This is an unofficial translation. Only the German version is binding.

Guideline for the safety assessment of substances for inclusion in Annex 14 Table 1 of the Consumer Goods Ordinance

Status 05/06/2025

The following information does not represent a conclusively defined scope of testing. Each dossier submitted is reviewed individually according to the current state of knowledge, which may result in additional requirements.

1. Introduction

This guideline serves as an orientation guide for the preparation of documents required for a risk assessment as a basis for the decision on the inclusion of substances in the list of substances authorised for food contact printing inks in accordance with Annex 14 of the Consumer Goods Ordinance.

A dossier describing the identity and quantity of the possible transfer of relevant substances into food must be submitted for the inclusion of new substances in the mentioned list. Depending on the determined level of possible transfers under the most unfavourable foreseeable conditions of use (see also 5.5), it is necessary to include corresponding Guideline-compliant toxicological studies. The determination of these data is based on the guideline of the European Food Safety Authority (EFSA Note for Guidance), which was developed for substances that are used in the manufacture of food contact materials.

2. Legal basis and other applicable documents

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with foodstuffs
- Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with foodstuffs
- German Food and Feed Code (Lebensmittel-, Bedarfsgegenstände- und Futtermittelgesetzbuch - LFGB)
- Consumer Goods Ordinance - BedGgstV in the version published on 23 December 1997 (BGBl. 1998 I p. 5)
- Guidance of the European Food Safety Authority 2017 EFSA Note for Guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials. Updated: 27 March 2021. EFSA Journal 6(2008)7, 21r. DOI: 10.2903/j.efsa.2008.21r
- Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials. EFSA Supporting Publications 14(2017)5, 1224E. DOI:10.2903/sp.efsa.2017.EN-1224
- Guidance of the European Food Safety Authority 2008. EFSA Note for guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorisation. Updated on 30/07/2008. https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2008.21r&file=efs221r-sup-0001-SupInfo.pdf

- JRC Technical Report, Testing conditions for kitchenware articles in contact with foodstuffs: plastics metals, silicone & rubber, paper & board, https://publications.jrc.ec.europa.eu/repository/bitstream/JRC134290/JRC134290_01.pdf.

3. Definitions

3.1 General

- Relevant substance:
  Substance for which a dossier is submitted and all substances whose transfer to food is causally related to the use of the substance to be listed.

- Migration (based on Regulation (EU) No. 10/2011):
  Release of a specific substance or group of substances from a material or article into food or food simulants. This is a legal definition that is broader than physicochemical migration (kinetic or thermodynamic) in the form of diffusion (see also the detailed explanation below under: "Transfer").

- Transition:
  Is used synonymously with migration. In connection with polymeric materials (e.g. plastics), where the transitions are often dominated by physical processes such as diffusion and distribution between different polymers or polymer and food (simulant), the term "migration" is usually used. In the context of the BedGgstV as well as Regulation (EU) No. 10/2011, transitions are referred to as "migration" regardless of the underlying process. A detailed description of the possible processes can be found at point 5.1 of this document.

- *Non-intentionally added substance* (NIAS):
  Impurity in the substances used or reaction intermediate formed in the manufacturing process, or a degradation or reaction product.
  NIAS can be categorised as follows:
  - foreseeable NIAS
    These can be derived from the chemistry of the manufacturing or application process and the process and usage conditions. Knowledge of the relevant literature and personal experience is helpful. For this reason, the synthesis conditions should also be listed in detail in the dossier.
  - Unforeseen NIAS
    Due to the complexity of the application or unforeseen external influences, further NIAS may occur. Therefore, an additional comprehensive analysis ("screening procedure") should be carried out to detect or exclude further NIAS.

  Even if substances are not intentionally introduced and are therefore NIAS by definition, their occurrence or formation is often intentional (e.g. reaction products of photoinitiators or stabilisers) or at least foreseeable. The same criteria apply for their risk assessment as for the substances to be listed[1] (see also point 4); corresponding data must also be submitted with the dossier for these substances.

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[1] EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2016. Scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA Journal 2016,14(1): 4357, 28 pp. doi:10.2903/j.efsa.2016.4357, see https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2016.4357
"Regarding the identification and evaluation of all substances that migrate, experience gained over the years has shown that more focus is needed on the finished materials and articles, including the manufacturing process used. Substances used in the manufacture of plastic materials or articles may contain impurities originating from their manufacturing. Furthermore, during manufacturing and use, reaction and degradation products can be formed, of which oligomers can be the dominant class.

3.2 Material-specific: Printing inks

- Printing inks:
  Printing inks or printing varnishes that are applied to food contact materials in a printing or varnishing process.

  These are:
  a) mixtures of colourants with other substances applied to materials (ink specific: substrates) to form a graphic or decorative pattern, alone or in combination with
  b) other coloured or uncoloured overprint varnishes/coatings or primers, normally applied in combination with a), to enable the printed design to achieve specific functions such as ink adhesion, rub resistance, gloss, slip, rub resistance and durability.

  Varnishes or coatings that are applied with the primary aim of giving the material or object a technical function such as heat sealability, barrier properties, corrosion resistance or similar, as opposed to a graphic effect, are not covered by the term "printing inks", even if they may be coloured.

