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

5th revised version

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0 Foreword

This Guidance document, for EuPIA members to use when creating their GMP policies, has been prepared by the European Printing Ink Association (EuPIA), a sector of the European Council of Paint, Printing Ink and Artists' Colours Industry (CEPE) to assist in controlling food safety hazards in the design and manufacture of inks, varnishes and coatings designed to be printed onto Food Contact Materials (FCM printing inks), and formulated for use on either the non-food contact or the food contact surfaces of food packaging and articles intended to come into contact with food.

Products developed and manufactured in compliance with this GMP are supporting manufacturers of food contact materials in supplying products compliant to the applicable legislation in Europe for materials and articles intended to come into contact with food such as the Framework Regulation (EC) No 1935/2004, and GMP Regulation (EC) No 2023/2006.

This GMP includes requirements on product composition, quality and hygiene management.

This GMP can be used by internal and external parties to assess the EuPIA member company organization's ability to meet customer and regulatory requirements applicable to FCM inks, and the organization's own requirements.

Adoption of this Good Manufacturing Practice (GMP) should be a management responsibility.

EuPIA members are expected to introduce this GMP from 1st January 2026.

Presentational conventions

The auxiliary verb “shall” is used in this document to express requirements.

Commentary, recommendations, explanations and general informative material are presented in *italic* type, using the heading NOTE or EXAMPLE.

1 Scope

For the purposes of this GMP when referring to “inks”, this covers inks, varnishes, coatings, and mixtures of solvents.

This Good Manufacturing Practice is applicable to all organizations, regardless of type or size that develop and/or manufacture inks for any type of food contact applications i.e. transient or long-term contact. This Good Manufacturing Practice is not designed or intended for use in other parts or activities of the food supply chain. In situations where substance migration is not possible, due for example to an absolute barrier present between the food and the print, resulting in no routes for migration then this GMP can be discarded.

This document describes requirements for a Good Manufacturing Practice implementation where an organization needs to demonstrate its ability to consistently provide food contact material inks that meet customer and applicable statutory and regulatory requirements.

Food contact material ink manufacturing organizations are diverse in nature, and not all of the requirements specified in this document may apply to an individual organization.

Where any requirement(s) of this Good Manufacturing Practice cannot be applied, the respective requirements can be excluded. Where exclusions are made, claims of conformity to this Good Manufacturing practice are only acceptable when the organisation does not perform activities affected by the excluded requirements. Any exclusion has to be documented. In addition, exclusions must not affect the organization's ability to provide food contact material inks that meet customer and applicable statutory and regulatory requirements.

This Good Manufacturing Practice is not a management system standard; however, it can be used in conjunction with management system standards such as EN ISO 9001:2015.

2 Normative References

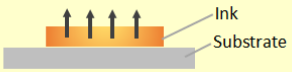
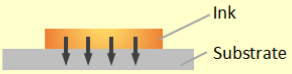
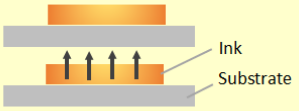
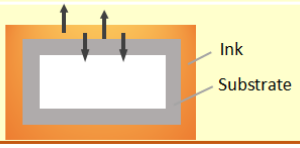
The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- Legislation referenced in the EuPIA Guideline on Printing Inks applied to Food Contact Materials.
- EuPIA Exclusion Policy for Printing Inks and Related Products.
- EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Listed Substances (NLS) in printing inks for food contact materials (short “EuPIA NIAS Guidance”)
- EuPIA Guidance on Migration Test Methods for the evaluation of substances in printing inks and varnishes for food contact materials (short “EuPIA Migration Guidance”)
- EuPIA Suitability List of Photoinitiators and Photosynergists for Food Contact Materials
- Guidance documentation classified as being for EuPIA members internal use only.

3 Terms and Definitions

For compatibility with other standards used in the food packaging supply chain the definitions in this GMP are identical or based on definitions of ISO/TS 22002-4 "Prerequisite programmes on food safety — Part 4: Food packaging manufacturing".

For the purpose of this GMP, migration is the transfer of substances from a FCM Printing Ink into food. The diagram below illustrates the different routes for migration.

What is migration?		
1	**Direct Migration** Direct migration from print to the food, in situations where the food is in direct contact with the print	
2	**Through 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 or reel	
4	**Gas Phase migration** Volatilisation and condensation of components after heating	

Note that in the vast majority of cases the migrating substance is not visible.

Food Contact Material (FCM) Printing Ink in this document means any ink applied to a material that is in contact with food; this includes both Direct Food Contact (DFC) and non-direct food contact inks (non-DFC).

Direct Food Contact (DFC)

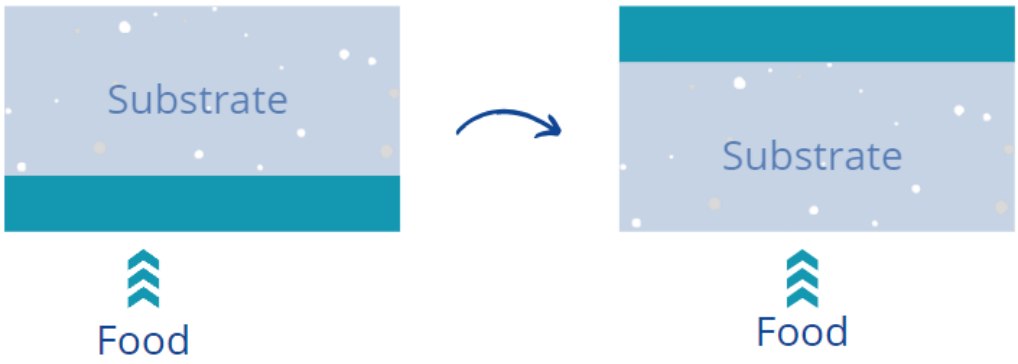
Direct Food Contact inks are a subset of FCM inks. A DFC ink is defined as an ink that is intended to be, or can reasonably foreseeable, to come in direct physical contact with food. For DFC applications the diffusion path between ink/coating and food is short and there is a strongly increased risk of migration into the food due to the missing functional barrier and a possible direct interaction of substances in the food with the ink layer (e.g. fat, acid).

DFC applications can be categorised according to the exposure probability (intentional/foreseeable) and the potential duration of the application (short term/long term) and temperature conditions (high, low and room temperature).

Transient food contact is a specific type of DFC in which inks can reasonably foreseeable be in contact with food for comparatively short periods of time. The diffusion path between ink and food is short, but there is also a very limited time in which migration can occur. In this case the potential for migration exists but is not as high as for long term DFC FCM's. This is reflected in the migration testing conditions.

Non-Direct Food Contact (Non-DFC)

Non-Direct Food Contact inks are a subset of FCM inks where the ink is used on the non-food-contact surfaces of food packaging and articles intended to come into contact with food. There is a potential for migration of components from the ink/coating/varnish.



Examples for typical DFC applications and the classification to the corresponding contact scenarios are listed in Annex D of the “EuPIA Guidance on Migration Test Methods”.

Establishment
Any building or area in which raw materials, intermediate products and chemicals for FCM Printing Inks are handled, and the surroundings which are under the control of the same management system.

See the glossary in Appendix A for additional terms and definitions.

4 Context of the organization

Manufacturers of FCM Printing Inks produce a wide variety of inks for use in many diverse food industries/applications. Customers expect that all FCM printing inks they purchase are safe for their intended use and produced to the quality agreed in the specification. However, it is recognised that production of FCM printing inks for some particular uses e.g. direct food contact places more stringent and demanding hygiene requirements on the manufacturer.

This GMP directs companies to determine the level of hygiene required for production FCM printing inks as well companies’ policy, procedures and processes through risk assessment (FMEA) in order to meet those requirements.

4.1 Quality Management system and its processes

Any organisation which designs or manufactures FCM printing inks shall have a documented Quality Management System in place.

It is not a requirement that the quality management system is certified in accordance with EN ISO 9001:2015. Nevertheless, this GMP uses EN ISO 9001:2015 as a reference.

5 Leadership

5.1 Leadership and Commitment

5.1.1 General

Top Management demonstrate leadership and commitment to GMP by:

(a) establishing and communicating a GMP policy appropriate to the size of the company and application,
(b) Identifying an overall process owner within organization for GMP implementation and maintenance
(c) conducting annual management reviews to ensure the suitability, adequacy, and effectiveness of the implemented GMP
(d) setting measurable objectives to maintain and continuously improve relevant GMP processes and product quality

5.2 Policy

5.2.1 Establishing the GMP policy

A documented GMP policy and objectives shall be established, implemented, and maintained.

5.2.2 Communicating the GMP policy

A documented GMP policy and its objectives shall be available, communicated to relevant interested parties, and understood.

5.3 Organizational roles, responsibilities, and authorities

Responsibilities and authorities shall be clearly defined and communicated within the organization to effectively establish, implement and maintain GMP.

6 Planning

6.1 Actions to address risks and opportunities.

6.1.1 Risk assessment.

Risk assessment is used to prevent failures by anticipating where they are likely to occur and evaluating their effects.

Usually, it is employed at the design stage of a new product or process with the aim of “designing out” failure by identifying potential causes and defining corrective actions. It can also be applied to existing processes, e.g. the manufacturing process.

For unintended or accidental contamination, the risk assessment shall be used to prevent failures that are reasonably likely to occur (e.g., equipment oil leaking contaminating your

product) while for intentional contamination, it shall be used to prevent failures that are not reasonably likely to occur.

Risk assessment for FCM Printing Inks shall be carried out to provide evidence that any contamination risk is under control. 'Under control' means, that a potential contamination arising from whatever origin of a FCM Printing Inks does not cause any contamination of food stuff above legal or acceptable limits. Contamination risks can be assessed and quantified by using an FMEA risk assessment.

There are three types of contamination:

- Chemical contamination: The primary issue is unintended substances in the FCM Printing ink, but higher levels of intended substances should also be considered.
- Microbiological contamination: For example, yeasts, moulds, bacteria, spores
- Physical contamination: Typically caused by foreign bodies, e.g. glass, wood, metal pieces etc.

The risk assessment shall be documented and signed off by the persons who carried out the risk analysis, along with the process owner(s) for the areas being risk assessed.

6.1.1.1 Chemical contamination

Chemical contamination can occur from raw material impurities by cross-contamination from the manufacturing / handling process or cleaning agents. Risk analysis shall assume worst case scenarios unless there is measured / modelled data.

Assessing chemical contamination should include:

- Contamination with chemicals from previous batches
- Known impurities that may arise from raw material manufacturing process (residual reactants) as well as raw material synthesis by-products, both communicated by manufacturers or arising from chemical knowledge.
- It is recommended to support chemical contamination assumptions with analytical data as long as an FMEA highlights an expected risk.

Risk analysis shall assume worst case scenarios, unless there is measured / modelled data. Worst case scenario for chemical contamination means, that any substance in a FCM Printing Ink, migrates 100% into the food. See Appendix D. The result of the risk assessment will determine whether any contaminating substance could be present at unacceptable levels.

EXAMPLE: see worst-case calculation for a cleaning agent in Appendix C.

6.1.1.2 Microbiological contamination

For water-borne inks, controlled additions of in-can, wet-state microbiological preservatives are used as an intentional part of the formulation to maintain the shelf-life of unopened containers.

For solvent-borne inks microbiological contamination is not possible due to the high organic solvent content which prevents microbial growth.

The UV-curable materials used in UV inks and varnishes are not a suitable media for the

growth of micro-organisms. Furthermore, the curing process involves exposure to UV light, itself used in other applications to destroy microbes.

The materials used in offset printing inks and associated varnishes do not provide a suitable medium for the growth of micro-organisms. The residual water content of such products is not significant.

