



07 April 2022 // 15:00 -16:30 CEST

Conformity of printed food contact materials in Germany – today and tomorrow

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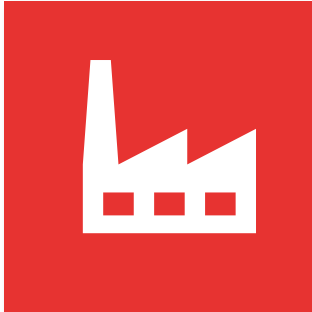
Verband der deutschen Lack-
und Druckfarbenindustrie e.V.



- The VdL
- Legal situation of printed food contact materials - Today
- What is changing after 2026?
- What has to happen until 2026?
- Which information is provided by the printing ink industry?
- What do the converters need to do?
- Comparison: GIO – Swiss Ordinance
- Outlook: What is currently happening at EU level?



About 200
members



9 billion
sales



25,000 direct
employees



VdL Represents 90 Percent of the Paint, Coating and Printing Ink Industry in Germany



Decorative Coat.
& Plasters



Performance
Coatings



Printing Inks



Powder Coatings

Decorative Coatings
Plaster & Decor

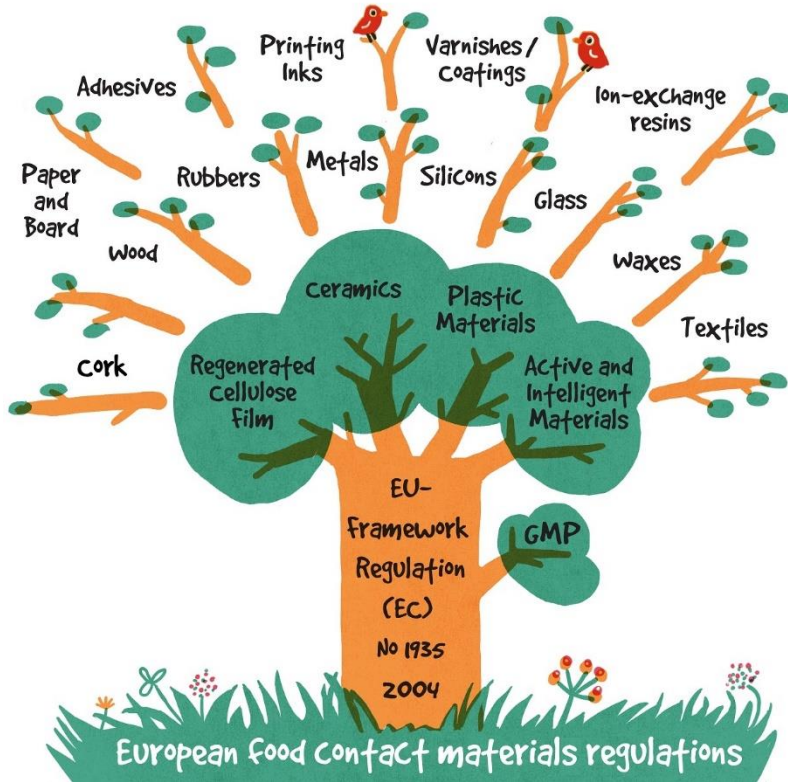
Industrial coatings
Wood coatings
Protective coatings

Offset
Flexo
Gravure printing
Screen printing
Digital

Powder Coatings



- **Responsibility ultimately lies with the person placing on the market**
 - Printer, Converter
 - Packer/Filler, Food manufacturer
- ⇒ **Safety of the FCM (Food Contact Material) must be proven with a confirmation of conformity**
- **When is a FCM safe?**
 - Which legal requirements must be met?
 - How do you make sure these are met?
 - Which influence has
 - the flow of information in the supply chain?
 - the selection of suitable raw materials?



Shoots at the top:

Materials not regulated specifically yet

Treetop:

Specific measures for groups of materials

- Regenerated Cellulose Film 2007/42/EC
- Plastic Materials (EU) No 10/2011
- Ceramics 84/500/EEC
- Active and Intelligent Materials (EC) No 450/2009

Trunk of the Tree:

EU-Framework Regulation
(EC) No 1935/2004



Printing Inks:

- No Europe-wide specific provisions for printing inks / varnishes for FCM applications



- **But:**
 - Printing inks / varnishes become part of the FCM after application
 - These must therefore be formulated in such a way that it is possible for the converter to produce compliant FCMs

EuPIA concepts: Printing Inks for Food packaging are safe!