- Printing inks that are not intended to come into direct contact with the food:
  The printing is applied on the side facing away from the food. In normal, foreseeable use, the printing cannot come into direct contact with the food. Applications in which the print is located within a multilayer packaging (e.g. sandwich print structure) fall into this category.

  Depending on the substrate, migratable ink components and production and application conditions, a transfer (e.g. via permeation or caking) may also occur if the ink is applied on the side facing away from the food. These possibilities must be taken into account when preparing the dossier. A detailed description of the possible processes can be found at point 5.1.

- Printing inks that are intended to come into direct contact with the food:
  The printing may come into direct contact (Direct Food Contact - DFC) with the food during normal, foreseeable use.
  a) the printing is applied to the food contact side/food-facing side of the article,
  b) during normal, foreseeable use, the printing may come into direct contact with the food (e.g. napkins, tray protectors, etc.)

4. Documents

For the evaluation of the substances for the purposes mentioned in point 1, a dossier according to the EFSA Note for Guidance with the following information shall be submitted:

- Identity of the substance
- Properties of the substance
- Planned use

These substances have become known as non-intentionally added substances (NIAS) and are referred to as such in Commission regulations. Whether their presence is intentional or not, it is necessary to evaluate the safety of all migrating substances and not just of the starting substances - for example the monomers or additives alone - and the guidelines should be updated to account more fully for this more comprehensive approach."

- Type and quantity of transfer of relevant substances from the food contact material or article into the foodstuffs coming into direct or indirect contact with it under the most unfavourable foreseeable conditions of use
- toxicological data, depending on the amount of substance transfer and, if applicable, on indications, for example, of carcinogenic, reprotoxic, endocrine or neurotoxic effects of a migrating substance from existing studies or due to structural properties.

This information is also required for impurities and reaction and degradation products ('NIAS', e.g. oligomers, reaction products of initiators or oxidation products of stabilisers/antioxidants).

When compiling these data, a technical dossier must be submitted in accordance with the requirements of the EFSA Note for Guidance. If clarifications or deviations from the EFSA Note for Guidance are described in this Guidance Document, the information in this Guidance Document applies. The EFSA Note for Guidance must be followed in all other respects.

The following documents must be submitted:

- a complete version of the dossier in paper form
- the substance overview provided by the BfR (see Annex 1)
- an electronic version of the complete dossier (in a searchable format, e.g. as a Word document or unprotected PDF; tables and calculations must be submitted in Excel or Word)
- If the dossier contains data to be treated confidentially, an additional electronic version without the confidential data is also required. In the case of requests under the Freedom of Information Act (IFG), the data can be forwarded in this form.
- A confirmation that the submitter of the documents is the rights holder of the documents or has been authorised by the rights holder.

The documents must be submitted in German or English.

5. Determination of the transitions

The scope of the toxicological data to be submitted must be based on the possible level of transfer into the food. The higher the potential exposure of consumers due to the transfer of substances, the more extensive the requirements for the toxicological information to be included (see section 6)

5.1 Possible processes for the transfer of substances from printing inks into foodstuffs

Before measuring or estimating the transfer of substances from a material or article into food or food simulants, the nature of the transfer must be clarified. The transfer can occur via the following routes:

- Diffusion from the interior of the food contact material or permeation through the material to the food contact surface;
- gas phase transfer (evaporation and recondensation), e.g. from the food contact material to dry food or from outer packaging via inner packaging (e.g. cardboard box with inner bag);
- *set-off*: via contact of the food contact side with the outside (e.g. printed side) in a roll or stack during storage of the material;
- Particularly in the case of printing inks that are in direct contact with the food, other mechanisms may be of importance that may need to be taken into account:
  - Hydrolysis and/or oxidation, e.g. when polymers or metals come into contact with acidic or alkaline foods (simulants);
  - Abrasion (especially with nanomaterials);

- Transfer from the surface of "dry" foods (e.g. through contact with fine dry foods, especially with a greasy surface);
- swelling or dissolving of the colour layer.

The transfer of the substance into the food depends on the physical/chemical properties of the substance, the nature of the food and the storage conditions.

- The transfer into liquid or pasty foods with wetting contact is determined by the distribution equilibrium (solubility ratio) at the boundary layer between the food contact material and the food.
- For coarse-grained, dry foodstuffs, migration occurs predominantly via the gas phase and is therefore particularly pronounced for volatile substances (boiling points up to the range of 350-400 °C when stored at room temperature). Coarse-grained, dry, non-fatty foods with a small free surface have a low adsorption capacity and therefore a limited absorption of substances, whereas coarse-grained, dry foods with fat on the surface have a high adsorption capacity and therefore a high absorption of substances.
- Fine powders (e.g. flours) also absorb significant quantities of substances via contact, i.e. without any limitation in volatility. This increases if the particles have moist/oily surfaces.
- When storing the food with the contact material, temperature and duration are particularly important.

Printing inks can enter the food via different routes, which must be differentiated for the assessment of migration. Printing on the outside/side facing away from the food, on the inside/side facing the food or on the inside of the food contact material can have different effects on migration.