6.1.1.3 Physical contamination

Generally physical particles inadvertently present in an ink or varnish container will not go onto the substrate through the printing unit but would typically lead to damage of the printing equipment.

Physical contamination for example by metal wood or glass fragments, is very unlikely, as the products are typically manufactured within closed systems or are filtered as the last step immediately prior to being transferred into the supply container.

6.1.2 Risk assessment method.

The EuPIA GMP uses the Failure Modes and Effects Analysis (pFMEA) method. The rationale for the use of the FMEA model is given in Appendix B.

FMEA is an analytical technique that may be applied at any stage of the manufacturing and supply chain process. It is a useful tool to ensure and document that potential problems have been considered and addressed.

In a FMEA failures are prioritized according to how serious their consequences are (severity), how frequently they occur (probability) and how easily they can be detected (detectability).

The aim of an FMEA is to come to an objective assessment of a potential failure by a risk priority number (RPN). The RPN is the result of the multiplication of the factors severity, probability of occurrence and the detectability of a failure. For details see Appendix B .

NOTE: It is recommended to determine the severity of the potential effect of a failure on the packed food and not on the ink. This gives maximum support to the manufacturer of a food packaging.

6.2 Objectives and planning to achieve them

6.2.1 Regular review of the risk assessment

The review of the risk assessment or FMEA should take place at periodic intervals of max. 3 years. Individual internal regulations with shorter intervals are possible specific to the company and application.

If changes occur (i.e. new product introduction) that activate the change management, an immediate review and, if necessary, revision is indicated. In this case, the 3-year period starts again.

For DFC materials, an annual review and confirmation of changes must take place as part of the management review.

6.3 Planning of changes

All changes with the potential to affect the suitability for use of an ink in its final application or the content of the information provided to the customer must be the subject of a controlled change control process. This includes both compositional and manufacturing process changes.

When a change affects the initial risk assessment then as part of the change management process this risk assessment needs to be re-evaluated.

See Appendix E for initiators of change, and triggers for change.

7 Support

7.1 Resources

7.1.1 People

The company's senior management shall provide the human resources required for the production of safe FCM Printing Inks to the required quality and in compliance with the requirements of this GMP.

7.1.2 Infrastructure

7.1.2.1 Establishment

Organisations which produce on the same premises FCM Printing Inks and other products shall document to which establishments this GMP applies. Based on the requirements of this GMP FCM Printing Inks and other products may be produced in the same establishments.

Establishments shall be designed, constructed, and maintained in a manner, that the food safety hazards associated with operations in the establishments are under control.

Adequate facilities for changing clothes, washing, toilets, rest rooms and refreshment rooms separate from the production areas should be provided.

EXAMPLES:

- *Segregated production areas separated by walls, doors or screens to prevent mix-ups or contamination.*
- *Designated and covered storage areas for raw materials and finished products.*
- *Dedicated areas for weighing and handling of raw material.*
- *Separate storage and handling of raw materials used for both FCM and non-FCM inks.*
- *Identification of potential contamination sources via risk analysis and implementation of risk mitigation measures.*
- *Monitoring of potential contaminants in quality control.*

NOTE 1:
In case DFC inks are not handled in segregated production and storage areas the implementation and documentation of risk mitigation measures and controls is particularly significant for food contact material safety.

7.1.2.2 Establishment security and processes included to control malicious contamination / sabotage of products

Access is restricted for non-authorized and non-accompanied personnel such that they are not permitted to enter the production and warehouse areas of the site.

Where agreed with customers, tamper evident closures are used.

7.1.2.3 Equipment

The equipment used is suitable to manufacture FCM Printing Inks and is maintained in good repair. It is clean and – where appropriate – calibrated.

Equipment should be designed in such a way that it is easy to clean to ensure cross-contamination is strictly minimised.

In the case of DFC Ink production then either dedicated manufacturing equipment is used, or there are effective validated cleaning processes in place. Validation typically requires recorded analytical controls to prove effectiveness. See Cleanliness and Orderliness Section 7.1.3.2.

Maintenance records shall be maintained.

EXAMPLES:

- *The use of dedicated equipment such as vessels, mixers, filling machinery, pipelines and filtering equipment is a measure to minimise the risk of cross contamination.*
- *The validated cleaning of non-dedicated equipment is a measure to control the levels of contamination.*

7.1.2.4 Maintenance and repair

Regular preventive maintenance ensures that the equipment is fit for purpose. Maintenance is a measure to reduce the risk of product contamination, e.g. chemical contamination through unnoticed leakage. However, any maintenance and repair activity itself is a contamination risk. Therefore, rules for maintenance and repair activities shall be implemented in the organisation. Any maintenance or repair activity by an external company shall be supervised.

NOTE: *Rules may include:*

- *instructions for internal and external maintenance personnel,*
- *requirements on instruction and Standard Operating Procedures (SOP)*
- *requirements on risk assessments for maintenance and repair activities.*
- *requirements of records' keeping of all activities*

7.1.3 Environment for the operation of processes - Hygiene Management

Hygiene management systems implement measures to prevent, detect and control chemical, physical and microbiological contamination of food and materials intended to come in contact with food stuff.

7.1.3.1 Employees and visitors / maintenance personnel

- The organisation shall establish, implement and maintain personal hygiene rules for employees, visitors and maintenance personnel.
- Smoking, eating and drinking shall not be allowed where materials used for the manufacturing of FCM Printing Inks are handled.
- Working clothes shall be changed regularly.
- Separate washing facilities and changing rooms shall be available.

Depending on the product type and based on the risk assessment hygiene rules may differ between production areas and type of zoning area.

NOTE: *Protective clothing, hand sanitary facilities may be required depending on the risk assessment.*

EXAMPLE: *Visitors must use shoes covers and coats in certain production areas.*

7.1.3.2 Cleanliness and orderliness

For both DFC and non-DFC inks, detailed cleaning requirements shall be specified based on the risk assessment. Cleaning requirements include which item shall be cleaned how, when and how often. A validated cleaning process shall be put in place and signed off cleaning records shall be maintained.

In the case of DFC inks validation typically requires recorded analytical controls to prove effectiveness.

Analytical testing should focus on the substances present in inks previously produced on the shared equipment.

NOTE 1: *This should prioritise substances which if they were to contaminate the DFC product, would result in migration above accepted limits.*

NOTE 2: *Cleaning schedules may exist for buildings, storage areas, production equipment, machinery, production tools. This will be driven by the risk assessment and zoning.*

7.1.3.3 Waste handling

Systems shall be in place to identify, collect, remove and dispose of waste in a manner that prevents contamination.

Containers for waste shall be clearly identified and removed on a regular basis from production areas.

7.1.3.4 Pest control

Establishments shall be in a condition which prevents an environment attractive to pest activity.

Pest monitoring programmes shall be implemented in storage and production areas. Pest monitoring and eradication measures shall be recorded. The records shall contain detailed information such as:

- map of detectors,
- type, quantity of detectors, pesticides,
- inspection frequency and results,
- conclusions, e.g. changed frequency of inspection.

Pest monitoring and eradication measures shall be carried out by trained personnel only, and preferably by appointed expert contractors.

7.1.4 Monitoring and measuring resources.

Where necessary, monitoring and measurement equipment shall be calibrated or verified at specified intervals. Test methods shall be developed to ensure repeatability and reproducibility of the results. Calibration or verifying records shall be maintained and the equipment shall have identification in order that the operator can determine its calibration status.

7.2 Competence

All personnel shall be aware of the principles of this GMP and how it affects them.
Training programmes and facilities are established to ensure that all personnel are fully aware of their functions and responsibilities and are competent to carry them out. Personnel include contractors. Records of training are signed by the employees. The minimum training extent can be tailored according to function and responsibilities of the personnel.

Definition for a competent person

Is a person who has acquired through training, qualification or experience the knowledge and skills to carry out and implement work specific to the GMP Guidelines required at his workplace.

Training requirements (covers Technical, Production and Sales)

- Regulatory awareness: regulation (EC) 1935/2004, regulation (EU) 10/2011, Swiss Ordinance on Materials and Articles (SR 817.023.21), Consumer Goods Ordinance (“German Ink Ordinance”, GIO) and others
- EuPIA Documentation as NIAS, GMP, Suitability list, Exclusion policy, EuPIA guidelines on FCM materials etc
- Raw materials selection process, including compositional data.
- Migration testing and interpretation.

- Regulatory communication such as Statements of Composition (etc)
- HACCP or equivalent
- Standard Operating procedures (SOP)
- Preparing, storing, updating, and implementing (training).
- Hygiene
- Maintenance programmes
- QA/QC programmes
- Awareness of DFC and Non-DFC substances – 3 main areas
    - Characterised raw materials
    - Formulated to compliance both chemically and physically.
    - Environmental - minimise contamination risk.
- Auditing.
- Change control process.
- Documentation to support available (SoC) or equivalent regulatory statement or declarations

7.3 Awareness

The entire workforce, involving all levels of management including top management shall be committed to the objectives of this GMP. The proof of awareness trainings needs to be retained according to companies' retention policy.

7.4 Documented information

7.4.1 General

Documents required by this GMP shall be controlled in accordance with the requirements defined in EN ISO 9001:2015. A documented standard operating procedure exists, which describes the controls needed.

The quality management documentation shall consist at a minimum of:

a) Documented GMP policy and related objectives
b) Documented standard operating procedures as required by this GMP,
c) Records to provide evidence of conformity to the requirements and of the effective operation of this GMP.

The documentation shall be a suitable reference for audits.
Documented procedures and instructions shall be archived for a period of at least 5 years or according to retention companies' policy.

Records shall be maintained for a period of at least 3 years or according to retention companies' policy. In some cases, the minimum archive period will be determined by National Regulations.

Documentation can be in any form or type of support.

NOTE 1: Where the term "documented procedure" appears within this document, this means that the procedure is established, documented, implemented and maintained.

7.4.2 Control of documented information

Document Control includes at least versioning, approval process, publishing and retention.

8 Operation

8.1 Operational planning and control

The organization shall plan and develop the processes needed for the production of FCM Printing Inks. The assessment of the suitability of the processes for the production of FCM Printing Inks shall be part of the risk assessment.