EuPIA Guideline on Printing Inks applied to Food Contact Materials

April 2020

(This document replaces the November 2011/July 2012 corrigendum version. It reflects the advancements of EuPIA's consumer safety and compliance concepts as the current state of the art)

1. Introduction and EuPIA commitments

EuPIA member companies have for many years shown strong commitments related to the manufacture and supply of printing inks for food contact materials (hereafter called 'FCM inks').

Amongst these commitments there is the principle of placing consumer safety first, the principle of transparency and information sharing and the principle of implementing Good Manufacturing Practices.

In order to demonstrate to external audiences that they are committed to the principles of protecting food consumer safety within the areas under their control, EuPIA member companies have been offered the opportunity to sign Compliance Commitments related to the manufacture and supply of FCM inks. A list of signatories is available on the EuPIA website (www.eupia.org) in the section: key topics – food contact materials.

Operating on the basis of these commitments has been and still is highly important especially since there is not yet any specific European Union legislation concerning FCM inks. The EU Framework Regulation (EC) No 1935/2004 is the legal basis for FCM inks resp. printed food contact materials.

EuPIA assists its members to meet their commitments by issuing a number of guidance documents which members are encouraged to implement to ensure legal compliance and safeguarding consumer safety when formulating, manufacturing and marketing printing inks for food contact materials.

This new edition of the EuPIA Guideline on printing inks for food contact materials gives a systematic overview of these guidance documents.

2. Field of Application

This Guideline applies to printing inks within the meaning of section 3, applied to a material that is in contact with food; this includes both direct food contact (DFC) and non-direct food contact (non-DFC).

Inks to be printed on food contact materials, for which migration of ink ingredients from the print layer to the food is impossible and set-off or gas phase transfer can be excluded, are not in the scope of this Guideline.

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

1. Introduction

The purpose of this guideline is to provide a systematic overview of the principles and methods for the risk assessment of NIAS and NLS in printing inks for food contact materials.

2. Scope

This guideline applies to the risk assessment of NIAS and NLS in printing inks for food contact materials.

3. Definitions

The following definitions apply to this guideline:

- NIAS:** Non-Intentionally Added Substances
- NLS:** Non-Lower Substances

4. Risk Assessment

The risk assessment of NIAS and NLS in printing inks for food contact materials is performed in accordance with the following principles:

- Identification of NIAS and NLS
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

5. Conclusion

The risk assessment of NIAS and NLS in printing inks for food contact materials is performed in accordance with the following principles:

- Identification of NIAS and NLS
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

EuPIA Guidance for RA of NIAS/NLS



Page 1 of 22

EuPIA Guideline on Migration Test Methods for the Validation of Experiments in printing inks and inks for food contact materials

1. Introduction

The purpose of this guideline is to provide a systematic overview of the principles and methods for the validation of experiments in printing inks and inks for food contact materials.

2. Scope

This guideline applies to the validation of experiments in printing inks and inks for food contact materials.

3. Definitions

The following definitions apply to this guideline:

- Migration:** The process of migration of ink ingredients from the print layer to the food

4. Risk Assessment

The risk assessment of migration in printing inks and inks for food contact materials is performed in accordance with the following principles:

- Identification of migration
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

5. Conclusion

The risk assessment of migration in printing inks and inks for food contact materials is performed in accordance with the following principles:

- Identification of migration
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

EuPIA Guidance on Migration Test Methods



Page 1 of 22

Good Manufacturing Practice (GMP) Printing inks for Food Contact Materials

1. Introduction

The purpose of this guideline is to provide a systematic overview of the principles and methods for the Good Manufacturing Practice (GMP) for printing inks for food contact materials.

2. Scope

This guideline applies to the Good Manufacturing Practice (GMP) for printing inks for food contact materials.

3. Definitions

The following definitions apply to this guideline:

- GMP:** Good Manufacturing Practice

4. Risk Assessment

The risk assessment of GMP in printing inks for food contact materials is performed in accordance with the following principles:

- Identification of GMP
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

5. Conclusion

The risk assessment of GMP in printing inks for food contact materials is performed in accordance with the following principles:

- Identification of GMP
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

EuPIA GMP



Page 1 of 22

EuPIA Suitability List of Photo-Initiators for Low Migration UV Printing Inks and UV Coatings - February 2015

1. Introduction

The purpose of this guideline is to provide a systematic overview of the principles and methods for the suitability of photo-initiators for low migration UV printing inks and UV coatings.