- Substances can migrate into the food from printings on the outside (side facing away from the food) if they migrate through the material, i.e. if the material is not an effective barrier under the conditions of use. Paper/cardboard and polyethylene normally have low barrier effectiveness, but other plastics can prevent migration over a longer period of time (up to years). Barrier effectiveness is also highly dependent on temperature.
- Transitions from printing on the outer side/the side facing away from the food are also possible via *set-off* during storage of the material, i.e. before the food is packaged: during storage, the printed outer side is often on the future side with food contact. As a result, substances from the printing first get onto the food contact side and from there into the food.
- Plastics are often printed on an inner layer. In this case, the barrier effect is important on both sides: for migration through the inner layer into the food as well as through the outer layer for a possible set-off.
- Substances from the print on the food contact side/food-facing side can migrate unhindered into the food if there is no effective barrier (e.g. barrier coatings). Some of the substances can also be sorbed into the substrate (e.g. plastic or cardboard).

5.2 General procedure for determining the transitions

As the transfer of substances to food is often difficult to determine, models (conventions) have been developed. These are usually conservative and can greatly overestimate the actual exposure. **The dossier compiler is free to derive an exposure that is closer to reality, whereby the assumptions made must be justified in a comprehensible manner. In any case, the most unfavourable conditions foreseeable in practice must be applied (*worst case*).** Because the models can also underestimate the transitions that actually occur in certain situations, they must be applied with caution.

The approaches described below can be used to determine the possible transition to food. They build on each other hierarchically, starting from deliberate overestimates. If the available

toxicological data meet the requirements for this, the following (more precise) investigations can be dispensed with.

5.3 Calculation assuming complete transfer, based on the quantity used in the process

In the simplest case, it is assumed that the substances used or the maximum amount produced remain on/in the material during production and are completely transferred to the food. If this (usually highly exaggerated) assumption proves that the migration is harmless, no further steps are necessary. If reactions of the substance (e.g. photoinitiators, stabilisers) are to be expected, this approach alone is not sufficient (see point 7.4). For polymeric compounds, the content in the formulation (commercial product) must be used.
These calculations and the entries in the table "Overview of substances" (Appendix 1) are mandatory, irrespective of subsequent refined provisions.

5.4 Calculation assuming complete transfer, based on the measured content on/in the food contact material or in the commercial product

In contrast to 5.3, the content of the substance to be listed in the commercial product (usually the ready-to-use printing ink) or in the finished food contact material is determined analytically. An extraction of the commercial product or the finished article is carried out. If this is not possible for technological reasons, the amount of substance applied to the test substrate or introduced into the material can also be determined analytically in *worst-case test prints/test articles* or test materials with the maximum amount of substance used. In any case, the completeness of the extraction must be documented.
Exemplary specifications for test prints can be found in Appendices A, B and D of this document.
The possible content in the food is then calculated assuming complete transfer from the food contact material or commercial product.

5.5 Determination of the transitions

For both the migration measurement and the migration modelling, the most unfavourable conditions that can be foreseen in practice must be used with regard to food or food simulants, temperature and time (*worst case*). The properties of the potentially transferring substances (e.g. general solubility, solubility in the simulants used, polarity, volatility) and knowledge of the possible use of the finished food contact material are important for this. If, when preparing the dossier (or specifying the material), the possible uses are restricted in relation to the most unfavourable conditions foreseeable in practice (e.g. by excluding food categories), this must be taken into account when selecting the migration conditions. These restrictions can be listed as additional restrictions when listing the substance.
In the case of amphiphilic substances, when selecting the extraction solvents or simulants, it must also be taken into account that emulsifying substances present in foodstuffs have an influence on the level of migration.
The extraction solvents/simulants/test foodstuffs listed in the annexes are to be understood as examples only. The dossier submitter must check whether they actually represent the *worst case* or whether an alternative should be selected. The suitability of the methods used must be clearly demonstrated.
The solubility of the substance in the simulants used must also be stated in the dossier under 2.1.4 Solubility.

5.5.1 Migration measurement

The detection and quantification limits, measurement uncertainty and recovery must be verified and documented for the analytical method.

5.5.1.1 Migration measurement in simulants

The starting point is the determination of the substances in simulants obtained with the finished food contact material or the test article prepared for testing purposes. Exemplary conditions are listed in the annexes. In addition, the conditions of Regulation (EU) No. 10/2011 (Annex V, Chapter 2) or the Kitchenware Guidance of the Joint Research Centre can be used.

The simulants used can be restricted according to the current state of scientific knowledge or adapted to the physico-chemical properties of the substances to be determined or printed substrates.

5.5.1.2 Migration measurements in foodstuffs

Measurements in foodstuffs are necessary if there is uncertainty as to whether the migration in simulants correctly reflects the migration in foodstuffs. The selection of test foodstuffs and contact conditions must be based on the current state of scientific knowledge and must be justified. The accuracy of the measurements in foodstuffs must be verified (e.g. by means of recovery tests).

5.5.2 Migration modelling

Migration modelling must be carried out and documented in a comprehensible manner in accordance with the current state of knowledge and technology. It must not underestimate the actual migration.