8.2 Requirements for products and services

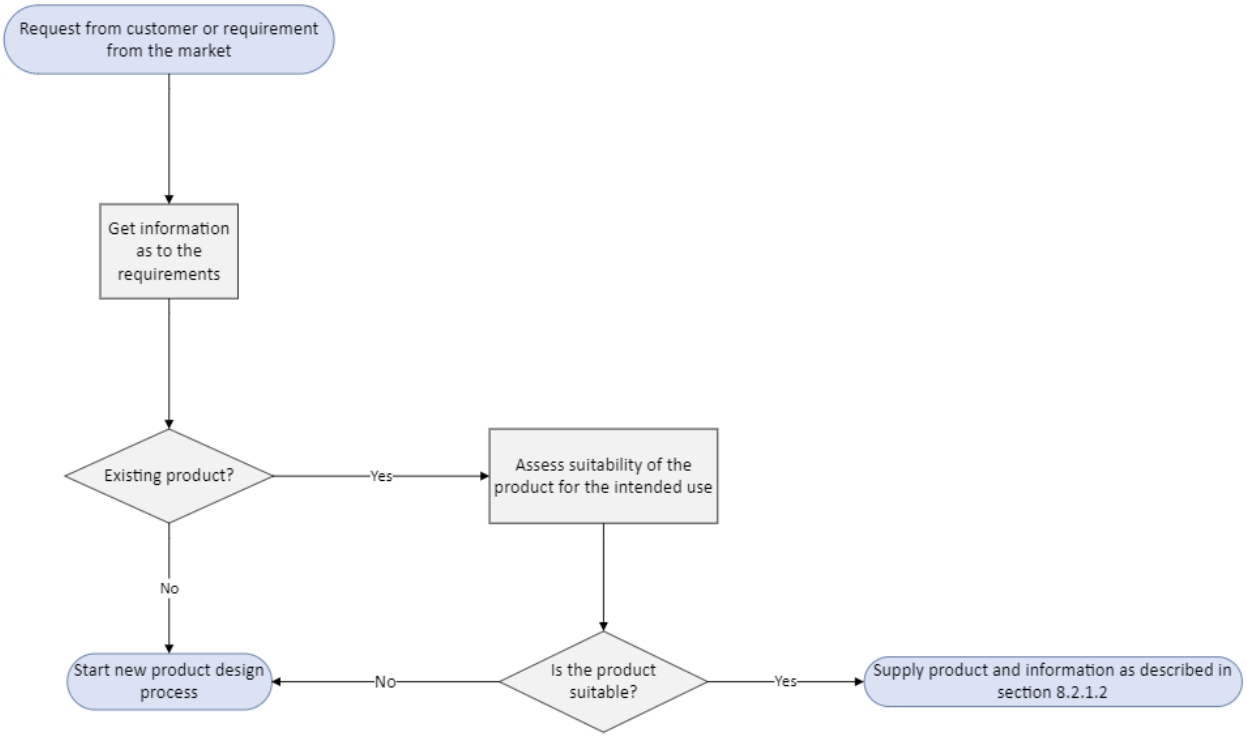
8.2.1 Customer communication

8.2.1.1 Customer requirements

In order to produce a food contact material compliant with regulations a close cooperation between the FCM Printing Inks manufacturer and the food contact material manufacturer is required. Therefore, it is a key factor that the application is known before making a recommendation for a specific FCM Printing Ink.

Only competent personnel shall make a recommendation for FCM Printing Inks (see Section 7.2)

Customer enquiry



1) For customer enquiries, the receipt of clear requirements is crucial, including an understanding of the food contact material structure and its intended end use, the foodstuff and any intended or foreseeable conditions of storage and use. This information shall be provided by the commissioning customer and for DFC ink be recorded.
2) This information will be submitted to the technical team for review and to ensure sufficient information has been provided. Experienced technical personnel will frequently be able to identify products from the existing portfolio matching these requirements.

When a customer orders different colour shades within a commonly supplied ink product series then this process is not required.

8.2.1.2 Customer communication package

Customer communication typically includes:

- Technical datasheet
  Including intended use and information for areas where the ink is not suitable.

- Regulatory information package
  - Safety Data Sheet (SDS)
  - Statement of Composition (SoC) (if applicable: regulatory relevant information on known NIAS and NLS in the printing inks should be included into the same

document)
    - Regulatory Statement (optional)

- Quality
    - Specification as agreed with customers.
    - Certificate of Analysis (CoA) (optional)

Internal EuPIA guidance documents exist to assist members with creating the above documents.

8.2.1.3 Product recommendation

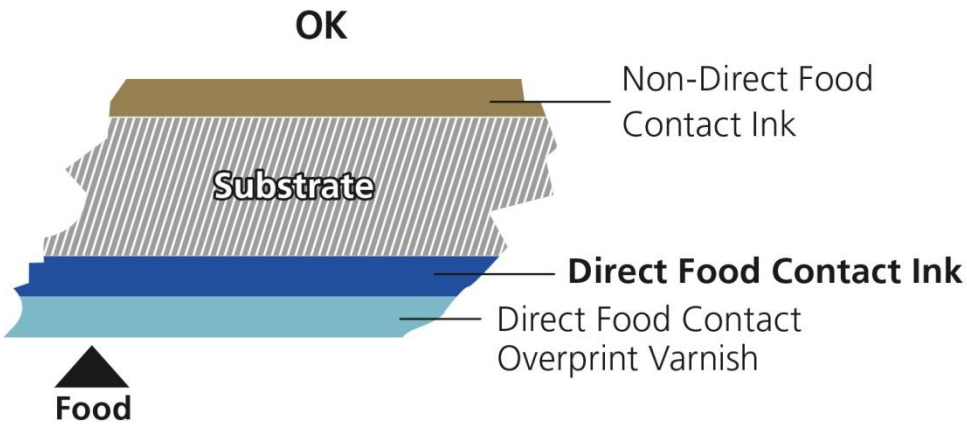
It is up to each EuPIA member company to implement and maintain a process to clearly communicate which of their products are suitable for which applications. This communication could be done in the form of Product Selectors. A generic example of a Product Selector is included for reference in Appendix F along with references to alternative options.

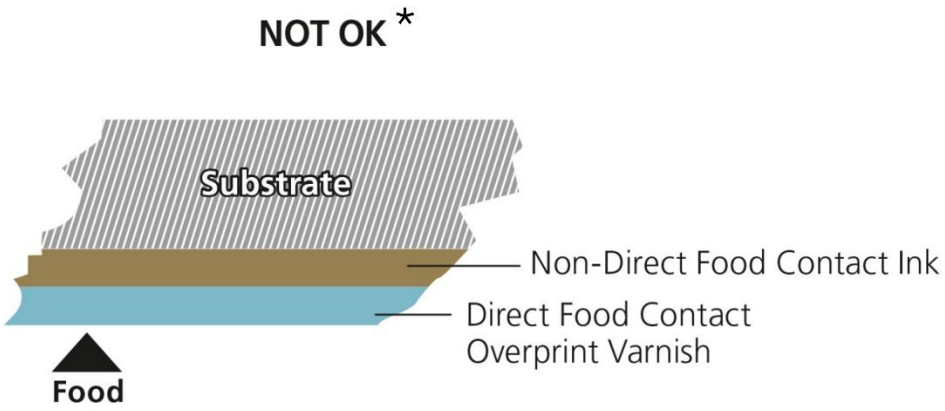
Product recommendation should also include references to suitable additives and press auxiliaries that are required in order to use the FCM Ink. In the case of a water-based ink this may include a press-side antifoam, in the case of an offset ink this may include a fountain solution. Similar conditions apply to these additives and press auxiliaries as apply to the FCM with which they are used.

For Direct Food Contact applications, a suitable ink is required. A **qualified** DFC overprint varnish can be regarded as a functional barrier, nevertheless, evidence has to be provided by a migration test described in the "EuPIA Guidance on Migration Test Methods Annex E". Therefore, the printing ink manufacturer should make a recommendation to the converter so that the compliance of the finished FCM can be proven via an experimental migration test, taking into account normal and foreseeable conditions of use of the final product. Characterization of regulatory relevant substances in raw materials is needed.

In addition, the manufacturing process needs to be suitable so that additional contamination can be minimized and substance migration can be properly tested.

Specific printing technologies using reactive components (e.g. UV-, UV LED, or 2K-systems) are generally not recommended for the use in DFC applications, not even if they are covered with an OPV which is based on non-reactive components.





*Deviation is possible, if raw material is characterized and respective migration tests are performed as described above.

8.2.2 Determining the requirements for products and services

8.2.2.1 Delivery, incoming goods

Incoming goods inspection instructions shall contain provisions with respect to cleanliness and package integrity of delivered products.
EXAMPLE: *Cleanliness of trucks, packaging, palettes, tanks, filling hoses*.

8.2.2.2 Packaging Specification

Packaging is selected to protect the FCM Printing Inks during shipment and storage and complies with legal requirements for the nature of the product packed and the means of transport.

An approval process for FCM printing inks, primary packaging shall be established and maintained.

Primary packaging for DFC inks shall be virgin, or alternatively dedicated reusable stainless-steel containers of a suitable quality. Reusable stainless-steel containers must be supported by a written and auditable procedure.

NOTE: *Virgin containers are new containers that have not previously been used. Virgin containers include re-bottled IBC's (new insert in an existing cage).*

8.2.2.2.1 Cleanliness

New primary packaging shall be inspected for cleanliness and intactness. Returned primary packaging is inspected and cleaned, if necessary, to avoid any contamination with other products or foreign materials.

Work instructions shall describe the necessary inspection of primary packaging after cleaning and before using. Cleaning procedures for returned primary packaging shall be assessed in the risk assessment.

Re-used primary packaging for non-FCM inks shall be dedicated or be used only for a defined product range or a product range of a similar composition, or if it is being used for a new

product range, it should be cleaned, with a validated cleaning process.

8.2.2.2.2 Storage

Primary packaging shall be stored in a dry covered area. Primary packaging and lids shall also be positioned so as to avoid the entry of air borne contamination (example: open buckets stored upside down, or with the lids closed etc).

8.2.2.2.3 Labelling of shipped containers.

Each primary packaging must be clearly marked with label. The label shall have as a minimum the following information:

- Identification of the producer
- Reference number and description of product
- Batch number.
- Net weight
- Health, safety and transport information as required.
- DFC inks shall be clearly marked as such.

Information about a product's shelf life shall be provided, e.g. on the label or in the technical data sheet.

8.2.2.3 Handling and approval of cleaning agents for production equipment and the facility

Cleaning agents may pose a chemical contamination risk for FCM Printing Inks.

EXAMPLE: *Carry over from equipment in direct contact with FCM Printing Inks, residues in production equipment and/or containers.*

- Cleaning agents shall be controlled and segregated.
- An approval process shall be established, implemented and maintained for the selection and use of cleaning agents.
- Approval records shall be maintained.
- A list of approved cleaning agents shall be maintained and be available to employees.

NOTE 1: *The approval of a cleaning agent may be restricted for a particular cleaning process.*

NOTE 2: *The agents that are used to clean manufacturing equipment are likely to contain substances that are not contained in the products that EuPIA members supply to their customers. In order to prevent the cleaning agent substances contaminating ink manufacturers' products at levels that would cause concern, it is necessary to do a risk assessment. This risk assessment requires that the typical amount of cleaning agent remaining in the equipment after cleaning is known, how much ink / coating that this cleaning agent will be mixed with, and which potentially migrating substances are in the cleaning agent. This allows a worst-case calculation for migration into food to be done. If the worst-case calculation exceeded the SML of the cleaning agent substances then it may be necessary to do analytical migration testing to understand how much substance actually migrates, or alternatively the*

cleaning process could be redesigned, perhaps including an additional rinsing step, so that after a worst-case calculation the product supplied is compliant.

See Appendix C for worked example.

NOTE 3: *Cleaning agents may adversely affect the organoleptic properties, even if migration does not exceed the SML.*

8.2.2.4 Handling and approval of auxiliary materials and lubricants

Auxiliary materials and lubricants are chemicals necessary in any production process but may pose a chemical contamination risk for FCM Printing Inks.

EXAMPLES*: Oil in compressed air, lubricants, hydraulic oil.*

NOTE*: Oil in compressed air is an example for an auxiliary material which may come in to contact with FCM Printing Inks, either directly or indirectly through production equipment.*

The contamination risk of auxiliary material shall be assessed and documented in a risk assessment. This follows the same principles as the approval of cleaning agents. A list of approved auxiliary material shall be maintained and made available to employees.

8.2.2.5 Sharp implements, knives, glass and brittle plastics

Based on risk assessment glass or brittle plastics shall be avoided in production areas of FCM Printing Inks.
Sharp implements, knives shall have non-breakable blades (primarily due to safety reasons).
There shall be a documented policy for the controlled use of sharp implements, knives, glass and brittle plastics to prevent contamination.