2. Scope

This guideline applies to the suitability of photo-initiators for low migration UV printing inks and UV coatings.

3. Definitions

The following definitions apply to this guideline:

- Photo-Initiator:** A substance that initiates the polymerization of monomers

4. Risk Assessment

The risk assessment of photo-initiators in UV printing inks and UV coatings is performed in accordance with the following principles:

- Identification of photo-initiators
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

5. Conclusion

The risk assessment of photo-initiators in UV printing inks and UV coatings is performed in accordance with the following principles:

- Identification of photo-initiators
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

EuPIA Suitability List of Photo-Initiators



Page 1 of 22

Company Logo

1. Introduction

The purpose of this guideline is to provide a systematic overview of the principles and methods for the Company Logo.

2. Scope

This guideline applies to the Company Logo.

3. Definitions

The following definitions apply to this guideline:

- Company Logo:** A logo that identifies the company

4. Risk Assessment

The risk assessment of Company Logo is performed in accordance with the following principles:

- Identification of Company Logo
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

5. Conclusion

The risk assessment of Company Logo is performed in accordance with the following principles:

- Identification of Company Logo
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

EuPIA members Self Commitments



Page 1 of 22

Statement of Composition of the following Printing Inks/Coatings and Variations Used in the Manufacture of Food Packaging

1. Introduction

The purpose of this guideline is to provide a systematic overview of the principles and methods for the statement of composition of printing inks/coatings and variations used in the manufacture of food packaging.

2. Scope

This guideline applies to the statement of composition of printing inks/coatings and variations used in the manufacture of food packaging.

3. Definitions

The following definitions apply to this guideline:

- Printing Inks/Coatings:** A substance that is used for printing inks/coatings

4. Risk Assessment

The risk assessment of printing inks/coatings and variations in the manufacture of food packaging is performed in accordance with the following principles:

- Identification of printing inks/coatings and variations
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

5. Conclusion

The risk assessment of printing inks/coatings and variations in the manufacture of food packaging is performed in accordance with the following principles:

- Identification of printing inks/coatings and variations
- Characterization of exposure
- Assessment of hazard
- Estimation of risk

Statement of Composition

Printing Ink Ordinance – In a Nutshell



- It is a German **national legislation** and **part of the consumer goods ordinance**
- Although it is colloquially called “ink ordinance” it has **printed food contact materials** in scope and addresses the converter/packer.
- The **compliance** with the provisions **needs to be demonstrated for the final article**
- The ordinance contains a list of **permitted substances (positive list)** for the production of printing inks for food contact materials and articles including specific migration limits. However, the **list is still incomplete and contains inconsistencies**.
- Hence, a **transition period of 4 years** applies until 1st January 2026, until then the current concepts remain fully applicable.
- **During the transition period the requirements for printing inks intended for food contact materials remain unchanged.**
- **EuPIA members** supply the relevant information via the **Statement of Composition**



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“National specific measure” according to Article 6 of Regulation (EU) 1935/2004



German Food and Feed Code (LFGB)



§ 32 legitimates the Federal Ministry of Food and Agriculture to issue specific ordinances for FCMs, in agreement with the Federal Ministry of Economics and Energy, and with the approval of the Bundesrat (Federal Council)



German Consumer Goods Ordinance



Ordinance amending the
Consumer Goods Ordinance ¹⁰



What is within scope of the ordinance?

- **printed food contact materials and articles:** *food contact materials and articles manufactured using printing inks;*
- **Printing inks:** *printing inks or printing varnishes, applied onto food contact materials and articles in a printing process or varnishing process;*
- *"Printing inks" and "printing varnishes" are established terms in the supply chain. Reference is made, for example, to the Packaging Ink Joint Industry Task Force (PIJITF) definition in this regard.**