The substance-specific migration can be calculated on the basis of the quantity used or the residual content of the substance in the material (in the case of multi-layered materials in the individual layers) using generally recognised diffusion models based on scientific findings. A conservative model, which was developed for commercially available packaging plastics on the basis of so-called Ap values as plastic-specific parameters for their basic diffusion properties[2] , has found scientific and regulatory recognition at European level[3] . If no polymer-specific constants (Ap values) are available in the literature for individual polymer-based layers (plastics, adhesives, coatings, printing inks, etc.) in multilayer composites, these can be conservatively estimated on the basis of scientific findings. For paper layers, a paper-specific constant of A_{PB}= 15 (no barrier) and for aluminium a material-specific constant of A_{Al}= -25 (absolute barrier) can be used. In addition, further estimation options are known from the literature, for example by interpolation via the glass transition temperature[4] , estimation using analytical measured values of other migrants, taking into account the molecular mass of the migrant, the temperature of the planned application and the matrix[5,6] , estimation of material-specific diffusion coefficients in the polymer using the molecular volume and the correlating activation energy for diffusion[7,8] .

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2 Begley et al, 2005 Evaluation of migration models that might be used in support of regulations for food-contact plastics. Food Additives and Contaminants, January 2005; 22(1): 73-90.

3 JRC, 2015. Practical guidelines on the application of migration modelling for the estimation of specific migration. EUR 27529 EN.

4 Rainer Brandsch, 2017. probabilistic migration modelling focused on functional barrier efficiency and low migration concepts in support of risk assessment. Food Additives & Contaminants, Part A, 34(10): 1743-1766, DOI: 10.1080/19440049.2017.1339235.

5 Mercea P. et. al, 2018 Modelling migration of substances from polymers into drinking water, Part 1 - Diffusion coefficient estimations, Polymer Testing, 65: 176-188.

6 Mercea P. et. al, 2019 Modelling migration of substances from polymers into drinking water. Part 2 - Partition coefficient estimations, Polymer Testing, 76: 420-432.

7 Welle F., 2013. A New Method for the Prediction of Diffusion Coefficients in Poly(ethylene terephthalate). J. APPL. POLYM. SCI. 2013, DOI: 10.1002/APP.38885.

8 Welle F., 2014. Activation energies of diffusion of organic migrants in cyclo olefin polymer. Intern. J. Pharmaceutics, 473 (2014): 510-517; DOI: 10.1016/j.ijpharm.2014.07.029.

In the case of direct contact, the suitability must be shown specifically for this case (absence of effects that are not taken into account in the model, such as material degradation, swelling, abrasion, etc.).

5.6 Specification of the results

The results from5.3 to5.5 must be presented in tabular form and discussed for plausibility. A template for the overview can be found in Appendix 1.

6. Toxicological part

The toxicological data to be submitted is regulated in a tiered approach in accordance with the EFSA Note for Guidance (see table below).

Measured migration or calculated theoretical maximum migration in mg/kg food (simulant)	Toxicological issues to be addressed
< 0,05	- Absence of genotoxicity
0,05-5	- Absence of genotoxicity - Oral, subchronic toxicity - Proof that there is no accumulation in humans
5-60	- Absence of genotoxicity - Absorption, distribution, metabolism and excretion - oral, subchronic toxicity - oral, chronic toxicity/carcinogenicity - Reproductive and developmental toxicity

7. Further information

7.1 Justification of confidentiality

For the claim of confidentiality of information, a justification according to the Administrative Guidance for the preparation of applications for the safety assessment of substances to be used in plastic Food Contact Materials, Annex C must be provided. According to Article 20 of Regulation (EC) No 1935/2004, the following information cannot be labelled as confidential:

- Name and address of the dossier submitter
- Chemical name of the substance (name and, if available, CAS No. and EC No.)
- information of direct relevance to the evaluation of the safety of the substance
- the analytical method(s) for official control laboratories.

7.2 Name, CAS No.

The name must comply with the IUPAC nomenclature rules and clearly describe the chemical structure and identity of the substances. If the CAS No. cannot be assigned to the substances and their structure using generally, publicly and free of charge accessible search tools, appropriate proof is required. A report from the CAS Inventory Expert Service, for example, is suitable for this purpose. The name and CAS number cannot be labelled as confidential in accordance with point 7.1 .

7.3 Manufacturing process

The manufacturing process of the substance must be described, as this provides information on the impurities and the reaction and degradation products. If the purity of the starting materials can have an influence on the purity of the substance, the purity of the starting materials and the impurities must be stated. Alternative production processes must be specified and any other impurities that may result from them must be mentioned.
The variability between production batches must be stated and it must be shown that the batches used for migration experiments and toxicological studies cover this variability.

