Rely on us.℠

Printing Inks for Food Packaging Materials

Trustworthy

FlintGroup

Contents

FlintGroup
Orange
Juice
100% ORGANIC PRODUCE
FlintGroup
Raspberry
Yogurt
FlintGroup
Aqua
Still Spring Water
infused with lime
500ml
FlintGroup
Water
Still mineral water
1.5 Litre
Rely on us.
FlintGroup
Beef & Veg
Dog Food
100% COMPLETE AND BALANCED

Introduction

As of January 1st, 2023, the global population has surpassed 8 billion people, with an estimated 2 billion individuals facing challenges in obtaining sufficient food, and over 800 million suffering from acute hunger[1]. However, approximately one-third of the world's food production goes to waste[2].

Food packaging materials play a vital role in addressing this concern and safeguarding the optimal condition of food, helping to significantly reduce the risk of food waste.

In the safety-centric food and drink industry, there are potential concerns regarding the transfer of substances from packaging to food. Ink formulations, for example, are created using chemicals that are not intended for human consumption, which may lead to health issues for consumers.

Flint Group is a dedicated supplier of printing inks for the food packaging and label industry, with extensive experience in creating Food Contact Material (FCM) inks. This guide serves as an overview of the macro issues related to food packaging design and regulations.

It provides definitions, highlights the most relevant legislation, and provides checklists and recommendations that help promote best practice in the choice of inks destined for food packaging.

For further details or to find out more about how Flint Group can support in all areas of FCM, contact our team today.

[1] https://www.dw.com/de/gr%C3%B6%C3%9Fte-nahrungsmittelkrise-seit-dem-zweiten-welt-krieg/a-64476944
[2] https://www.fao.org/news/story/en/item/196402/icode/


FlintGroup
Aqua
Still Spring Water
infused with lime
500ml ℮
Rely on us
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Beef & Veg
Dog Food
100% COMPLETE AND BALANCED
Rely on
FlintGroup
Milkshake
Strawberry
Flavour
400ml ℮
PER SERVING
Calories 56 kcal
Fat 1.8g 3%
Salt 0.2g 3%
Sugar 16g 18%
of your guideline daily amount
Rely on u
tGroup
FlintGroup
Mustard
Classic yellow
ORGANIC
Iced
Green

1. Legislation

European Legislation on Food Packaging Materials

The main principles of food contact material legislation are described in the European Parliament framework "Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food", repealing Directives 80/590/EEC and 89/109/EEC[3].

Article 3 requires that 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."

In Annex I of the framework regulation, 17 different groups of materials and articles are listed for which specific measures may be adopted to further define requirements. Such specific measures for example can include lists of substances which may be authorised to make these materials and articles. Printing inks are one of the listed groups of materials, but so far there is no specific measure in the EU for printing inks to be used on Food Contact Materials (FCM).

The most comprehensive regulation for a material group , according to Annex 1 exists for Plastic materials and Articles intended to come in contact with Food[4]. This Plastic Regulation includes a list of monomers and additives that are authorised to be used in plastic materials and articles for food packaging under Annex I, is also called the 'Union list'. This substance list is updated in regular amendments and updates.

Although printing inks are not directly covered by the Plastic Regulation, printed plastic materials fall under the regulation. Some substances which may be used in plastic food contact materials, such as polymer production aids, colourants and solvents, may not be included in the Union List.

Furthermore, in printing inks which are applied on the non-food contact side of plastic multilayer materials, substances may be used which are not listed in the Union List. This is provided they are not classified as 'mutagenic', 'carcinogenic' or 'toxic to reproduction' in accordance with the criteria set out in sections 3.5, 3.6. and 3.7 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and the Council[5].

Substances that are used to produce printed food contact materials and not yet officially evaluated need to be assessed in accordance with internationally recognised scientific principles on risk assessment in order to demonstrate compliance with Art 3 of the Framework Regulation.

The EU Commission is working on a complete revision of the Framework Regulation.

However, based on latest information, this revision will not be completed before 2025 at the earliest.