NOTE: *Depending on the type of ink glass containers may be used to keep retained ink samples. In those situations, glass should not be used for sampling in the manufacturing area.*

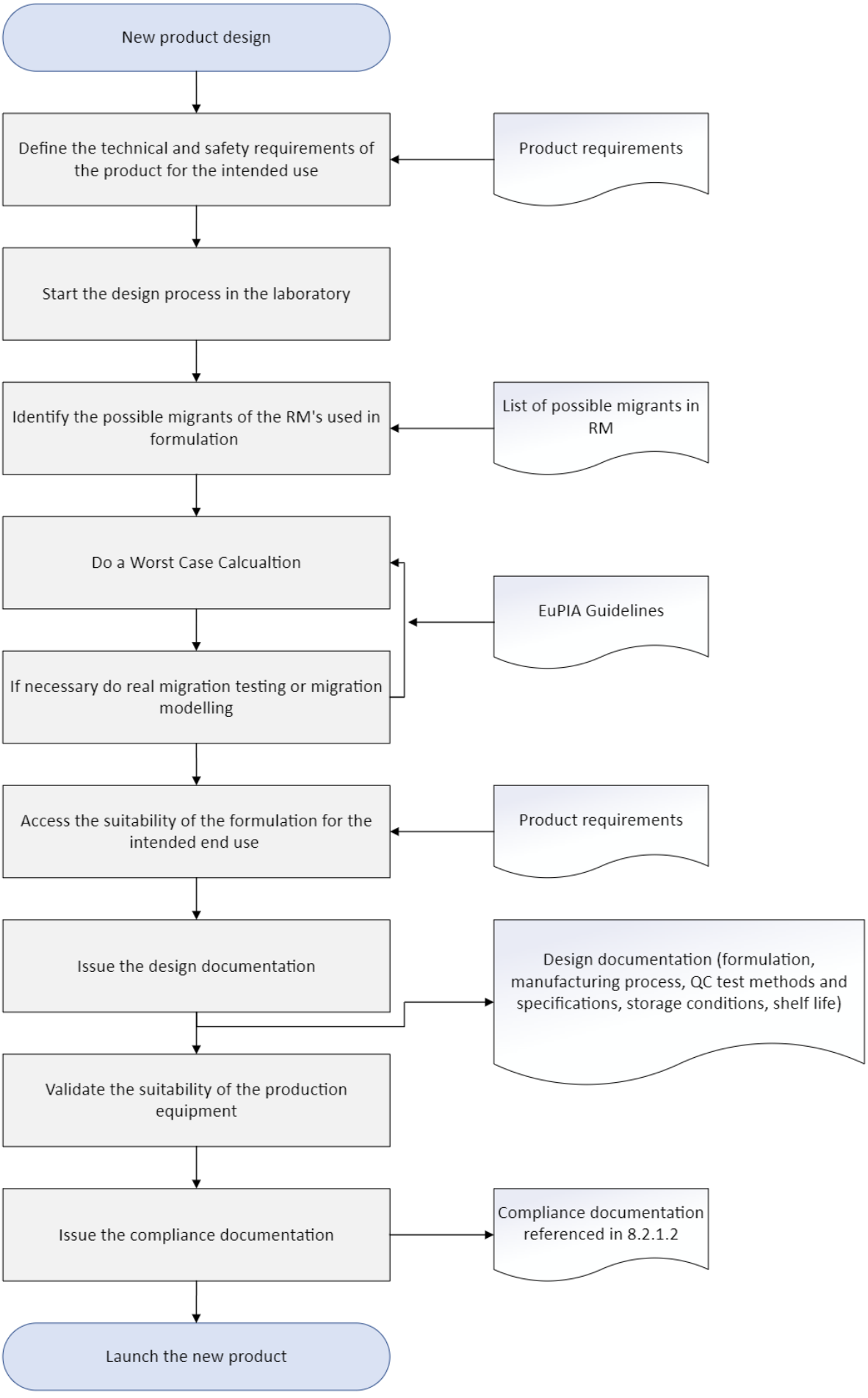
8.3 Design and development of products and services.

8.3.1 General

Customer requirements related to design and development of the new products shall be documented and agreed with the customer.

8.3.2 Design and development planning.

In cases where a new product needs to be designed, then the main steps in the process flow are described in the flow-chart below.


New product design
Define the technical and safety requirements of the product for the intended use
Product requirements
Start the design process in the laboratory
Identify the possible migrants of the RM's used in formulation
List of possible migrants in RM
Do a Worst Case Calcualtion
EuPIA Guidelines
If necessary do real migration testing or migration modelling
Access the suitability of the formulation for the intended end use
Product requirements
Issue the design documentation
Design documentation (formulation, manufacturing process, QC test methods and specifications, storage conditions, shelf life)
Validate the suitability of the production equipment
Issue the compliance documentation
Compliance documentation referenced in 8.2.1.2
Launch the new product

8.3.3 Design and development inputs.

Enquiries for new FCM Printing Inks typically originate from customer and brand owner requirements but may also arise from internal ideas or from the recognition of emerging market trends.

8.3.4 Design and development controls.

Notes specifically for Direct Food Contact inks & coatings.

A. Before initiating work for direct food contact product design, it is important to have a full understanding of the ink / coating performance requirements. As the print / coating will be in direct food contact, considerations such as the resistance properties to that food become critical. It is recommended that EuPIA member companies create a Direct Food Contact enquiry checklist document so that there is a reminder to check the critical product requirements.
B. Laboratory work may involve testing currently existing products to see whether they have the required properties or designing a new product. In either case organoleptic properties need to be taken into consideration, together with the intended or foreseeable contact conditions (temperature and time).
C. When doing worst case calculations for the potentially migrating substances in direct food contact applications, then **all** potentially migrating substances need to be considered. This includes:
    a. The intentionally added substances
    b. The unintentionally added substances which are known or can reasonably be expected to be present given by the chemistry of the ink / coating (e.g. monomers of a used polymer
    c. The unintentionally added substances which are not known, and which require analytical work to determine presence and concentration (e.g. substances created by unexpected side-reactions (isomers) or degradation reactions).

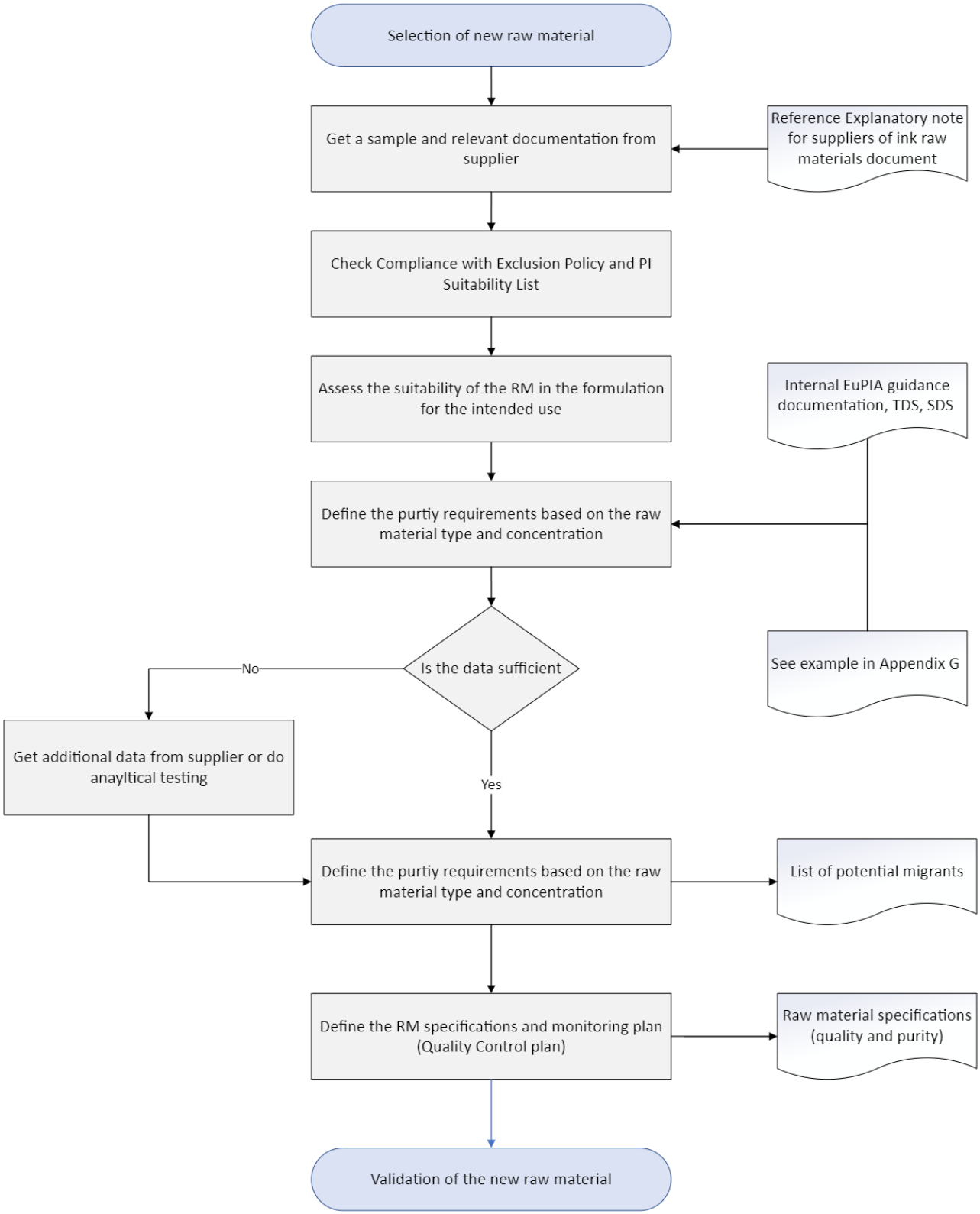
If a WCC shows for the actual packaging design, that the substance migration would be above the SML, then migration testing or migration modelling is required. If the product % coverage and / or coating weight and / or pack geometry in the actual package is such that the substance migration by WCC does not exceed the SML, then migration testing / migration modelling is not necessarily required but strongly recommended, as an experimental migration test of the FCM can be seen as an additional contribution to the safety of food packaging.
Specific test methods for DFC applications are described in Annex E of the “EuPIA Guidance on Migration Test Methods”.

See Appendix D for examples of Worst-Case Calculations.

8.3.5 Design and development changes.

New raw material introduction

The flowchart below represents the typical steps required in raw material approval, in some cases companies may choose to adjust the order in which the activities take place.


Selection of new raw material
Get a sample and relevant documentation from supplier
Reference Explanatory note for suppliers of ink raw materials document
Check Compliance with Exclusion Policy and PI Suitability List
Assess the suitability of the RM in the formulation for the intended use
Internal EuPIA guidance documentation, TDS, SDS
Define the purtiy requirements based on the raw material type and concentration
Is the data sufficient
No
Yes
See example in Appendix G
Get additional data from supplier or do anayltical testing
Define the purtiy requirements based on the raw material type and concentration
List of potential migrants
Define the RM specifications and monitoring plan (Quality Control plan)
Raw material specifications (quality and purity)
Validation of the new raw material

1) The raw material review shall be undertaken by a competent person, either a dedicated regulatory/product stewardship or technical person.
2) As for any printing ink, compliance with the latest version of the EuPIA 'Exclusion Policy for Printing Inks and Related Products' is mandatory.
3) The assessment of the raw material shall follow the applicable EuPIA guidelines. Worked examples can be found in Appendix G. NIAS and NLS, which may be present in every raw material, need to be considered and they shall be assessed according to the EuPIA NIAS Guidance.
4) Once sufficient satisfactory information is received, the new raw material will be approved and given a unique raw material code. This code and the associated compositional data are used to drive the generation of statements of composition, safety data sheets, batch and 'where-used' type traceability requirements and also prevents the commercial purchase and use of non-approved raw materials.
5) For commodity raw materials with identical technical specifications and chemical composition, it may be appropriate to code a number of raw materials with a single raw material code, an example of this may be some solvents.