7.4 Impurities and reaction products

Impurities and reaction products (including oligomers and degradation products) occurring during the manufacturing process and use of the substance to be listed must be identified and quantified. They can be partially derived from the chemistry of the manufacturing/application process, but must be analytically verified and quantified and checked for completeness. A comprehensive analysis ("*non-targeted screening*" or "*general unknown screening*") using methods adapted to the substance type and matrix should also detect unexpected substances. The required detection limit results from the toxicological specifications. In particular, if the LC-MS(/MS) method is used, the simple comparison of base peak chromatograms (BPCs) or total ion chromatograms (TICs) is not sufficient.
For points 2.2.4 (hydrolysis) and 2.2.5/2.2.6 (decomposition/transformation) of the EFSA Note for Guidance, in addition to the behaviour under thermal stress, relevant possible reactions in the manufacturing process, during storage and use (e.g. irradiation, pH value) as well as reactions with the food (during preparation/heating) and in the digestive tract must be taken into account. The latter is to be seen in connection with the general information on toxicology from point 6.

7.5 Method for official monitoring

As described in 5.1.8 and 6.5 and in Annex 1 to Chapter IV of the EFSA Note for Guidance 2008, a method for the determination of the substance in the finished product and/or food that can be used by official control laboratories must be provided. This method must be described as a validated test instruction (SOP) in accordance with the applicable standards. It is not permitted to label this method as confidential.

7.6 Traceability, raw data

All data must be documented in a traceable manner. For chemical analysis, this includes selectivity, detection limits, limits of quantification, linearity of the method and, if applicable, the specification of measurement uncertainties and calculations. At least exemplary typical chromatograms or spectra of standards, samples and blanks with clear labelling should be provided. For analyses, the date of the measurement must also be provided. Raw data required for the calculation (peak areas etc.) must be provided **in full** and should be available in a copyable table format (Excel) (see also the specific requirements listed below). The electronic versions must not be created or protected in a way that prevents searching and copying (e.g. texts or tables must not be inserted as pixel graphics).

The P-SDS should be used to provide a summary of the results. A reference to the annex with the respective data and raw data, stating the page on which the relevant information can be found, is required. Data from different studies should not be summarised in one annex.

Analysis reports must be clearly structured and contain at least the following elements:

- Detailed table of contents,

- List of figures and tables,
- Summary of the analyses and the most important results,
- clear assignment of the codes used to the samples measured,
- precise description of the methods and results
- results including a discussion of the same.

The following notes should be observed:

- Only chromatograms, spectra, tables and similar that are necessary for immediate understanding should be included in the main body of the report. Reference should be made to further figures or tables.
- Further data should be included in an appendix to the report. Each figure or table should be precisely described and numbered.
- Non-annotated, automatically generated analysis reports are not acceptable.
- It must be easy for the auditor to find information. To this end, the data must be structured accordingly and references inserted in relevant places. The documents must be searchable. Text must not be inserted as a non-searchable graphic (simple scan). Raw data must be stored and made available to the BfR if necessary.

The method description should include:

- Device description and analytical parameters,
- all measurement and validation parameters (e.g. linearity, LOD/LOQ, recovery) and their determination (data on this are provided in the annex as far as possible),
- Information on the production of the standards.

Review of the calculations: It must be possible for the BfR to check all calculations. This includes in particular

- The production of standards (weights and dilutions),
- Calculation of LODs/LOQs,
- recoveries,
- calibration lines and
- analysis results.

All raw data and pipetting schemes for calculating the parameters specified above must be available in an Excel file to enable verification with reasonable effort.

7.7 Reference material

In deviation from the requirements of the EFSA Note for Guidance, the following address should be used for sending the reference material:

Bundesinstitut für Risikobewertung
Nationales Referenzlaboratorium für
“Stoffe, die dazu bestimmt sind, mit Lebensmitteln in Berührung zu kommen“
Max-Dohrn-Str. 8-10
D - 10589 Berlin

The substance (250 g) should be packaged in inert containers, e.g. glass with PTFE lid seal, and must be accompanied by information on stability and storage conditions. The packaging must ensure that the chemicals reach the BfR undamaged. The safety data sheets must be sent electronically in advance (by e-mail to: nrl-fcm@bfr.bund.de).

Annex 1: tabular overview of the results (substance overview / substance data sheet)

An Excel version of the table can be found at http://www.bfr.bund.de/link-noch-spezifizieren/Bezeichnung-der-Datei.xls. The Excel version must be completed, the presentation here is for information purposes only.

Substance name	CAS no, EC no.	SMILES	Structure	Calculation assuming complete transition, based on the amount used in the process		Calculation assuming complete transfer, based on the content in the food contact material (Point 6 DATA ON THE RESIDUAL CONTENT of the EFSA Note for Guidance)		Measured or modelled migration (point 5 MIGRATION DATA ON THE SUBSTANCE of the EFSA Note for Guidance)		Existing restrictions, e.g. according to Regulation 10/2011	Remarks
				Content in the formulation [mg/kg]*	Content in the food at complete transfer [mg/kg]	Analytically determined content in the finished food contact	Content in food at 100 % transition of the content in the	Measured or modelled migration [mg/kg]			
								in simulants	in food		
1. polymer/oligomers:											
Monomer(s)											
Oligomer proportions < 1000 Da											
By-products and impurities											
Catalysts/initiators/others (e.g. decomposition products)											
2. non-polymeric substances:											
Substance											
By-products and impurities											
Catalysts/initiators/others (e.g. decomposition products)											
3. reactive substances (catalysts/initiators/inhibitors/stabilisers):											
Substance											
Decomposition/ reaction products											
By-products and impurities											

* For substances whose quantity was determined analytically in the formulation (e.g. oligomers in a resin), this quantity must be stated here and labelled under comments

The model systems and tests described in Annexes A to D were provided by the Association of the German Paint and Printing Ink Industry (VdL). The test systems are optimised with regard to the substrates for printing on the side facing away from the food. If the dossier refers to an application in direct contact of the printing with the food, it is recommended to test the printing directly on an inert substrate (e.g. aluminium foil, provided the adhesion is comparable) in order to avoid entries and their interpretation from the substrate.