* Not part of the legal text, but the official justification



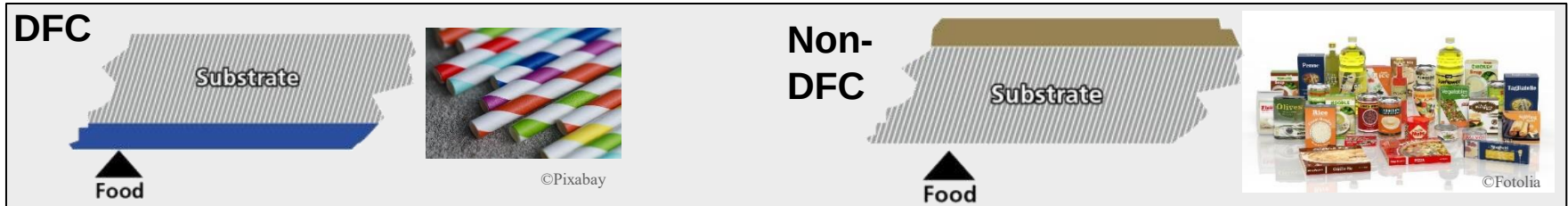
Printing inks are:

- a) Mixtures of colourants with other substances which are applied on materials to form a graphic or decorative design together with or without
- b) Other coloured or uncoloured overprint varnishes/ coatings or primers which are normally applied in combination with a) in order to enable the printed design to achieve specific functions such as ink adhesion, rub resistance, gloss, slip/friction, durability, etc.

Printing inks do not include coatings which are applied with the prime objective of enabling the material or article to achieve a technical function such as heat sealing, barrier, corrosion resistance etc., as opposed to a graphic effect, even though they may be coloured.



- **Background:** Adds provisions for printed food contact materials to the German Consumer Goods Ordinance.
- **Scope:** Printed food contact materials in direct (incl. transient) as well as indirect food contact





- Table 14.1 contains positive listed substances (incl. some pigments)
- Table 14.2 contains pigments which can be used for non intended but foreseeable direct food contact during an extended transition period of 5 years, in this period data need to be provided to move the pigments to table 14.1 or they can not be used for DFC anymore
- Substances from the "Union List" of regulation (EU) 10/2011 if there are no restrictions in column 9 or 10

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
7	30370	—	acetylacetic acid, salts	yes	no	no				
8	30401	—	acetylated mono- and diglycerides of fatty acids	yes	no	no		(32)		
76	77732	—	polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate	yes	no	no	0,05		Only for use in PET	

Ok can be used

Restrictions,
reference to PIM
cannot be used



- **Polymers** made from listed monomers
- **Colourants, solvents, reactive diluents, photoinitiators** or other additives
 - Table 14.1
 - Union List (Plastic Regulation) if no restrictions (see slide 16)
- Migration limits in these positive lists are to be observed
- Used substances must fulfil the specifications and purity requirements in the mentioned positive lists
 - Substances must be of “good technical quality”
- Nanomaterials are only allowed if this is specifically defined in Table 14.1 column 8
- Salts of listed acids, phenols and alcohols with Al, Ammonium, Ba, Ca, Fe, K, Co, Cu, Li, Mg, Mn, Na, Zn
 - If salts are specifically listed, then only these salts are allowed
- DFC inks with non intended, but foreseeable food contact:
additionally pigments according table 14.2 until the end of the 5-year transition period



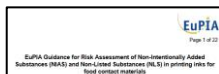
- Same as DFC inks and in addition
- **Polymers** made from other monomers and **colourants, solvents, reactive diluents, photoinitiators or other additives** if they are **not classified as CMR** (according to CLP)
- for non-listed substances (NLS) a migration into food must **not be detectable**
 - Accepted non-detection limit (except for nanomaterials): **0,01 mg/kg** of food



- If substances are present as NIAS which are not listed in table 14.1 or 14.2 column 8 then compliance to Art. 3 of Regulation (EC) No 1935/2004 needs to be demonstrated

cis-endo-bicyclo[2.2.1]heptan-2,3-dicarbonsäure, Salze		38507	27				x		5		Nicht zur Verwendung im unmittelbaren Kontakt mit sauren Lebensmitteln Reinheit $\geq 96\%$.
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- The responsible business operator has to demonstrate compliance of NIAS