[3] https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=celex:32004R1935
[4] https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=celex%3A32011R0010
[5] https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX%3A32008R1272

National legislation on Printing Inks for Food Contact Materials in European countries

a. Switzerland SR 817.021.23

In 2008, Switzerland adopted a national legislation on "printing inks to be used on food contact materials" as part of the General Consumer Goods Ordinance, usually called Swiss ink Ordinance or SiO. The ordinance has been amended several times since 2008, but the principles remain the same.

The SiO only covers printing inks to be applied on the non-food contact side of food packaging. According to the Swiss legislation, only substances listed in the ordinance Annexes are allowed to be used in inks. The substances are divided into two groups; A list substances and B list substances.

A list substances have been officially evaluated by the Swiss authorities and a Specific Migration Limit (SML) has been defined.

B list substances are known to be potentially present but have not been officially evaluated yet. B list substances may be used in printing inks, but they are not allowed to migrate into food.

As an analytical limit to demonstrate non-migration, 0.010 mg/kg food is accepted (10 ppb).

Swiss authorities announced 2022 to work on a complete revision of the Swiss Consumer Goods Ordinance, including the ink ordinance.

b. German Ink Ordinance

At the end of 2021, Germany adopted the German Ink Ordinance, or GiO, as part of the German Food and Feed Consumer Good Ordinance[6].

Currently there is a transition period until January 1st 2026, before the requirements of the GiO must be fulfilled. Until then, the general requirements from the EU Framework Regulations are applicable in Germany.

[5] https://eur-lex.europa.eu/legal-content/DE/ALL/?uri=CELEX-%3A32008R1272
[6] https://www.gesetze-im-internet.de/bedggstv/BJNR008660992.html

2. Migration

The transfer of substances from packaging materials into food or drink

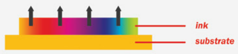
The term "migration" is typically used to describe the mechanism of substances being unintentionally transferred from a packaging material into a foodstuff.

There are several mechanisms that describe how this substance transfer can occur.

What is Migration?

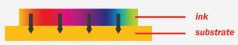
1 ***Direct Migration***

Direct migration from the printed surface to the food where the food is in direct contact.



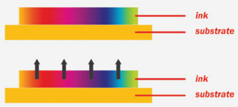
2 ***Penetration Migration***

Penetration through the substrate to the reverse side of the print



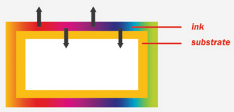
3 ***Set-off Migration***

Set-off from the print to the reverse side while being stored in a pile (invisible set-off)



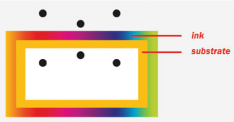
4 ***Vapour phase Migration***

Volatilisation of compounds during cooking



5 ***Condensation Extraction***

Condensation of critical components when cooking/sterilisation



Direct Migration:

Substance migration from the packaging to food, where the food is in direct contact with printed surface

Penetration Migration:

This is the typical migration process if an ink is applied on the non-food contact side of a plastic packaging material. The process of penetration migration is well understood and can also be simulated through migration modelling.

The main factors are the type of substrate (for example, paper, polyolefin or PET film), molecular weight and chemical nature (i.e. hydrophilic or hydrophobic) of the migrating substance, the type of food or food simulant, time and temperature.

Set-off Migration:

In a printed reel or stack of printed material, the printed side will inevitably have contact with the unprinted back side of the substrate. Some substances from the print may be transferred to the backside, even if there is no penetration migration.

The process may even occur over several production steps (for example, printing and lamination) and a substance may unintentionally end on the food contact side creating a risk of direct migration. This process needs to be carefully controlled.

The container illustrated below demonstrates the areas of opportunity for set-off:

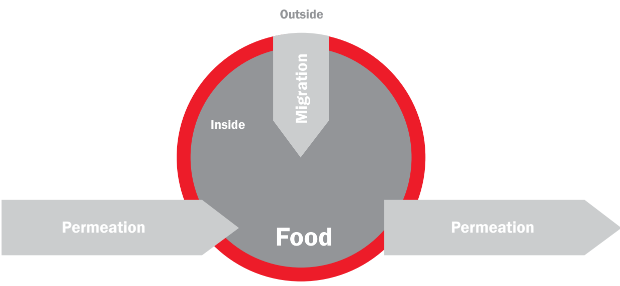
Aluminium Lid
Full barrier properties but potential set-off to the reverse side, especially when printed reel to reel or stacked and stored.