Appendix A: Print samples for indicative migration tests

Test prints that have been produced and dried under typical industrial conditions should preferably be used for testing. This applies in particular to systems where processing and/or drying has a significant influence on the composition of the ink and/or varnish layer, e.g. reactive (UV/EB, 2K systems) or solvent-based systems. The ink or varnish film weight must be within the range given in brackets in Annex B, Table 2.

The test can also be performed on printed, three-dimensional containers (examples: Cups, directly printed, labelled or sleeved plastic containers).

Alternatively, the printing ink or printing varnish can be applied under laboratory conditions to the side of the suitable substrate facing away from the food in such a way that the printing and drying processes correspond as closely as possible to those used in practice. The amount of printing ink or printing varnish applied should correspond at least to the value for the representative film weight given in Annex B, Table 2. The basis weight of the model substrate used (BOPP, cardboard or paper) should be at the lower end of the range specified in Appendix B.

The size of the test pieces must be large enough for a migration cell (preferably DIN A4). The colour coverage should be 100 %.

Appendix B: Packaging setups and simulants

Model packaging structures and test conditions

Table 2 lists model printing ink and printing varnish systems, substrates and film weights. These models represent the majority of all typical practical applications.

Test prints made and dried under typical industrial applications may be made with different substrates, provided it can be demonstrated that the test system is equivalent and represents the majority of all typical practical applications for the ink or varnish system in question.

Table 2: Model ink and varnish systems, substrates and film weights

Printing ink or -varnish system		**Substrate**	**Representative film weight, dry [g/m²]**	**Note**
oil/resin-based	Conventional offset (peel-off)	Cardboard	1,5 (1-2)	Print coated with water-based overprint varnish
UV/EB-curing	UV/EB offset	Cardboard PP cup	1,5 (1-2)	only for use on the side facing away from the food
	UV/EB flexo	BOPP	1,5 (1-2)	
	UV/EB coatings	Cardboard	6 (4-7)	
	UV/EB pad/screen printing	PP	15 (10- 20)	
	UV/EB inkjet	Cardboard BOPP / PP	15 (10-20)	
solvent or water-based	Gravure printing	BOPP cardboard	1,5 (1-2)	
	flexo	BOPP paper Cardboard	1,2 (1-1,5)	
	2K systems, solvent-based	BOPP	1,5 (1-2)	
	Overprint varnishes for offset printing, water-based	Cardboard	2,5 (2-3)	
	Pad/screen printing, solvent-based	BOPP/PP	12 (10-15)	
	Inkjet	cardboard BOPP	3,5 (2-5)*	
	Digital printing with liquid toner	Cardboard BOPP	1,5 (1-2)	

* Note: For *continuous inkjet* printing (CIJ), it is recommended to use practical prints with a typical colour allocation for the intended application. For a generic test, if no intended application is known, it is recommended to print the test samples according to 100 % area coverage.

The composition of the ink and varnish systems used for the tests should correspond to the models listed in Appendix D. Any deviations must be explained.

Selection of substrates:

- Plastic films: BOPP (25-40 µm) is a typical film material for food packaging and is generally not a sufficient barrier for migratable substances. If the test is carried out on printed, three-dimensional containers, the extent to which the selected material and wall thickness represent the *worst case* must be justified.

- Plastic mouldings (e.g. PP cups): Plastic mouldings are usually deep-drawn or injection-moulded. The wall thicknesses are typically in the range of 160-350 µm. A typical material is polypropylene (PP).

- Cardboard: Primary fibre cardboard, coated on one side (virgin fibre cardboard made from bleached cellulose or wood pulp), international designations SBB, SBS or FBB, basis weight 200-300 g/m². Such cartons[9] have no barrier properties and are representative for typical folding carton applications and for applications on corrugated board.

- Paper: Primary fibre paper, basis weight 50-80 g/m². Does not represent a barrier. If results of migration tests on paper are available, no additional tests on cardboard are required.

Selection of simulants:

The selection of simulants must reflect the most unfavourable of the foreseeable conditions of use in practice (*worst case*). The properties of the potentially transferring substances (e.g. general solubility, solubility in the simulants used, polarity, volatility) and knowledge of the possible use of the finished food contact material are important for this. Corresponding specifications can be found, for example, in the Annex to Regulation (EU) No. 10/2011 or the JRC Kitchenware Guidance.

- For plastics, ethanol 95 %(v/v) serves as a universal simulant, as it represents *the worst case for* the majority of the practical cases listed in Regulation (EU) No. 10/2011.