EuPIA Guidance for RA of NIAS/NLS





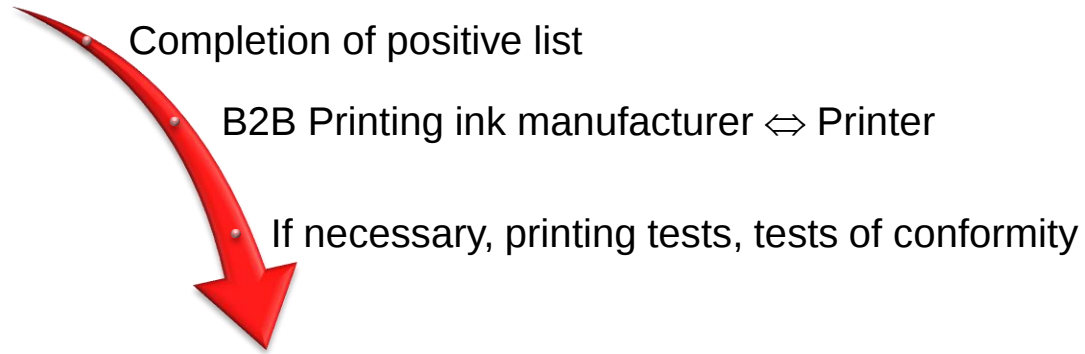
- Specific limits according Table 14.1, 14.2 column 6 & 7 and table 14.3

cis-endo-bicyclo[2.2.1]heptan-2,3-dicarbonsäure, Salze		38507	27				x		5		Nicht zur Verwendung im unmittelbaren Kontakt mit sauren Lebensmitteln Reinheit ≥ 96 %.																
											<table><tr><td>1</td><td>2</td><td>3</td><td>4</td></tr><tr><td>Gruppengrenzwert-Nr.</td><td>Substanz-Nr.</td><td>SMG (T) [mg/kg]</td><td>Gruppengrenzwert-Spezifikation</td></tr><tr><td>1</td><td>84 137 141</td><td>30</td><td>berechnet als Ethylenglykol</td></tr><tr><td>2</td><td>219 220</td><td>30</td><td>berechnet als Maleinsäure</td></tr></table>	1	2	3	4	Gruppengrenzwert-Nr.	Substanz-Nr.	SMG (T) [mg/kg]	Gruppengrenzwert-Spezifikation	1	84 137 141	30	berechnet als Ethylenglykol	2	219 220	30	berechnet als Maleinsäure
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Gruppengrenzwert-Nr.	Substanz-Nr.	SMG (T) [mg/kg]	Gruppengrenzwert-Spezifikation																								
1	84 137 141	30	berechnet als Ethylenglykol																								
2	219 220	30	berechnet als Maleinsäure																								

- Migration limits for Ba, Fe, Co, Cu, Li, Mn, Zn according Table 14.4
- Listed substances with no specific limits: OML of 60 mg/kg applies
- Non listed substances which are used in non-DFC inks: 0,01 mg/kg (10 ppb)



- **December 2021:** Publication in the Official Journal
- **2022 – End of 2025:** Implementation of provisions by supply chain



- **January 2026:** Transition period has ended → the provisions of the GIO apply
- **January 2027:** Transition period has ended for table 14.2 (pigments)

In case the Commission presents a measure on printed food contact materials until the end of the transition period, then the German government agreed to further delay the applicability



