regularly updated to reflect changes

EUPIA GMP

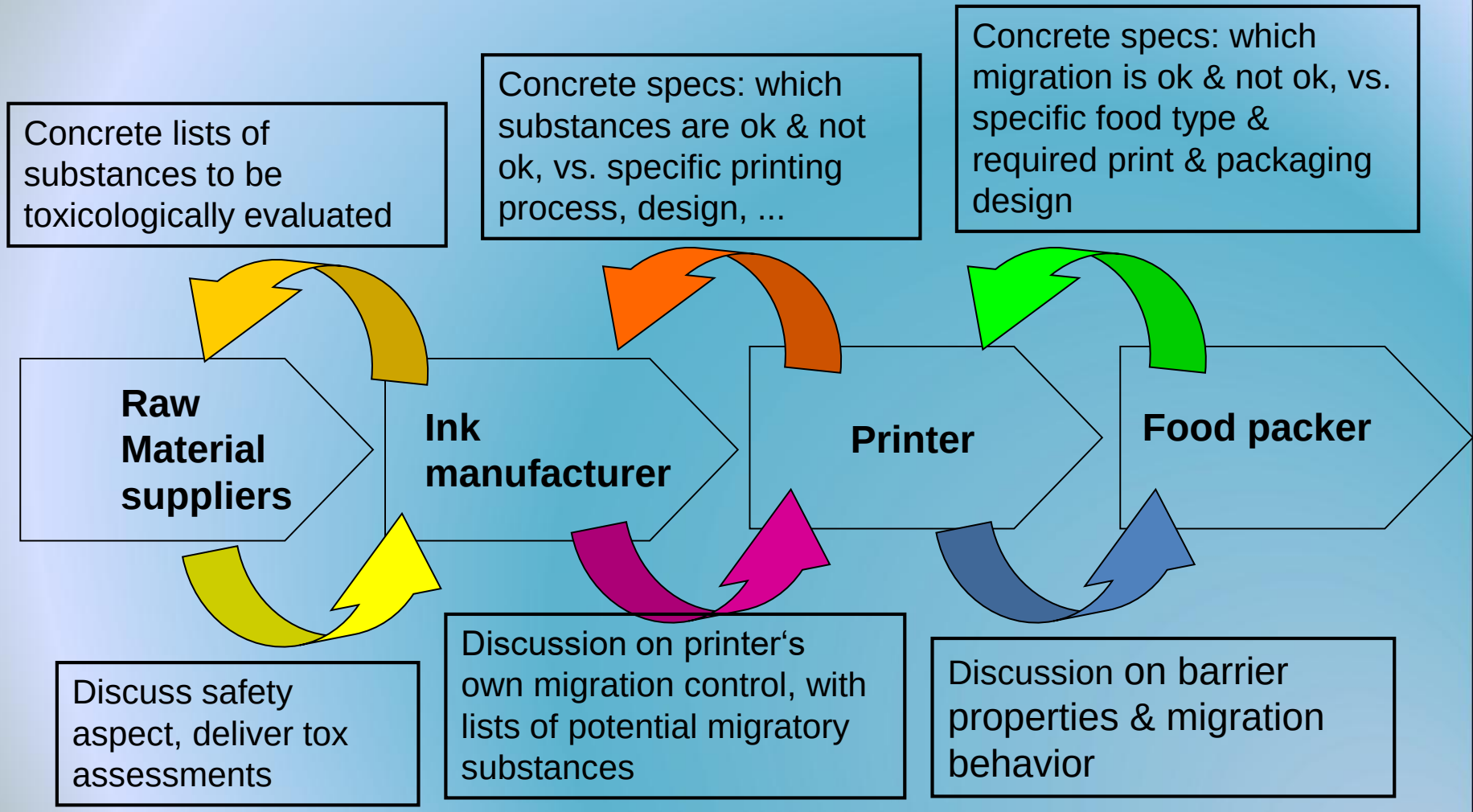


DFC inks and surfaces



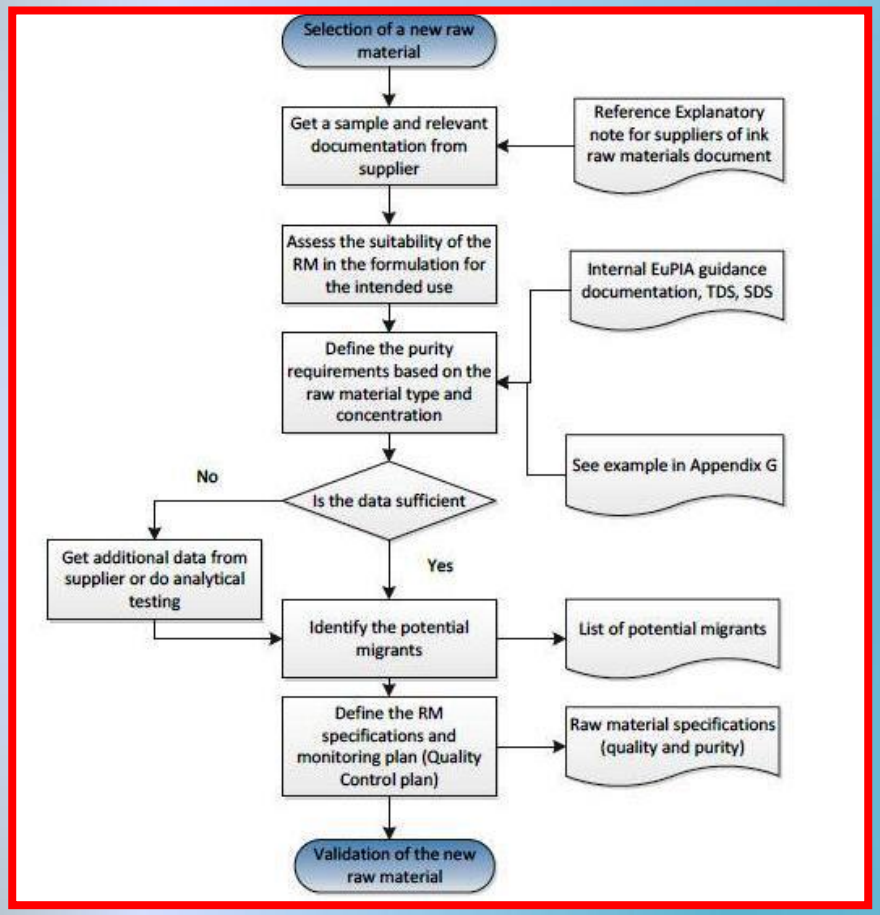
SEETING THE STANDARDS

EUPIA GMP



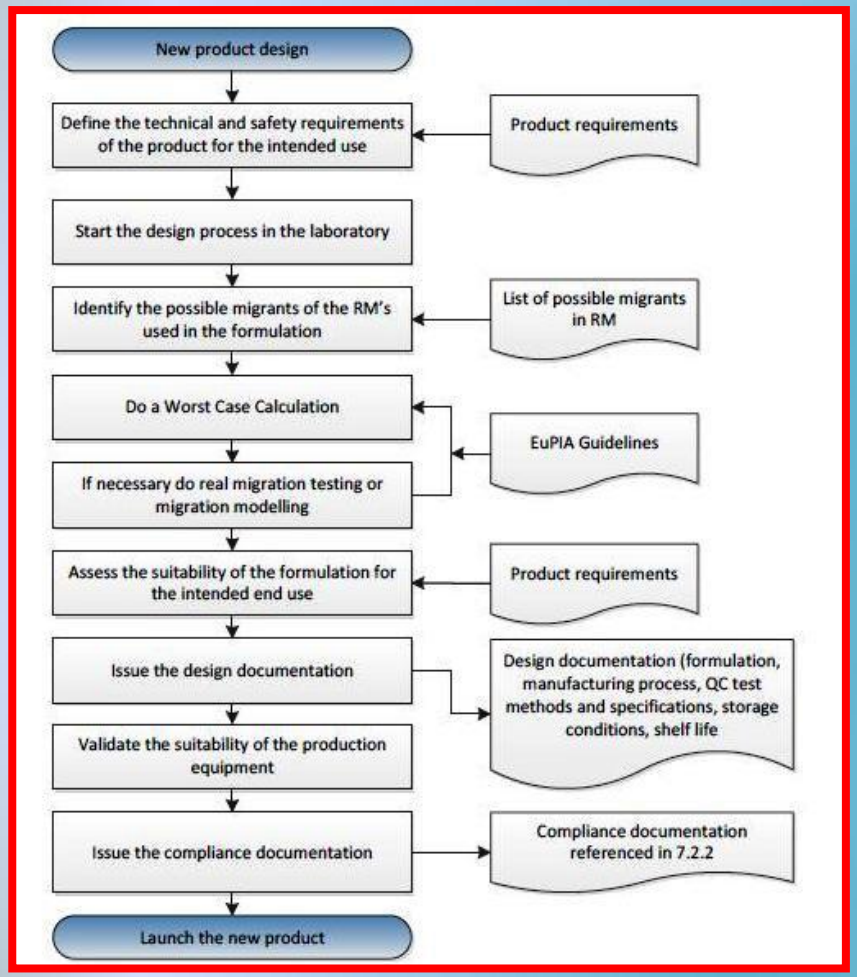
The materials packaging chain

EUPIA GMP



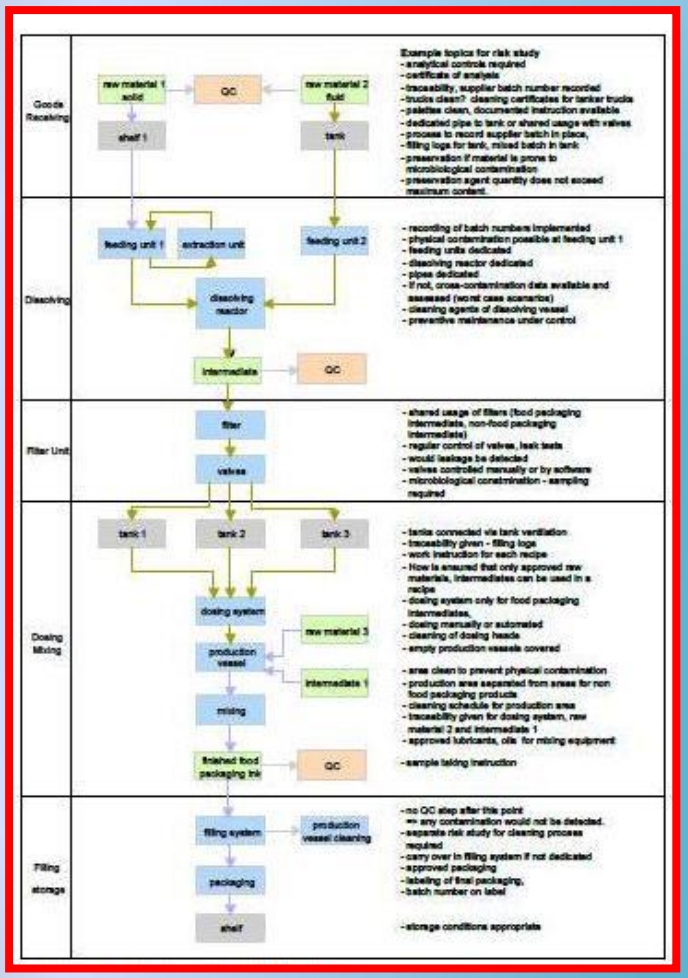
Example flow chart for new raw material introduction

EUPIA GMP



Example flow chart for a new product design

EUPIA GMP



Risk assessment study in every production step

Is GMP enough?

Update on Food Contact Materials

Plastics and Paper in Contact with Foodstuffs
08 December 2016

Bastiaan Schupp and Jonathan Briggs

European Commission
DG SANTE, Unit E2 – Food Processing Technologies and Novel Foods – Food Contact Materials

Example of an aspect that needs evaluation