NOTE: *Once identified as being suitable for a particular end use, raw materials may be placed in a toolbox to enable relevant competent technical personnel to select raw materials most likely to meet the requirements of a defined development project. For example, ink manufacturers may have a raw material toolbox for Direct Food Contact inks. For each new application, the suitability of raw materials needs to be reassessed.*

8.4 Control of externally provided processes, products and services.

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to the requirements. Therefore, the organization shall consider:

- Supplier
- Raw material
- Outsourcing

8.4.2 Type and extent of control.

8.4.2.1 New supplier selection

As the manufacturer of the FCM printing ink, it is the responsibility of each EuPIA member to ensure that all raw materials are fit for purpose from both a regulatory and technical perspective.

Information exchange between FCM printing ink manufacturer and raw material supplier should be as transparent as possible. This will ensure end use requirements and specifications are clearly communicated. Suppliers should be made aware that the intended end use is for food contact applications. If it is not possible to provide a supplier with detailed chemical and technical specification information, then the FCM printing ink manufacturer should ensure a

robust internal validation process is in place.

Suppliers should be in a position to supply all necessary information on composition to enable a thorough regulatory suitability assessment as set out in the raw material selection process.

EUPIA members should have a robust supplier performance management programme in place to ensure quality, delivery and service levels are maintained to acceptable levels.

8.4.2.2 Raw material controls

The raw material selection process defines the monitoring plan and Quality Control plan. This will determine the necessity of raw material testing.

Where appropriate, raw materials are tested in house or alternatively are supported by a Certificate of Conformity (CoC) or Certificate of analysis (CoA) from the raw material supplier, relating to the agreed specification. In some instances, pre-delivery samples representing the batch may be submitted to the ink manufacturer for special tests prior to the delivery being accepted.

If certificates of analysis are used, then the information on the certificate has to be relevant to the intended end application for the raw material.

The raw material control results shall be recorded.

For raw materials identified by FMEA as being critical then testing every batch of raw material or testing on statistically sampled batches is required.

8.4.2.3 Outsourcing

Outsourced toll manufacturing / subcontracting that affect product conformity with this GMP shall be controlled by the outsourcing organisation. The type and extent of control to be applied to an outsourced process shall be defined and documented.

The principles of this document also apply to all outsourced / subcontracted products. It is the responsibility of the company doing the outsourcing / subcontracting to ensure that the correct processes and controls are in place.

8.4.3 Information for external providers

Each raw material should include the following documentation:

- Safety Data Sheet (SDS)
- Technical Data Sheet (TDS)
- Completed EuPIA RM Compliance Questionnaire (or equivalent)
    - especially detailed information on migratable substances, NLS and NIAS
- Specifications, agreed with the supplier.

- Certificate of Analysis (if applicable)

NOTE 1: *Where it is not possible to agree raw material specifications with suppliers then incoming raw material testing needs to be done.*

NOTE 2: *Purchasing department shall refer to the change management process when changing the supplier of a raw material.*

Each raw material has a purchasing specification, typically this is agreed between the supplier and the FCM Printing Inks manufacturer. The specification should include physical and chemical properties to maintain agreed ink manufacturing quality, purity and print end-use requirements.

8.5 Production and service provision

8.5.1 Control of production and service provision

8.5.1.1 Production Instructions

Manufacturing instructions are issued and followed for each batch, giving details of the raw materials, the quantities, and the equipment to be used. Critical parameters in the process are recorded and checked by the operator.

NOTE: *This could include temperature during a production step.*
The production instruction is available to the employee at the workplace and included into trainings.

8.5.1.2 Control of Manufacturing Formulation

Proper controls to ensure that only raw materials are used in manufacturing formulations, which have been approved for the use in FCM Printing Inks. In case the approval restricted the maximum content of a raw material in a FCM Printing Inks, the control shall include a check for the maximum content.

NOTE: *Maximum contents of a raw material in a formulation may be specified during the approval of a raw material or in change management processes.*

8.5.1.3 In process controls

If in-process controls are carried out during the production process test specifications shall exist. Test specifications shall consist of test methods and test limits. The test specifications shall be defined during the design of the FCM Printing Ink production process. The test specifications and the results of the in-process controls shall be documented.

8.5.2 Identification and Traceability

Traceability is a key means to protect consumer health and safety and is therefore implemented in the food supply chain (refer to Section 2 for normative references).
In case a contaminated food stuff is detected, traceability is the most effective way to identify the root cause and to recall contaminated products.

Traceability is a two-way process:

a) In the manufacturing and supply process batch numbers shall be recorded from the raw material to the finished FCM Printing Inks through the entire supply chain including delivery at customers' level.

b) In case a customer reports a contamination, it shall be possible to determine the raw material batches used in the production of the reported finished FCM Printing Ink batch.

Traceability requires that:

- Materials are identifiable by an appropriate system such as labelling, referencing relevant documentation and information.
- Retained samples of raw materials and finished FCM Printing Inks are maintained, and a system exists that allows them to be retrieved. See Section 8.5.2.3.
- The company should test the traceability system at least annually and keep the records of those tests.

8.5.2.1 Raw material to finished good.

At any stage of the production process batch numbers of used materials shall be recorded:

- Supplied materials:
  The original supplier's batch numbers may be used, or a new batch number may be created at goods receiving. If a new batch number is created the original supplier's batch number shall be linked to newly created numbers. Fluid materials stored in tanks require time logging of tank fillings. Withdrawals may be based on time logs or alternatively new batch numbers are generated on fillings and recorded in production. A documented instruction is in place on how to calculate temporarily existing compound concentrations in case of a product recall.

- All of the following have a unique batch number.
  - Produced semi-finished materials
  - Reworked semi-finished and finished materials.
  - Any finished FCM Printing Ink

The batch numbers of finished FCM Printing Inks delivered to a customer shall be linked to the customer.

A documented instruction shall exist which describes how to determine:

- all finished goods batches containing a specific raw material batch,
- all customers, affiliated companies, sales agents, distributers which have received a finished good batch containing a specific raw material,
- all warehouses where a specific raw material batch or finished good batch produced from this raw material batch is stored.

This procedure shall be applied when a raw material supplier recalls a batch, a customer reports a potential contamination, or internal tests show contamination of a FCM Printing Ink.

8.5.2.2 Finished good to raw material.

In case a customer reports a finished good batch as being potentially contaminated, a supplier informs about a contaminated raw material batch, or an internal test indicates a contamination, it is essential that the potential contamination can either be confirmed or rebutted quickly.

Therefore, a documented instruction shall exist which describes how to determine all raw material batches used in the manufacturing of a FCM Printing Ink. Together with the procedure described in recalling of delivered contaminated batches is possible.

8.5.2.3 Retained samples.

The necessity of raw material retained samples shall be assessed in a risk assessment. Samples for each raw material batch shall be retained at least for 1 year.

Retention samples for FCM printing ink batches shall be maintained at least for 6 months in addition to the shelf life of the FCM Printing Ink.

NOTE 1: *In terms of GMP retained samples are needed when a customer reports a possible contamination of a FCM Printing Ink.*

NOTE 2: *The obligation to retain raw material samples may be passed onto the supplier.*

8.5.3 Property belonging to customers or external providers.

In case customer property is used for the production of FCM Printing Inks, customer's responsibility for the conformance of the FCM printing ink shall be clearly defined and documented.

NOTE: *This may include stirring, blending or dispensing equipment. It may also include raw materials (for example solvent).*

8.5.4 Preservation

All products (including raw materials) are stored in conditions to prevent, as far as possible, any deterioration of the material. Where appropriate a procedure exists to test stock that may have been held for some time to ensure it has not drifted from specification. Where they exist, the test instructions shall be documented. Rejected stock is clearly marked as such and quarantined / isolated to avoid accidental use.

Cross contamination during storage or mix up of products on stock removals shall be avoided. Open packaging shall be safely reclosed before put in storage.

NOTE: *Non-conforming products shall be labelled as such. If a warehouse management*

system cannot prevent that a non-conforming product is used, non-conforming products shall be physically quarantined.

8.6 Release of products and services

8.6.1 Quality control objectives

Quality control for FCM Printing Inks shall ensure that parameters affecting product performance are tested, at appropriate intervals, as detailed by the Risk Assessment FMEA.

Quality control tests shall also be done to verify the effectiveness of risk control measures derived from the FMEA Risk Assessments.

8.6.2 Final quality control

Product test specifications shall exist for each finished FCM Printing Ink. Test specifications shall consist of test methods and test limits. Test specifications shall be defined during the design of a FCM Printing Ink.

Additional tests could be done based on the Risk Assessment e.g. for NIAS components in DFC inks. The test depth and frequency for finished FCM Printing Inks depends on

- the test level of intermediates and raw materials,
- the degree of segregation in production areas,
- the degree of dedication of equipment to the production of FCM Printing Inks,
- the type of application (DFC – NON-DFC ink).

NOTE 1: *As quality control typically takes place before filling, any contamination during the filling process will not be detected.*

If filling equipment is not dedicated to FCM Printing Inks, control measures for carry over and cleaning (see section 7.1.3.2) shall be implemented.

NOTE 2: *Cleanliness of filling equipment is of particular significance for DFC inks.*

NOTE 3: *Final quality inspection is not a means to prove that an ink is fit for its intended use. Fitness for intended use is validated during the design.*

8.7 Control of nonconforming outputs

8.7.1 Recall of defective FCM Printing Inks

A documented procedure shall exist defining roles and responsibilities in the event of a product recall. For every recall an employee shall be named who is responsible for the co-ordination

of the recall and the completeness of the recall.

This procedure shall ensure that the manufacturer reacts appropriately and quickly to minimise negative effects for customers and the manufacturer.

The goals of a recall are:

- to inform customers about details of the issue and its potential effects,
- to confirm the batch number, its size and identify and if other batches might similarly be affected,
- to determine the quantity of the FCM Printing Ink used, at which customers and on which designs,
- to identify, locate and quarantine any unused FCM Printing Ink,
- following investigation quarantined product should either be returned or safely disposed of by the customer.
  In case a contamination leads only in specific applications (for example at high coating weight) to a contamination of packed foodstuff, it may not be necessary to physically return all contaminated products to the ink manufacturer. Guidance on safe use under appropriate conditions or specific restrictions must be provided to affected customers if product is not returned, and records of the communication should be maintained.

The product recall procedure shall define at a minimum:

- Which information customers should provide in order to be able to react appropriately on a reported contamination?
- Internal communication rules
- External communication rules
- Responsibilities and duties
- Documentation requirements

A product recall shall be simulated at regular intervals (at least every two years and preferably annually). Documentation of the simulation shall be maintained.

8.7.2 Rework of non-conforming FCM Printing Inks

It may be possible to rework non-conforming FCM Printing Inks. Rework of a FCM ink may be necessary due to compositional, quality or performance criteria.

Records shall be maintained for any rework. Full traceability shall be maintained.
Corrective and preventive actions shall be applied to prevent reoccurrence.

NOTE: *When considering reworking, special attention should be given to substance migration limits or other restrictions. Where it is not possible to meet required migration limits it may be possible to rework a FCM Ink into a less critical end use. If this is the case the ink shall be relabelled and delivered with a technical data sheet describing the application.*

8.7.3 Handling of returned goods (defective or non-defective)

FCM Printing Inks returned may be booked into stock as long as the packaging has not been opened. Records of returned FCM Printing Inks shall be maintained. They shall be booked into stock under the same description and batch number.