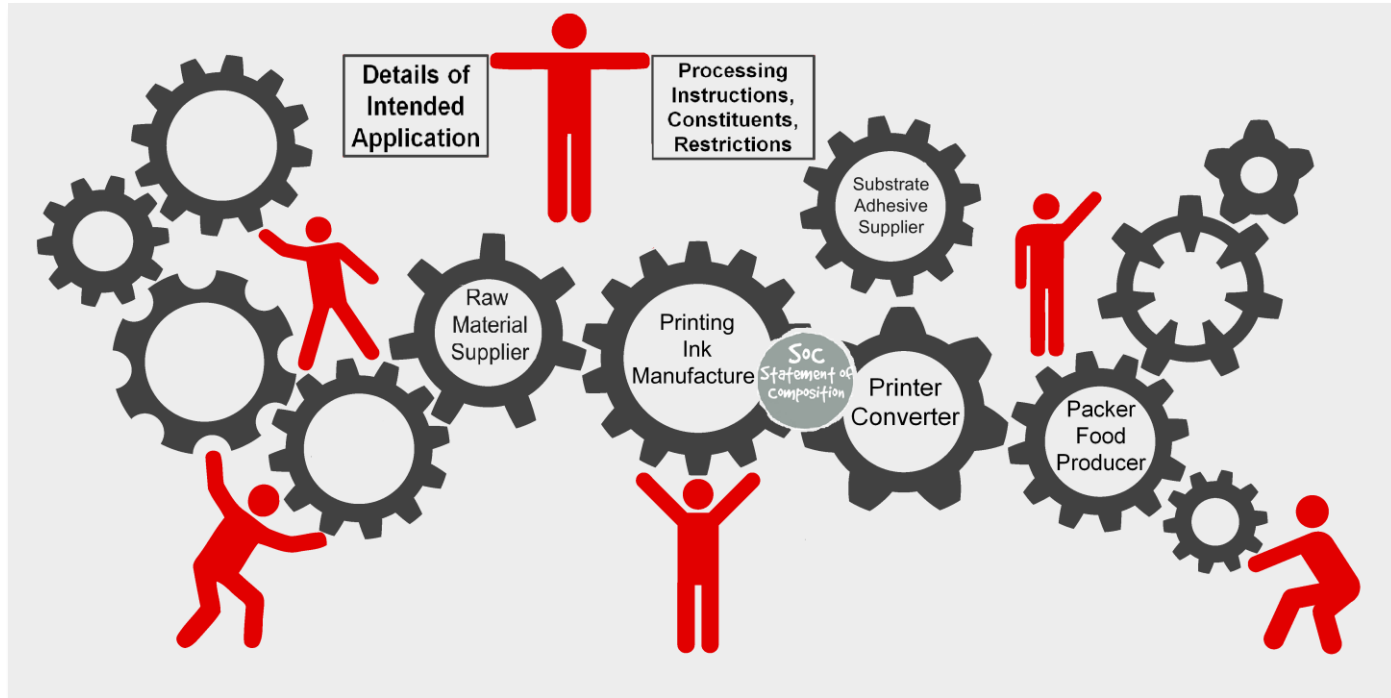
- To complete the positive **list**, **dossiers according EFSA note for guidance need to be submitted** to the German BfR, which contain information on toxicology and worst-case migration.
 - Data-owners are typically the **raw material suppliers**, hence they need to compile the dossiers
 - EuPIA members support the raw material suppliers.
- Due to the incomplete positive list and the transitional period set for completing the list, there is currently no basis for requesting confirmations of compliance with the requirements of the draft ordinance



- The **compliance** of the food contact material with the Consumer Goods Ordinance **must be established on the end product**
- Ink manufacturers can only specify the substances used in the products or present as known NIAS and demonstrate by modeling that migration limits can be met. However, the actual **migration limits must be verified for the end product**
- The converters/packers need information on the composition of the printing inks for their compliance work
- However, the ordinance does not contain any requirements for the transfer of information within the supply chain
- Therefore, ink manufacturers will continue to use the proven "**Statement of Composition**" developed within the European Printing Ink Association (EuPIA) to provide relevant information



- The "**Statement of Composition**" is a key document in the supply chain communication for food contact materials



The „Statement of Composition“ (SoC)



- Includes a table of potential migrants that are "used or known to be present," including NIAS (non-intentionally added substances) and NLS (non-listed substances)
- Is in accordance with the "Recommendation for Adequate Information for a Non-Plastic Intermediate Material (inks, adhesives, coatings) ", from the Union Guidance to Regulation (EU) No. 10/2011
- A "Customer Guidance Note" is available from EuPIA



Customer Guidance Note
for using Ink Statements of Composition when considering
compliance of food packaging



- 1. example: Bis(2-ethylhexyl)adipate (M = 371 g/mol)
Plasticizer frequently used in printing inks

**As of 2026: New column
indicating listing status in the
GIO.**

CAS-No	PM/FCM Ref-No	Name	Restrictions and specific migration limits (SML) [mg/kg]			Regulations (EC) No 1333/2008 1334/2008 [E, FI # or No]	For non- volatile/non- reactive substances: Maximum amount in dried ink film [%]	Comments [e.g. on presence of volatile/ reactive substances; in this case, a footnote should be included such as "The amount of these (volatile/reactive) substances in the dried ink film and/or the final packaging is under control of converter"]
			Regulation (EU) No 10/2011	GIO BedGgstV [either "SML" or "<10ppb"]	Swiss Ordinance 817.023.21 [either "SML" or "part B"]			
103-23-1	31920 / 207	Bis(2-ethyl- hexyl)adipat	18	18	18		5	
925246-00-0	-	2-({2-[4-(dimethyl- amino)benzoyloxy]eth yl}(methyl)amino)ethyl 4-(dimethylamino) benzoate	-	0.05	0.05		-	Reactive substance