> 10.000 substances in non-harmonised

FAR more than 10.000 EFSA evaluations required

- **6 main organic materials: plastics, coatings, printing inks, adhesives, rubbers, paper and board**
- **multiplication:** per (sub) material >6x, per condition of use >3x, NIAS …x, age groups …x, specific exposure scenarios…x, foreseeable use …x, …
- **Centuries of work: >10.000 evaluations @ 50/year**

Plastic

- **~950 listed substances, 4 decades work, approx. 25/yr**
- **Still not fully harmonised (e.g. colorants, NIAS)**
- **are evaluations older than 15 years still acceptable?**

NIAS position paper

EuPIA Guidance for Risk Assessment of Non Intentionally Added Substances (NIAS) and Non Listed Substances (NLS) in printing inks for food contact materials

NIAS position paper

- TERMS AND DEFINITIONS
- **Printing Ink**
- The term “printing ink”, or in short just “ink”, in this paper includes not only coloured products, but also clear primers, overprint varnishes and any other components which may be added to inks to make them printable and give them the final property (so-called press side additives like waxes, extender, adhesion promoters etc.).
- **Food Contact Material (FCM)**
- FCM according to this paper refers to the printed packaging material. Usually the ink does not have direct contact with the food; the printed side is the non-food contact side of FCM’s or in case of laminated material the ink is sandwiched by other films. Inks with direct food contact (DFC inks) are a special case and additional requirements must be fulfilled, however this guideline is also suitable for intended DFC inks.