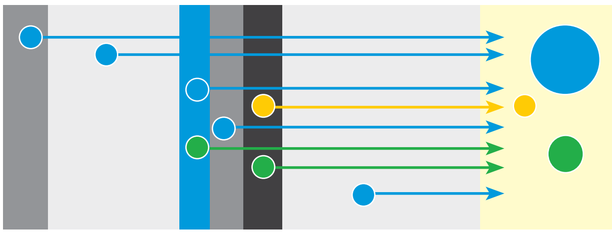
Container
Independent of barrier properties risk of potential set-off to the reverse side when stacked and thus bringing the printed outer surface in contact with the unprinted inner side of the container before filling.

Vapour phase migration:

Especially in cases of dry food, the food is usually not in direct contact with the packaging material. Volatile substances may be transferred via the gas phase from the packaging material into the food.

Vapour gas migration is also a typical effect in the case of fibre-based substrates (paper and board). The migration in such materials is a combination of vapour phase migration, adsorption, and desorption processes, and may be also migrated via capillaries. At present, the migration in fibre-based materials cannot reliably be simulated.





Substance migration from various layers of a food packaging material

Condensation/Extraction:

This is a specific case if a packaged food is specially treated (sterilised or cooked in bag). Water vapour and/or fat can cause a specific extraction of ingredients in the packaging material and needs to be considered for each specific application.

It is important to understand that a substance may be present in a single layer of the packaging material, or in various layers

In order to be able to estimate how much of a substance may migrate into the food, we must understand this substance in each layer of the packaging material.

Evaluation of Migration

As a first indication, a worst-case-calculation (WCC) can be done.

In a WCC, it is assumed that the total amount of a substance which is present in the packaging material is transferred into the food. In many cases the WCC already demonstrates that the maximum concentration of a substance is not exceeding any limit.

However, a WCC tends to vastly overestimate real migration. If the WCC shows that the concentration of a substance in the food exceeds a limit, then a migration simulation may be used. These models use substance-specific data and give a more realistic picture of the potential migration. However, migration simulation programmes still overestimate real migration.

If simulation calculations are not sufficient to demonstrate that the substance is not migrating over a safe limit, then migration tests need to be carried out. Typically, the migration is tested with food simulants, but migration testing with real food is an option. If food simulants are used, it is much easier to analyse the amount of a migrating substance. The Annex in the Plastic Regulation contains details about the test conditions (time, temperature) and the suitable food simulant depending on the food type.

Migration limits

Overall Migration Limit (OML) or Global Migration Limit (GML):

The Overall Global Migration Limit, or Global Migration Limit, describes the maximum amount of all substances which may migrate from packaging material into the food.

The OML/GML is not substance-specific and is limited to 60 mg/kg food. In the reference image above, this means all substances in the blue, green and yellow bubbles would need to be summarised.

Specific Migration Limit (SML):

The Specific Migration Limit is based on toxicological evaluations for an individual substance. The value of SML is based on the Tolerable Daily Input, TDI. It describes the maximum amount of a substance within a food that is considered not harmful to consumer health.

In Europe, the assumption is to calculate the SML based on the EU-Cube model: A person of 60 kg body weight eats 1 kg food each day during their lifetime, which is packed in 600 cm^2 of packaging material.

The general assumptions of the SML model may not always be correct for certain consumer groups (such as infants or toddlers) or foods (such as lightweight food, for example chips/crisps or tea), and therefore it can require some corrections.

In order to demonstrate compliance with Article 3 of the Framework Regulation, it is required to demonstrate that the total amount of substances transferred from the packaging material into the food does not exceed the OML of 60 mg/kg **and** that the specific migration limit (SML) for each individual substance is also not exceeded.

3. Risk Assessment

How does a business demonstrate that contamination of the food with a certain substance, which has been migrating from the packaging material, does not endanger human health?

In order to answer this question, the toxicological profile for a substance must be known. As food is eaten, the use of oral toxicological data is important. Typically, toxicological data about substances after oral consumption are generated by feeding studies on animals.