NOTE 1: *In case a non-conforming FCM Printing Ink is returned, the ink may be reworked (see section 8.7.2)*

NOTE 2: *In case a returned FCM Printing Inks is close to the end of its shelf life, the shelf life may be prolonged after an appropriate quality check. Documentation shall be maintained, and traceability shall not be affected.*

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The effectiveness of the hygiene management system shall be monitored. Records of sampling and results shall be maintained.

NOTE: *The product type and the risk assessment will drive the monitoring that is required. Testing is especially required to monitor microbiological contamination for water-based inks. In many cases biocide suppliers are able to provide this service.*

A documented procedure specifying corrective actions for non-conforming monitoring results shall be established, implemented and maintained.

9.2 Internal audit

Internal audits shall be conducted at planned intervals to determine whether the GMP is effective and conforms with this Guideline.
Records of the audits, audit findings and follow up activities shall be maintained.

9.3 Management review

9.3.1 General

The company's senior management shall ensure that annual management review is undertaken to ensure that GMP' s requirements are fully implemented and effective and that opportunities for improvement are identified.

9.3.2 Management review inputs

The following aspects shall be considered in the management review (as it applies):

(a) status of actions from previous management reviews.

(b) changes in external and internal issues affecting GMP,

(c) information on the effectiveness of GMP measures, including in particular trends in the following items:

1) level of fulfilment of set objectives/ established actions.
2) process performance and conformity of products.
3) non-conformities and corrective actions
4) results from monitoring and measurements
5) audit results
6) performance of external suppliers
7) effectiveness of risk management measures implemented.
8) opportunities for improvement
9) risk assessment of new product introductions along with management of changes
10) training status of personnel working in GMP perimeter
11) waiver to release (if applicable) a product that fails a specific test
12) customer feedback or complaint
13) critical documents and records review

9.3.3 Management review outputs

The following decisions and actions shall be included in the annual management review:

(a) opportunities for improvement

(b) any need for changes in the internal GMP system.

(c) resource requirements

(d) DFC materials: confirmation of a non-changed status

The documented information shall be retained as evidence of the results of the management review.

10 Improvement

10.1 General

Company shall be able to demonstrate that it uses the information from failures in its systems and processes to take any necessary corrective and preventive actions. Results of audits, processes monitoring, quality control data and other available data sources shall be analysed and used to continuously improve product quality and implemented processes.

10.2 Nonconformity and corrective action

Nonconformities with requirements of this GMP shall be evaluated in order to determine its cause and if needed to define and implement actions to prevent recurrence.

10.3 Continual improvement

Company's senior management shall define and maintain a clear and effective plan for continual improvement of FCM Printing Inks quality and safety.

Appendix

Appendix contents:

A. Glossary

B. FMEA

C. Worked example of cleaning agent worst case calculation

D. Migration and Worst Case Calculation

E. Change Management

F. Product Selector

G. Worked Examples for Raw Materials Selection

A. Glossary

certificate of analysis (COA)
document that indicates results of specific tests or analysis, which may include test methodology, performed on a defined amount of material or product. [SOURCE: ISO/TS 22002-4, 2013, 3.1]

cleaning
removal of soil, dirt, solvents, grease or lubricant, ink residues or other objectionable matter. [SOURCE: ISO/TS 22002-4, 2013, 3.2]

coatings
EuPIA members may supply antimist coatings and heatseal coatings which may be in direct contact with food. These coatings are regulated differently to the internal can coatings, which are managed by the CEPE trade association.

contaminant
any biological or chemical agent, foreign matter or other substance not intentionally added to the product which may compromise food safety.[SOURCE: ISO/TS 22002-4, 2013, 3.3]

contamination
introduction or occurrence of a contaminant in the product.

NOTE to entry: *In the context of this Good Manufacturing Practice, "contamination" may also refer to the impurities in the raw materials used in, or a decomposition or reaction product formed during, the production process or application, which might compromise food safety.*

food packaging
any product to be used for containment, protection, handling, delivery, storage, transport and presentation of food.

NOTE to entry: *Food packaging may have direct or indirect contact with the food.*

- Direct food contact surfaces or materials are in contact (i.e. physically touching the food or in contact with the headspace) or will be in contact with the food during intended or foreseeable use of the food packaging. Note that there is a distinction between actual food contact and contact via the headspace (often called indirect food contact). Contact via headspace involves transfer via the vapour phase only (including evaporation/condensation). However, if the foodstuff has the opportunity to directly contact the printed surface (e.g. by turning the container upside down), then this becomes a direct food contact situation.

- Non-direct food contact surfaces or materials are not in direct contact with the food during intended or foreseeable use of the food packaging, but there is the possibility for substances to be transferred into the food.

The classification of the food packaging as direct or non-direct food contact should be part of the hazard analysis. [SOURCE: ISO/TS 22002-4, 2013, 3.7]

food packaging hazard
microbiological, chemical or physical agent in FCM Printing Inks, or condition of use, with the

potential to cause an effect in the food leading to adverse health effects. Note that many food packaging hazards are not caused by FCM Printing Inks, but they are not in scope of this GMP. [SOURCE: ISO/TS 22002-4-2013, 3.8]

FCM Printing Ink withdrawal (recall)
Recall of non-conforming FCM Printing Inks from any part of the FCM Printing Inks supply chain because its application could lead to a defective, non-compliant food contact material.

EXAMPLE: *Any part of the **FCM Printing Ink** supply chain includes trade warehouses, distribution centres or customer operations and warehouses.*

Non intentionally added substance (NIAS)
Substances and raw materials used in the manufacture of printing inks may contain impurities originating from their manufacturing or extraction process. These impurities are non-intentionally added (NIAS) but present in the substance which is intentionally used in the manufacture of the printing ink. Further, during the manufacture and use of printing inks reaction and degradation products of used substances can be formed. These reaction and degradation products are non-intentionally present in the printing ink (NIAS).

[SOURCE: EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Evaluated or Non-Listed Substances (NLS) in printing inks for food contact materials]

Non-Evaluated or Non-Listed Substances (NLS)
NLS are substances which are not required to be listed according the current FCM legislation and in many cases not yet officially evaluated. According to the current legislation printing inks for FCM may contain substances which are not listed or fully evaluated. The safety of such substances needs to be demonstrated in accordance with internationally recognised scientific principles on Risk Assessment.

[SOURCE: EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Evaluated or Non-Listed Substances (NLS) in printing inks for food contact materials]

FCM Printing Ink containers / packaging
any kind of product or material used to hold and protect FCM Printing Inks during shipping, transport and storage.

safety
condition of a product being free from unacceptable hazards. [SOURCE: ISO/TS 22002-4, 2013, 3.18]

specification
detailed description of the properties and requirements of a material, in particular in relation to its technical and specific suitability. [SOURCE: ISO/TS 22002-4, 2013, 3.20]

statement of composition (SoC)
a document that is provided by printing ink manufacturers to help printing converters and end users to assess the compliance of printed packaging. The statement of composition provides adequate information (e.g. potential migrating substances and their maximum levels in the ink) to downstream users, to enable them to issue their “Declarations of Compliance”.

waste

any substance or object that the organization discards or intends or is required to discard. [SOURCE: ISO/TS 22002-4, 2013, 3.21]

B. FMEA

Both HACCP and pFMEA require a process flow and quality system in place. They are team-based approaches to identifying hazards/failures and managing risks.

pFMEA analyses all possible ways processes and products can fail and impact the product's performance, safety, or quality. It considers every aspect of customers' satisfaction and requirements. It considers any **risk** at all steps of the process flow, prioritizes the risks, and determines actions needed to eliminate or reduce them. FMEA failures are assessed **quantitatively** based on **severity, likelihood, and detection**.

HACCP evolved from FMEA to control food safety hazards. It is a preventive approach for ensuring the safety and quality of food products. It is a standardized and regulated requirement for food producers and aims at ensuring quality and safety from biological, chemical, and physical hazards in production processes. HACCP risk assessment is a **qualitative approach** to determine the criticality of **hazards** (hazard severity and likelihood of occurrence) and **only** establish limits, monitoring, and corrective actions (following 7 principles) **for critical control points** (CCP). **Not every step of the process is applied in the HACCP** but only **hazards that are 'reasonably likely to occur at an unacceptable level in the absence of control, and for which control is essential given the intended use of the food'** (Codex Alimentarius).

Manufacturers of printing inks are industrial companies, part of the food packaging chain but they do not supply directly to the food industry. Printing inks for food packaging can affect food safety and quality in case of migration of ink components into the food but this risk is being taken into consideration via disclosing information to the supply chain which has the liability to perform their risk assessment or migration testing on the final application.

The use of HACCP-type assessment for printing ink manufacturers would require control of the chemical, biological, and physical hazards associated with the production of printing ink in relation to food safety.

- Chemical hazards – are controlled by understanding the impurities of the raw material (information from supplier and/or in-house analysis, EUPIA GMP 6.1.1.1). In addition, ink products are formulated in accordance with the EuPIA exclusion policy, excluding the use of toxic, carcinogenic, and mutagenic materials.

The risk of cross-contamination during production (EuPIA GMP 6.1.1.1) is assessed via a risk assessment and additional controls are put in place, monitored, and documented, if necessary, in addition to the routine cleanliness requirements).

- Microbiological hazards – this is only applied to water-based printing inks where microorganisms can develop. In such a system, preservatives are usually used to maintain the shelf life. This is also required to satisfy customers' requirements (shelf-life of the product). It is part of the (EuPIA GMP 6.1.1.2) and may require monitoring.

- Physical contamination hazards – Physical contamination of the food from printing ink is very unlikely, as ink is produced and then filtered to achieve the required end-user properties before being packed. In the event of physical contamination of the ink due to something being present in the container before filling, then this would likely impact

the printer's performance (EUPIA GMP 6.1.1.3) and stop the ink from being printed onto the food packaging.

In the case of direct food contact ink, offset needs to be considered and assessed and it is part of the migration risk assessment to be conducted by the supply chain.

As a result, the hazards coming from printing inks that could impact the quality and safety of the food may not **all** be considered critical control points (cf Codex Alimentarius CCP Decision Tree) in the HACCP program as they either are being considered under EUPIA GMP or are necessary requirements for the customers' satisfaction or product properties and already controlled.

If some of these hazards are deemed to be **significant food safety hazards** that cannot be controlled sufficiently by EUPIA GMP, then this will need additional control step to be considered. In this instance, HACCP assessment would not bring additional information to the risk hazard assessment.

pFMEA allows printing ink manufacturers to consider and address all the risks, including the above discussed, and act accordingly to prevent/minimise potential risks/hazards in relation to food safety in addition to addressing legal and customer requirements. The comprehensive and quantitative analysis of pFMEA may also help in improving the reliability and performance of the manufacturing processes and ensure the quality of the products delivered to the customer.

Although both pFMEA and HACCP could be used by manufacturers for printing ink intended to be used in food contact materials, the implementation of EUPIA GMP and pFMEA should be enough to address the hazards related to food safety and document prevention steps.

A completed FMEA fulfils two requirements:

- Risks are analysed in a structured, internationally accepted way
- Documentation of the status before and after risk minimisation means have been implemented

1. FMEA template

Item/Function	Potential failure mode(s)	Potential effect(s)	Severity	Potential causes of failure	Probability	Current Design Control	Detectability	RPN

FMEA column headers (assessment of status before risk minimisation means)

In a FMEA failures are prioritized according to how serious their consequences are (severity), how frequently they occur (probability) and how easily they can be detected (detectability).

The aim of an FMEA is to come to an objective assessment of a potential failure by a risk

priority number (RPN). The RPN is the result of the multiplication of the factors severity, probability of occurrence and the detectability of a failure.