NIAS position paper

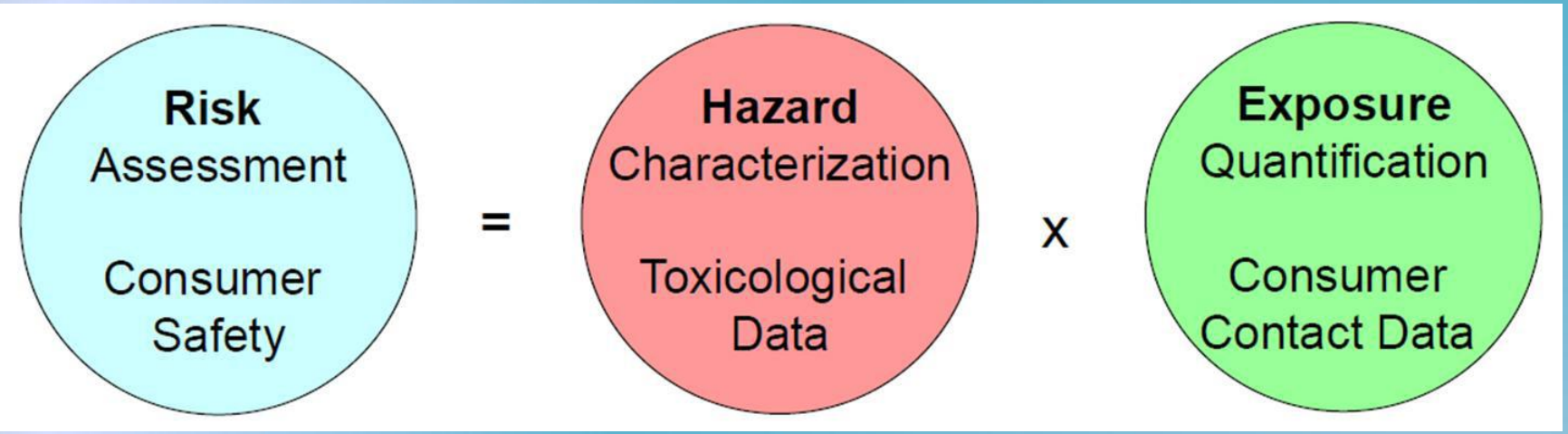
- TERMS AND DEFINITIONS
- **Intentionally Added Substances in printing inks for FCM's (IAS)**
- IAS in inks are all chemical substances which are intentionally added in the production and use of the printing ink and which have an intended and specific function within the final ink and without this the performance of the inks would change. These substances may be added as single components or as mixtures of various substances. The term "use" of raw materials or substances in inks in this paper means always that these raw materials or substances are added intentionally.

NIAS position paper

- TERMS AND DEFINITIONS
- **Non Intentionally Added Substances in printing inks for FCM's (NIAS)**
- NIAS are all chemical substances which are not IAS and do not have an intended and specific function within the ink formulation. Such NIAS may come from impurities in used raw materials from former production steps, but can also be created due to contamination in the ink production or handling, and also during the application process of the inks (unintended side reactions during curing, drying, crosslinking or decomposition for example).

NIAS position paper

Risk assessment tools presented



Other reference lists and docs

- The BCF (British Coatings Federation) Guide to Printing Inks for Use on Food Wrappers and Packages
- Exclusion list of the British Coatings federation (BCF).
- Japan voluntary regulation concerning printing inks (Japan printing ink makers association)
- Brand owners exclusion lists (eg. Kraft, Danone, Tesco, Nestle)

Swiss Norm

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Annex 6 of the Ordinance of the FDHA on articles and materials of 23 November 2005, (RS 817.023.21) replaced by

Anhang 10 der Verordnung des EDI über Materialien und Gegenstände, die dazu bestimmt sind, mit Le-bensmitteln in Berührung zu kommen, May 2017

inventory list of 5290 permitted substances for the manufacture of packaging inks, subject to the requirements set out therein: binders (monomers), dyes and pigments, solvents (including the "energy curing monomers"), additives (without the additives used in the preparation of pigments), photo-initiators.

Swiss Norm

The inventory lists contain evaluated substances, subject to the requirements set out therein, intended to be used in the manufacture of food contact materials. For the substances without a numerical value in the column SML, the value of the global migration of 10 mg/dm2 or 60 mg/kg according to the cases (cf Art. 3 of annex 1) is considered as the limit value

The non evaluated substances - must not be detectable in a migration test in the lowest possible concentration at which a substance may be detected using a valid method of analysis. The detection limit depends on the composition of the substance; this limit, expressed as a concentration, must in no case exceed 0.01 mg/kg of food or food simulants (including the analytical tolerance). For substances that can be allocated to a group of compounds with similar toxicology or similar basic structure (e.g. isomers), this limit value applies to the sum of the concentrations of the substances

GIO (German Ink Ordinance)

- 6th draft is available
- European Commission requested German Authorities to postpone the application of GIO
- **EU is willing to launch European regulation for printing inks and printed FCM**

REACH: substances of very high concern, SVHC

- **Regulation 1907/2006, Registration, Evaluation, Authorisation and Restriction of Chemicals**

  All substances identified in the REACH Regulation (EC) No 1907/2006, Title VIII and Annex XVII (restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles) and its amendments, if their use in a packaging ink would lead to an infringement of Article 3 of the Framework Regulation.

Our research is on progress