**For NIAS:
Result of NIAS-
Risk
Assessment**

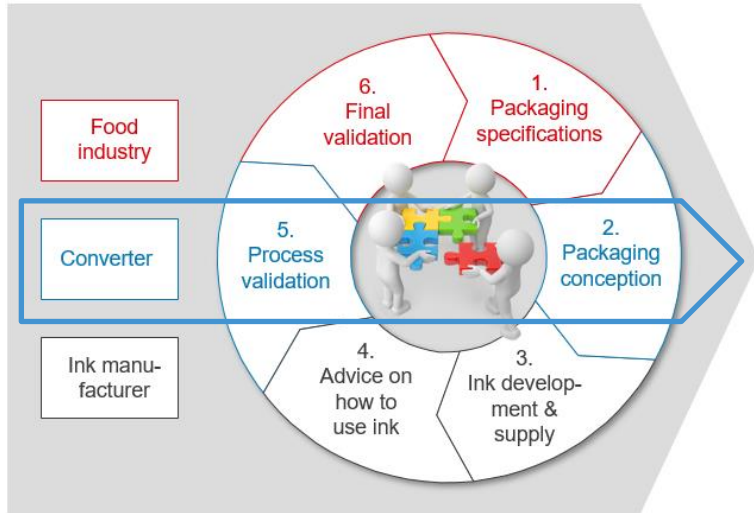


- 2. example: A198 (M = 414 g/mol)
Photosynergist used in UV inks

**As of 2026: New column
indicating listing status in the
GIO.**

CAS-No	PM/FCM Ref-No	Name	Restrictions and specific migration limits (SML) [mg/kg]			Regulations (EC) No 1333/2008 1334/2008 [E, FL # or No]	For non- volatile/non- reactive substances: Maximum amount in dried ink film [%]	Comments [e.g. on presence of volatile/ reactive substances; in this case, a footnote should be included such as "The amount of these (volatile/reactive) substances in the dried ink film and/or the final packaging is under control of converter"]
			Regulation (EU) No 10/2011	GIO BedGgstV [either "SML" or "<10ppb"]	Swiss Ordinance 817.023.21 [either "SML" or "part B."]			
103-23-1	31920 / 207	Bis(2-ethyl- hexyl)adipat	18	18	18		5	
925246-00- 0	-	2-({2-[4-(dimethyl- amino)benzoyloxy]eth yl}(methylamino)ethyl 4-(dimethylamino) benzoate	-	0.05	0.05		-	Reactive substance

**For NIAS:
Result of NIAS-
Risk
Assessment**



What are the tasks of the Converter?

- Adherence to the applicable FCM regulations
- Compliance with the relevant SML per substance
- Preparation of compliance documents
- Observation of GMP requirements
- Information about possible restrictions (e.g. to upstream users regarding DFC application)

Substances permitted to be used subject to the conditions specified in the lists

Permitted Substances		Application		
		“indirect” food contact	intended “direct” food contact only 	non-intended, foreseeable direct food contact only 
Evaluated substances				
Annex 10, part A	Annex 14, table 1	X	X	X
Annex 2	gliding reference to EU Plastics Regulation	X	X	X
--	transitional list of pigments (annex 14, table 2)	X		X
non-evaluated substances (no CMR, 10 ppb)				
Listing requirement: Annex 10, part B	No listing requirement	X		



- The core of the legal framework is around 40 years old, is not familiar with "new" developments, such as REACH
- The EU Commission is working on a revision of the legal framework (→ Farm-to-Fork Strategy).
- Concerns all types of food contact materials
- The Commission recognizes that positive lists are not a useful approach for the future and is considering other approaches that include industrial self-assessments

Impact Assessment

1. Inception Impact Assessment ('IIA'): consultation on policy options + problem definition (start mid 2020)
2. Impact Assessment ('IA'): Assessment of policy options (Q4 2020 – Q4 2021)
3. Publication of Evaluation + IA results (likely together, beginning 2022)
4. Drafting of new legislation

Approach + Timeline tentative

This presentation does not reflect the official position of the Commission; it is meant to facilitate discussion and understanding of existing and potential new legislation, but should not in anyway be seen as giving a final interpretation of existing legislation or a proposal of new legislation.





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