Each factor is rated independently of the others. Independence of the factors is crucial to achieve objective, comparable results. The factors are ranked from 1 – 10 where 10 means the worst case.

It is recommended not to use all factor levels as it would not be easy to clearly separate 10 factor levels by factor definitions. In addition, selecting repeatably and reproducibly the same factors out of 10 levels for similar hazards is difficult.

<table>
<tr><td>Item/
Function:</td><td>Process step where failures can happen:
Cluster steps e.g.
incoming goods (raw material)
storage of raw materials
production process, production equipment
quality control
packaging
storage of finished product
delivery to customer
raw materials selection</td></tr>
<tr><td>Potential
failure
mode(s)</td><td>What or who can cause a failure:
Typical failure modes are:
employee
maintenance personnel
facility, physical environment and operating conditions
production equipment and pipes
storage tanks
packaging material
cleaning agents and cleaning processes
rework
raw materials
semi-finished products
Authorized and Non-authorized person with the intend to harm</td></tr>
<tr><td>Potential
effect(s)</td><td>- kind of contamination (chemical, physical or microbiological)
- traceability not given
- ...</td></tr>
<tr><td>Severity</td><td><table><tr><td>Critical: One dead</td><td>10</td></tr><tr><td>Damage to health of end user, medical assistance necessary</td><td>8</td></tr></table></td></tr>
</table>

	Recall of packaged food, because legal requirements are not met (e.g. due to migration above accepted limits, traceability not given	8
	Insignificant damage to health of end user	6
	Recall, ink/varnish not usable	4
	Ink/varnish does not meet technical specification	2
	Detection of unwanted substances possible, however within specification limits	1
Potential causes of failure	What exactly causes the effect?	
Probability of occurrence	Likelihood of the occurrence of the failure:	
	Sure	10
	Occurred already and root cause not eliminated	8
	According to expert opinion possible and conceivable, process is according state of the art technology. Question: Do you believe that the failure occurs? Answer: yes	5
	According to expert opinion possible, but hardly conceivable Question: Do you believe that the failure occurs? Answer: No, but I am not 100% sure.	2
	According to expert opinion not conceivable	1
Current design control	What controls are in place to reduce severity, decrease the probability of occurrence or increase the detectability?	
Detectability	Likelihood that the potential effect will be detected when it occurs.	
	Impossible	10
	By accident	8
	Control by sample testing	6
	Control by 100% testing of product/process, but may not be able to detect nonconformity with a 100% probability	4
	Failure is obvious and can be detected easily/ test(s) exists with 100% detection rate of nonconformity and is used for all batches, no sampling	1
Risk priority number (RPN)	RPN = Severity * Probability * Detectability Maximum value 1000 Maximum RPN for DFC: <= 160 Maximum RPN for Non-DFC: <= 240	

Example topics

Recommended Action	Responsible/ target date	results of action(s) taken				
		Action(s) taken	Severity	Probability	Detectability	RPN

FMEA column headers 2 (after definition of risk minimisation means)

When an individual RPN limit is exceeded, take corrective actions, re-determine the three factors and re-calculate the RPN.

2. Conducting a FMEA

The process for conducting a FMEA is a multi-phase process.

Phase A: Define FMEA scope and FMEA team.

The scope of a FMEA shall be defined.

The FMEA team for a production related FMEA should combine the following knowledge:

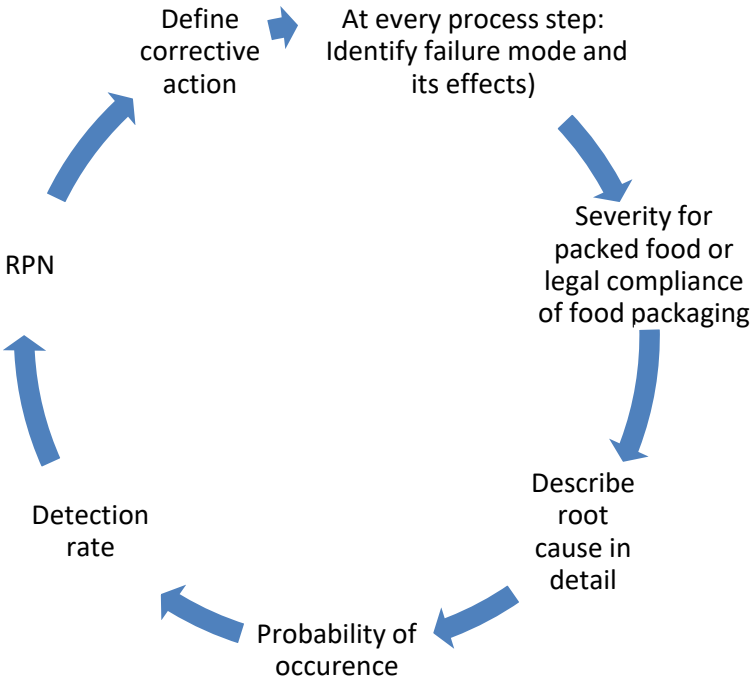
- Someone who is trained and familiar with the FMEA tool. This person does not need to be a product or production expert.
- A local specialist who knows the manufacturing tool set and facility
- A product specialist who knows the formulations.
- A production specialist.
- At least one member must have sufficient chemistry knowledge in order to be able to identify/address process and reaction contamination risks for the raw materials involved
- A product safety and compliance specialist on demand.

Phase B: Pre-work

When a production process is assessed a flow chart of the material flow from incoming goods to loading the truck should be created.

Phase C: Course of action

In Phase C the team develops the FMEA as shown in the figure below:

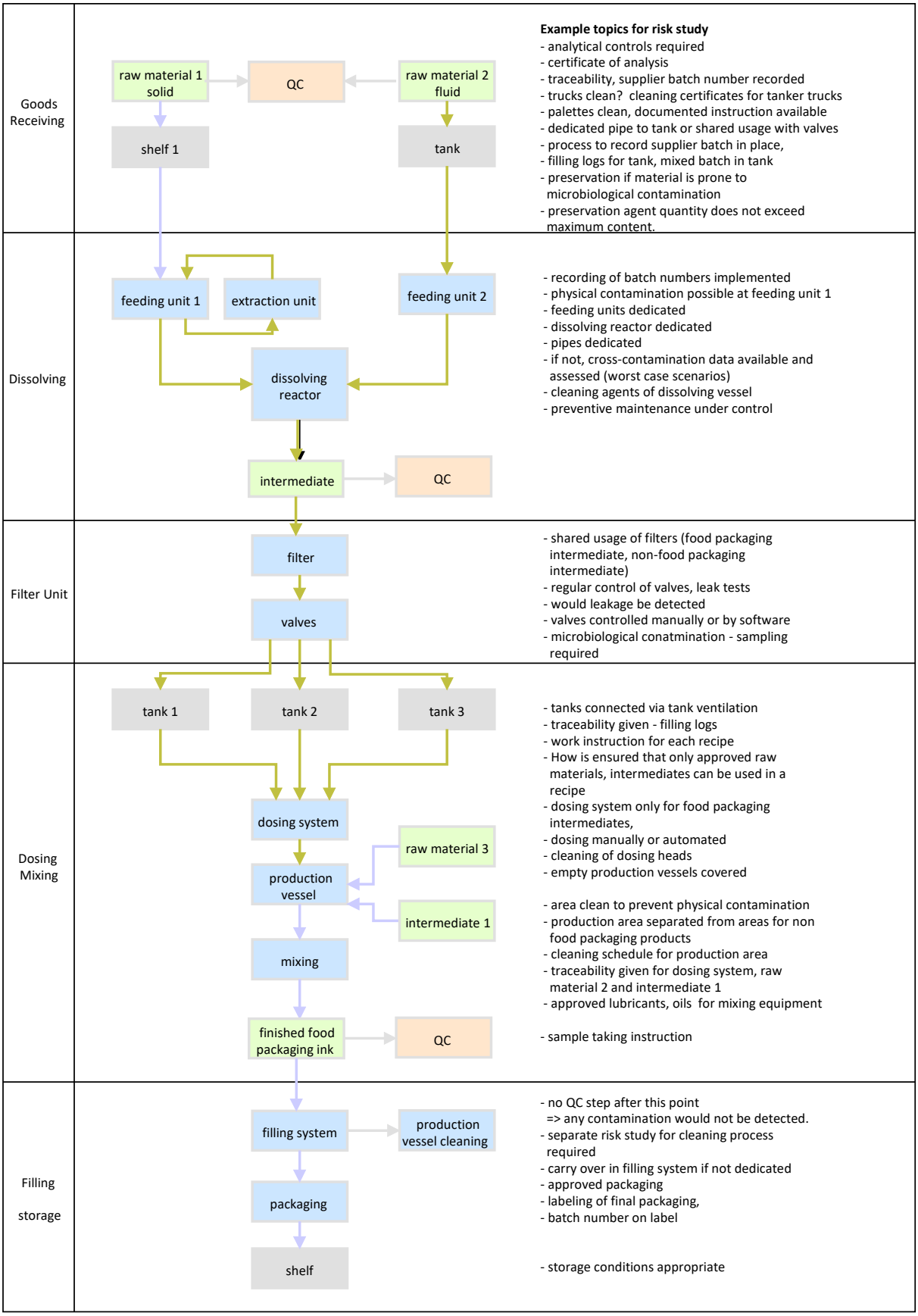


FMEA steps

If the RPN limit is exceeded, define a corrective action, which reduces the probability of occurrence (first choice) or increases the detectability of the failure (second choice). Hint: In general, it is not possible to reduce the severity when assessing an existing production process.

Closing the FMEA

The FMEA shall be printed and signed by the FMEA team.



Example flow chart with topics for FMEA study

C. Worked example of cleaning agent worst case calculation

Example: Equipment that is used to manufacture water-based inks is cleaned with a surfactant-based cleaning agent. After two rinsing steps it is estimated that 20 grams of cleaning agent remains in the equipment, which is used to manufacture 500 Kg batches of ink. The migrating substance within the cleaner has a migration limit of 0.05 mg/Kg food.

A worst-case calculation assumes that 4 g of wet ink (solids 50% - so equivalent to 2 g dry ink) are applied at 100% coverage per square metre of print, and that 0.06 m2 of print are used to package 1 Kg of food.

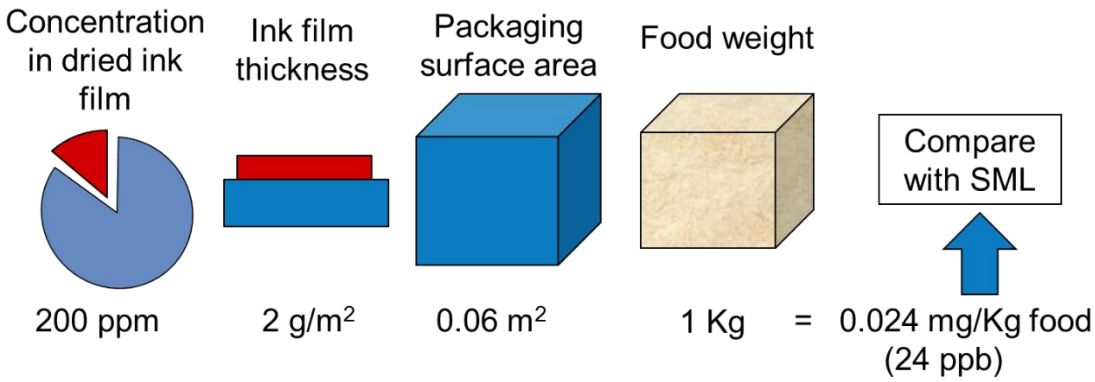
The calculation gives a result of 0.16 mg of the cleaning agent substances per m² of print. This would result in 0.0096 mg/Kg Food migration, which is significantly less that the migration limit. A risk assessment would therefore consider this to be acceptable, this risk assessment should be documented.