- By far the most common application of printing inks for paper and cardboard articles is the printing of outer packaging (e.g. secondary packaging) or the outside of primary packaging for dry foodstuffs. Poly(2,6-diphenyl-p-phenylene oxide)[10] (MPPO, Regulation (EU) No. 10/2011: Food simulant E) is a suitable simulant for these applications as well as for paper and board printing in direct contact with exclusively dry and non-greasy foodstuffs.

- If it is foreseeable that the paper/cardboard will come into contact with moist and/or fatty foods, the test for migrating components is carried out under the following conditions:
    - If the printing is intended to come into direct contact with fatty foodstuffs, the solvent extract according to DIN EN 15519 is used to determine hydrophobic substances capable of migration.
    - If the printing is intended to come into direct contact with moist foodstuffs, the water extracts according to DIN EN 645 and DIN EN 647 are used as a standard test to determine hydrophilic substances capable of migration.
    - For items where the printing is not intended or foreseeable to come into direct contact with the food (e.g. printing on the outside), as well as for fillable and other items that can withstand a migration test with aqueous food simulants (e.g. drinking straws or cutlery), a migration test can also be carried out under the following conditions:
        - The most unfavourable surface-to-volume ratio in actual or intended use should be assumed. If this cannot be determined (e.g. due to unknown

[9] Examples include the grades Invercote T (Iggesund); Ensocoat, Kopparwhite (Storaenso); Metsäboard Classic, Pro, Prime (Metsäboard).

[10] Particle size 60-80 mesh, pore size 200 nm.

or widely varying use), a surface-to-volume ratio of 13.3 dm^2/kg food should be assumed.
- The selection of time-temperature conditions and simulants should be based on the specifications for plastic food contact materials in Regulation (EU) No. 10/2011 and in the JRC Kitchenware Guidance for the most unfavourable foreseeable (contact) conditions.
- A migration cell, for example, can be used to simulate one-sided contact.

Possible set-off migration must also be taken into account during the test. For further details, see Appendix C.

Specific packaging set-ups/test conditions

The models listed in Table 2 describe the majority of cases that occur in practice.

Specific printing ink or printing varnish systems, packaging structures, filling and storage conditions that cannot be adequately described with the models listed in Table 2 must be tested accordingly in specific model formulations or test conditions. These must be disclosed when submitting the data.

Examples include substances that are only used in practice in printing inks and varnishes for printing on materials with a barrier effect, but where invisible set-off or migration via the gas phase cannot be excluded (e.g. in certain metal decorating or cup printing applications), or in printing inks and varnishes for packaging and objects for use at elevated temperatures or under different storage conditions.

Another example is plastic-coated or plastic-laminated paper and cardboard if they are intended for direct contact with liquid food or for temporary contact with the packaged food (e.g. fresh bakery and butchery products). Liquid simulants should be used here (see above and Appendix C for further information).

Printing inks in direct contact with food are a special case. These must be inert to the food as a dried printing ink film. Due to the variety of printing ink formulations, foodstuffs and application conditions, no generally applicable specifications can be made here.

Appendix C: Migration test

The printed or coated samples are tested, for example, in suitable migration cells under the appropriate test conditions with suitable simulants.

If test prints from the practice are used, a possible substance transfer due to set-off migration is already taken into account, provided that the treatment of these prints corresponds to the possible *worst case* (stack size and contact pressure, storage time, etc.).

If print samples produced in the laboratory are used, they must be conditioned accordingly before the migration test in order to detect a possible mass transfer by set-off (sheet stacks, roll windings, three-dimensional objects standing inside each other).

Test conditions for the migration tests on plastic materials: The migration tests on plastic materials are carried out in accordance with the test methods specified in Regulation (EU) No. 10/2011. The chemical/physical properties of the materials and simulants must be taken into account. A chemical/physical change in the materials under the influence of a simulant that does not occur under the conditions of use in contact with real food (e.g. swelling or destruction of the surface) should be avoided if it leads to an increased release of the substances to be analysed into the simulants. However, if no health risk results even from a correspondingly overestimated release of the substances, the test results can be used for the dossier to be submitted.

Since food contact materials made of paper and cardboard are not yet regulated by a specific EU regulation or directive, it is recommended that the time and temperature conditions specified in Regulation (EU) No. 10/2011 or the JRC Kitchenware Guidance be used for testing printed samples made of cardboard, taking into account the technical properties of paper and cardboard in comparison with plastics (see DIN 14338). For the selection of possible simulants, see Annex B of this guideline.

Instead of laboratory tests with simulants, the transfer of substances can also be determined by worst-case calculations, by migration modelling or by analytical tests on foodstuffs (see section 5 of this guideline).

Conditioning

The conditioning of the print samples depends on the delivery form. Print samples in sheet form are first cut to a suitable size (usually DIN A4), stacked (front side against back side, preferably > 20 test samples) and the stack is then wrapped in aluminium foil. Care must be taken to ensure that the aluminium foil has no varnish/coating that could interfere with the intended migration test. Ideally, a stack of unprinted material should be wrapped separately in aluminium foil and subjected to the same conditioning and test procedure as the printed samples to be tested.