If a substance is directly used in food, Acceptable Daily Intake (ADI) is used. For substances which are unintentionally contaminating food, Tolerable Daily Intake (TDI) is used.

In feeding studies of animals, the lowest concentration of a substance in the diet is defined as that which does not show any adverse effect on the animal (NOAEL). Based on this NOAEL, the TDI is calculated taking in consideration that the study was done with animals and that there are also differences in the human population.

In case there are official substance lists for various FCM types (plastic, inks), the evaluation of the test results is completed by the EU (EFSA) or national authorities (e.g. FSVO, BfR).

The results of the official substance evaluation are published, such as through EFSA opinions or in the Union List, or the substances lists of the SiO.

The limits given in this official evaluation must be considered and met for the migration of a specific substance from any Food Contact Material into the food.

However, as described in Sections 1 and 2, printing inks used on the non-food contact side of packaging materials substances may also be used, which are not officially evaluated. The compliance to Article 3 of the Framework Regulation, or to national legislation, needs to be demonstrated by internationally recognised scientific methods for risk assessment. The compliance needs to be demonstrated for both intentionally added (used) substances, and for non-intentionally added (impurity) substances.

The concept of intentionally used (IAS) and non intentionally used (NIAS) substances.

Raw materials that are used to make food contact materials (such as inks) must be specifically controlled and must be of good technical quality. Importantly, along with substances that are intended to be present in the food contact materials because of their specific function, each chemical substance or mixture may contain impurities.

Such impurities may originate from previous production steps of the substances, or from side reactions during synthesis.

Usually, such impurities are not intended to be present, but result from unavoidable contamination in the raw materials used. Typical examples are starting substances that are used for pigment production.

Azo-Pigments, for example, are made by the reaction of primary aromatic amines (PAA) with specific coupling substances. In the final pigment residuals of both, the PAA and the coupling components remain.

In the ink, only the pigment is intended to be used, but it comes with unavoidable impurities. The same problem exists for any chemical reaction and the substances made by it.

The European Printing Ink Industry has developed guidance for the Risk Assessment of non-intentionally added (NIAS) and non-listed (NLS) substances in printing inks for food contact materials[7].

Based on this guidance, the risk assessment of non-officially evaluated substances can be completed. The hazard evaluation for such substances is based either on existing toxicological data, on in-silico predictions (QSAR tools) and/or on the Concept Threshold of Toxicological Concern (TTC).

Based on these tools, a so-called self-derived SML can be defined for a specific substance, and compliance with Article 3 of the Framework Regulation can be demonstrated.

4. Communication along the supply chain

The production of food packaging material is a complex process with many moving parts, and various players, such as producers of polymers, films and adhesive materials, and ink makers, may all be involved.

Substances that are present in printing inks may also exist in other parts of the packaging material. This complexity in the packaging supply chain requires transparency in all steps of the supply chain.

Therefore, the compliance of a final packaging material to Article 3 of the Framework Regulation can only be demonstrated at the last step of the supply chain, and with the final material.

In order to enable the producer of this final material to do the required compliance work, they need detailed and comprehensive information about substances that may be present in the various parts of the packaging material, and which may migrate into the food.

The members of the European Printing Ink Association (EuPIA) have agreed to the concept of 'Statement of Composition' as a tool to communicate throughout the supply chain.

In the Statement of Composition, all relevant data about potential migrating, reactive or volatile substances are disclosed. This includes the chemical name, CAS number, FCM reference number, migration limits (Union List, SiO, self-derived), information about dual-use substances, the concentration of the substance in the dry ink film, and, finally, a worst-case calculation model for the migration.

Substances that may not migrate do not need to be disclosed in the Statement of Composition.

For example, this includes polymers, pigment, and fillers.

The amount of solvent in the dry ink film depends on the drying conditions and, therefore needs to be controlled by the printer.

[7] https://www.eupia.org/key-topics/food-contact-materials/risk-assessment/

Looking to learn more about migration and printing inks for food packaging materials?

Contact the Flint Group team today: info@flintgrp.com

References

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[6] GiO

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