In a situation where there is not a full substance disclosure for the cleaning agent then all of the undisclosed portion of the cleaning agent shall be assumed to be a NIAS and can be assessed using the EuPIA Guidance for Risk Assessment of Non-Intentionally Added Substances (NIAS) and Non-Evaluated or Non-Listed Substances (NLS) in printing inks for food contact materials.

D. Migration and Worst Case Calculation

Risk analysis shall assume worst case scenarios unless there is measured / modelled data. Worst case scenario for chemical contamination means, that any substance in a FCM Printing Ink, migrates 100% into the packed food.

Example of a Worst-Case Calculation:



CI = Concentration in dried ink layer (mg/Kg or ppm)
F = Dried ink layer weight (g/m2)
P = Pack surface Area (m2)
W = Weight of food (Kg)
CF = Concentration in food (mg/Kg or ppm)

$$CI\ x \frac{F}{1000} x\ P\ x\ \frac{1}{W} = CF$$

$$\frac{CF}{P} x \frac{1000}{F}\ x\ W = CI$$

Ink Jet

For ink Jet due to the variable nature for the amount of ink deposited, the WCC can be done based on the number of drops deposited and the nozzle and/or drop size.

Worst case (mg/Kg)=(Mass of ink deposited mgx Percentage of migrant)/Mass of food in pack (Kg)

As an example of these two tables are provided below, the first provides the mass of ink deposited as a function of the number of drops in the printed code (at the common printer nozzle sizes) and the second gives the amount of migration that could be achieved for a given number of drops. The example shown below looks at the worst case for 0.25% of a migrant in the wet ink printed onto 1kg, 500g and 100g of packed food and the areas shown in red highlight where the >10ppb (0.01mg/Kg) value could be exceeded.

Example: specific ink jet ink:			
	Total Mass deposited/g		
Number of drops	**75 µm nozzle**	**60 µm nozzle**	**40 µm nozzle**
2000	0.00353475	0.001809792	0.000536235
1500	0.002651063	0.001357344	0.000402176
1000	0.001767375	0.000904896	0.000268117
800	0.0014139	0.000723917	0.000214494
600	0.001060425	0.000542938	0.00016087
400	0.00070695	0.000361958	0.000107247
200	0.000353475	0.000180979	5.36235E-05

	Food mass in g		
	1000	500	100
Number of drops	**75 µm**	**75 µm**	**75 µm**
2000	8.837E-03	1.767E-02	8.837E-02
1500	6.628E-03	1.326E-02	6.628E-02
1000	4.418E-03	8.837E-03	4.418E-02
800	3.535E-03	7.070E-03	3.535E-02
600	2.651E-03	5.302E-03	2.651E-02
400	1.767E-03	3.535E-03	1.767E-02
200	8.837E-04	1.767E-03	8.837E-03
	60 µm	**60 µm**	**60 µm**
2000	4.524E-03	9.049E-03	4.524E-02
1500	3.393E-03	6.787E-03	3.393E-02
1000	2.262E-03	4.524E-03	2.262E-02
800	1.810E-03	3.620E-03	1.810E-02
600	1.357E-03	2.715E-03	1.357E-02
400	9.049E-04	1.810E-03	9.049E-03

	Food mass in g		
200	4.524E-04	9.049E-04	4.524E-03
	40 µm	**40 µm**	**40 µm**
2000	1.341E-03	2.681E-03	1.341E-02
1500	1.005E-03	2.011E-03	1.005E-02
1000	6.703E-04	1.341E-03	6.703E-03
800	5.362E-04	1.072E-03	5.362E-03
600	4.022E-04	8.044E-04	4.022E-03
400	2.681E-04	5.362E-04	2.681E-03
200	1.341E-04	2.681E-04	1.341E-03

There are three basic limit types:

- SML for listed and fully evaluated substances. Such migration limits can be taken from
  - Regulation (EU) No 10/2011 and amendments
  - Listed substances in the Swiss Ordinance SR 817.023.021
  - German Consumer Goods Ordinance (GIO)
  - Officially evaluated substances on national authority level according to the EFSA requirements
- The Overall Migration Limit (60mg/kg food): the sum of all substances migrating into food.
- Self-derived SML for NIAS or NLS, for which no officially evaluated limit exists. Self-derived SML shall be based on a risk assessment in line with the EuPIA NIAS Guidance
- Non evaluated substance where the 'No detection limit" is applicable, typically 0,01 mg/kg food (10 ppb) is used.

E. Change Management

Initiators of change

Examples of events that may initiate the formal change management process include, but are not limited to the following:

- Regulatory change, including changes to EU, national or international legislation or recommendations.
- Toxicological or classification changes relating to the raw materials their components or impurities.
- New information regarding the raw material composition or purity
    - includes anything that would affect the initial RM Compliance questionnaire.
- Raw material manufacturing process changes
- Raw material sourcing change
    - including packaging changes
- Ink manufacturing process change.
    - including QC/QA changes
    - packaging changes
- Ink application information change.
    - including actual migration studies (analytical or exposure data) as well as new applications, substrates and processing

There are four distinct "triggers" for design change and these can all follow one of the three flow routes used for the initial assessment of product suitability as proposed documented in the formulation design process:

A. An existing product design is proposed for use in a new application. Under these conditions it is recommended that the formulation design flow chart be used and the results be recorded and where appropriate the product data be updated. This could include new worst case calculations or new migration test data for the application.
B. A raw material change in an existing product design (including any significant process changes in the manufacture of the raw material). This event shall be treated as the introduction of a new raw material and follow the formulation design flow chart. All the steps involved in the selection and approval of a new raw material shall be considered and the assessment recorded.
C. A change in formulation where no new materials are introduced. In the context of change management this is likely to include the effective development of a new product from existing ingredients (i.e.: a significant change to the formulation quantities – outside of the levels of the initial product design). Again the formulation design flow chart can be followed for this and the assessment recorded.
D. A regulation change is imposed either locally or internationally. (This might include

customer specific requirements.) For this type of change it is recommended that C above is followed.

Remember the important questions to ask are:

- Will or could the change impact the information that is provided with the product?
- Could the change impact any downstream customer compliance assessments?

If the answer to either is yes then a formal change control process following the principles listed in A-D above must be started.

Records documenting the outcome of the change control process shall be maintained.

See Appendix D for examples of Worst Case Calculations.

F. Product Selector

A product selector such as illustrated by the example below should make it easy for customers and internal staff to understand what the correct product for a specific end use is. If there is a specific end use where the EuPIA members company does not have a product (a market in which he is not active), then this should also ideally be communicated. For Direct Food Contact applications the Product selector may refer to individual products or small families of products, for non-Direct Food Contact applications the Product selector is likely to refer to Product Families.

Application	End Use	Example	Product or Product family reference
Surface print on OPP	Non-DFC	Deep freeze	xxxxxxxxxxx
Surface print on OPP	Non-DFC	Confectionary	xxxxxxxxxxx
Surface print on paper	DFC	Paper plates	xxxxxxxxxxxx
Surface print on OPP	DFC	Antimist coating	xxxxxxxxxxxxx
Surface print on OPP	DFC	Ink for promotional info inside of pack	xxxxxxxxxx
Surface print on OPP	Non FCM Not in scope of GMP	Ink for label to be applied to glass bottle	xxxxxxxxxxxx
Surface print on a different substrate	…….	……	…….
Another application …	……	…….	…….

G. Worked Examples for Raw Materials Selection

Examples:

- *Polystyrene/acrylate dispersion, intended to be used in liquid ink at max. 95%*
- *defoamer, to be used in liquid ink at max. 5%*
- *wax emulsion, to be used in liquid ink at max. 20% (16% after final reduction)*
- *pigment, to be used in paste ink at max. 25%*

Step 1: Information and Assumptions for Worst case calculation:

based on the EU cube: 1 kg of food in 6 dm² packaging material
max. ink amount:
6 g/m² (ink as supplied to the printer) for *L* - liquid flexo and gravure inks.
2 g/m² (ink as supplied to the printer) for *P* - paste (offset) inks.

See Appendix D for examples of Worst Case-calculations.

Result:
28 mg/kg of a substance in *liquid* inks will result in à 10 ppb in food.
83 mg/kg of a substance in *paste* inks will result in à 10 ppb in food.

this means that

dependent on max. intended use	ingredients are relevant. if present in amounts above …
- dispersion, intended max. 95% in *L* -	30 ppm
- defoamer, intended max. 2 % in *L* -	1400 ppm (0.14%)
- wax emulsion, intended max. 16% in *L* -	175 ppm
- pigment, intended max. 25% in *P* -	333 ppm

Adequate information from **Raw Material Supplier** must be in place.

- confirmation that all intentionally used substances are listed in relevant European or national regulations
- identify all substances used *or known to be present*, which have the potential to migrate, together with their concentration (range),
- and CAS No. and/or FCM No or PM_Ref No,
- and SML or other relevant toxicological information, if any.

Remark: Information provided in the SDS (hazardous substances > 0.1%) is not sufficient.

For all FCM applications, the adequate information should include information about every regulatory relevant substances of the raw material (regardless of molecular weight), and should include information on NIAS. Because not every relevant NIAS may be known to the raw material supplier, analytical testing of the raw material is required for all DFC applications.

Step 2: Assessment of migration potential based on Worst Case Calculation

Case A: SML cannot be exceeded: Raw material can be used.
Case B: SML can be exceeded: Migration testing or modelling required. Assessment based on migration testing/modelling (step 4) is required.

Step 3: Migration Testing or Modelling, Analytical Work

3.1 Migration Testing (MT) or Modelling (MM)

- raw material used in max. intended amount in a suitable model formulation (laid down for each relevant type of ink - see footnote)
- simulants laid down for each relevant use
- simulant to be placed on the food contact surface (usually reverse side; printed/varnished side in case of DFC)
- alternative: Migration Modelling

Details on migration testing of printed FCM can be found in the EuPIA Migration Guidance.
For specific applications or raw materials it might be justified to deviate from the recommended methods. This shall be documented in the risk assessment.

3.2 Analytical Work on the raw material
The amount of testing to be done must consider the higher probability of transfer of substances to foodstuff in DFC systems (due to the direct contact) compared with non-DFC.

For raw materials for DFC applications:

- identify and quantify migratable substances, assess detectability
- search for NIAS
- if NIAS are found, identify (if possible) and check three different batches

For raw materials for Non-DFC applications:

- identify and quantify migratable substances, assess detectability
- search for NIAS, if NIAS are found, identify (if possible) and check three different batches
- risk assessment may be used to reduce the amount of analytical testing

For both DFC and Non-DFC, the following applies:

- Migratable NIAS and NLS shall be assessed considering the max. amount that is expected to be present and following the EuPIA NIAS Guidance.

Step 4: Assessment of Migration Potential based on Migration testing or modelling results.

See step 2, case B (WCC shows that SML might be exceeded)

∗ Migration Testing /MM shows that the SML will not be exceeded.
→raw material approved for the intended max. % (as used in the MT/MM) and product type

∗ MT/MM shows that the SML will be exceeded, or MT/MM results are inconclusive
→ raw material is not approved for the intended max. % and product type.

Raw material either

- not to be used, or
- to be used at lower max.%, and/or restricted to specific uses only, after additional migration testing and re-assessment.

Restrictions to specific uses to be clearly described in the Technical Data Sheet.

Listing of potentially migratory substances in the SoC is mandatory in both cases.

To perform migration tests it is highly recommended to follow the EuPIA Migration Guidance, where all details are explained.