No further conditioning is necessary for samples in roll form, provided that the printed material on the roll has been treated in practice in accordance with the typical worst-case conditions. Otherwise, proceed as with printed samples in sheet form.

Three-dimensional objects should, if possible, be stacked in the same way as two-dimensional objects and wrapped in aluminium foil.

Print samples that have already been conditioned under practical conditions are preferred. If this is not possible, the wrapped print samples must be exposed to temperature and humidity conditions typical for production or specified by the customer, or alternatively stored at normal humidity for 10 days at 23 ± 2 °C.

The stacks of two-dimensional print samples wrapped in aluminium foil must be subjected to uniform pressure during conditioning. If no values are known from practice, the pressure should be at least 1 kg/dm² so that the print samples are in close contact. The influence of the pressure on the observed impression is of secondary importance.

In the case of three-dimensional objects, the pressure should correspond to typical practical conditions so that the three-dimensional structure is not deformed. The contact between the individual objects should correspond to the real situation.

After conditioning, the top and bottom 5 layers (for stacks > 20 layers) should be removed and the samples for the migration tests should be taken from the centre of the remaining stack.

Appendix D: Characterisation of the model printing ink and printing varnish systems as supplied

Pigments are not included in the systems listed here.
Typical pigment content of a printing ink: 5-25 %
Printing varnishes are typically unpigmented.

Printing ink and varnish systems, oil/resin-based

	Leading components	**typically**
Conventional offset (fading)	vegetable oils (triglycerides) and/or esters of fatty and/or other carboxylic acids	30-60 %
	rosin resins	20-40 %
	alkyd resins	10-30 %
	Other ingredients: (fillers, waxes, dispersing additives, siccatives)	0-10 %

Printing ink and printing varnish systems, radiation-curing (UV/EB)

	typical [%]				
Leading components	**UV/EB offset**	**UV/EB flexo**	**UV/EB varnishes**	**UV/EB pad/ screen printing**	**UV/EB inkjet**
Functional, reactive acrylate polymers and oligomers, partly with functional amine groups	30-60	20-50	20-40	20-40	0-30
Functional, reactive acrylates, low molecular weight, partly with functional amine groups	30-60	40-70	50-80	50-80	40-80
Photoinitiators, reactive; (not in EB colours)	5-10 (EB: 0)	5-10 (EB: 0)	5-10 (EB: 0)	5-10 (EB: 0)	5-10 (EB: 0)
Other ingredients [waxes, additives (e.g. organic and inorganic gelling agents, dispersing agents, matting agents)]	0-10	0-10	0-15	0-15	0-15

Printing ink and printing varnish systems, solvent-based

	typical [%]			
Leading components	**Gravure/flexographic printing, NC-based**	**Gravure/flexographic printing, PVB-based**	**Gravure printing, PVC-based**	**2-component systems**
Nitrocellulose	10-30			
Polyurethane resins	0-20		0-20	
Polyvinyl butyral		10-30		
Polyethyleneimine		0-5		
PVC copolymer resins			10-30	
Polyester resins			0-20	
Nitrocellulose and/or PVC/acrylic copolymers				10-30
Polyether and/or polyester resins containing hydroxyl groups				5-20
Hardener: trimeric TDI prepolymer				+ 20-25 (to be added separately)
Solvent	50-80 Ethanol, ethyl acetate and/or glycol ether	50-80 Ethanol, n-propanol	50-80 Ethyl acetate and/or 2-butanone	50-80 Ethyl acetate

Other ingredients (optional) [Adhesion promoters, lubricants, monomeric plasticisers (citrates, adipates, sebacates)]	5-15			
Other ingredients (waxes)			0-5	0-5

Printing ink and printing varnish systems, <u>solvent-based</u> (cont.)

	typical [%]		
Leading components	**Pad/screen printing**	**Inkjet colour systems**	**Liquid toners**
PVC copolymer resins, polyester resins, polyurethane resins, acrylate polymers	10-40	5-20	
Polymer resins (e.g. polyethylene)			10-30
Solvents: esters, alcohols, ketones, hydrocarbons	50-80		
Solvents: esters, alcohols, ketones		60-90	
Carrier liquid (hydrocarbons)			50-90
Other ingredients (e.g. waxes, additives)	0-5	0-10	1-20

Printing ink and printing varnish systems, <u>water-based</u>

	typical [%]			
Leading components	**Gravure/flexo printing**	**Pad/screen printing**	**Inkjet colour systems**	**Overprint varnishes Offset**
Styrene/acrylate copolymer and/or pure acrylate emulsions and/or resin solutions	20-50 (solids)		0,5-30 (solids)	20-50 (solids)
Polyurethane resins, acrylate polymers		20-50		
Ammonia, organic amines	0-5	0-5	0-5	0-5
water	50-80	50-80	50-80	50-80
Co-solvents (e.g. glycerine, glycols, glycol ethers, pyrrolidone)			0-25	
Other ingredients (waxes, wetting agents, defoamers, preservatives; optional: film-forming agents, pigment dispersants, matting agents)	0-10	0-10	0-10	0-10