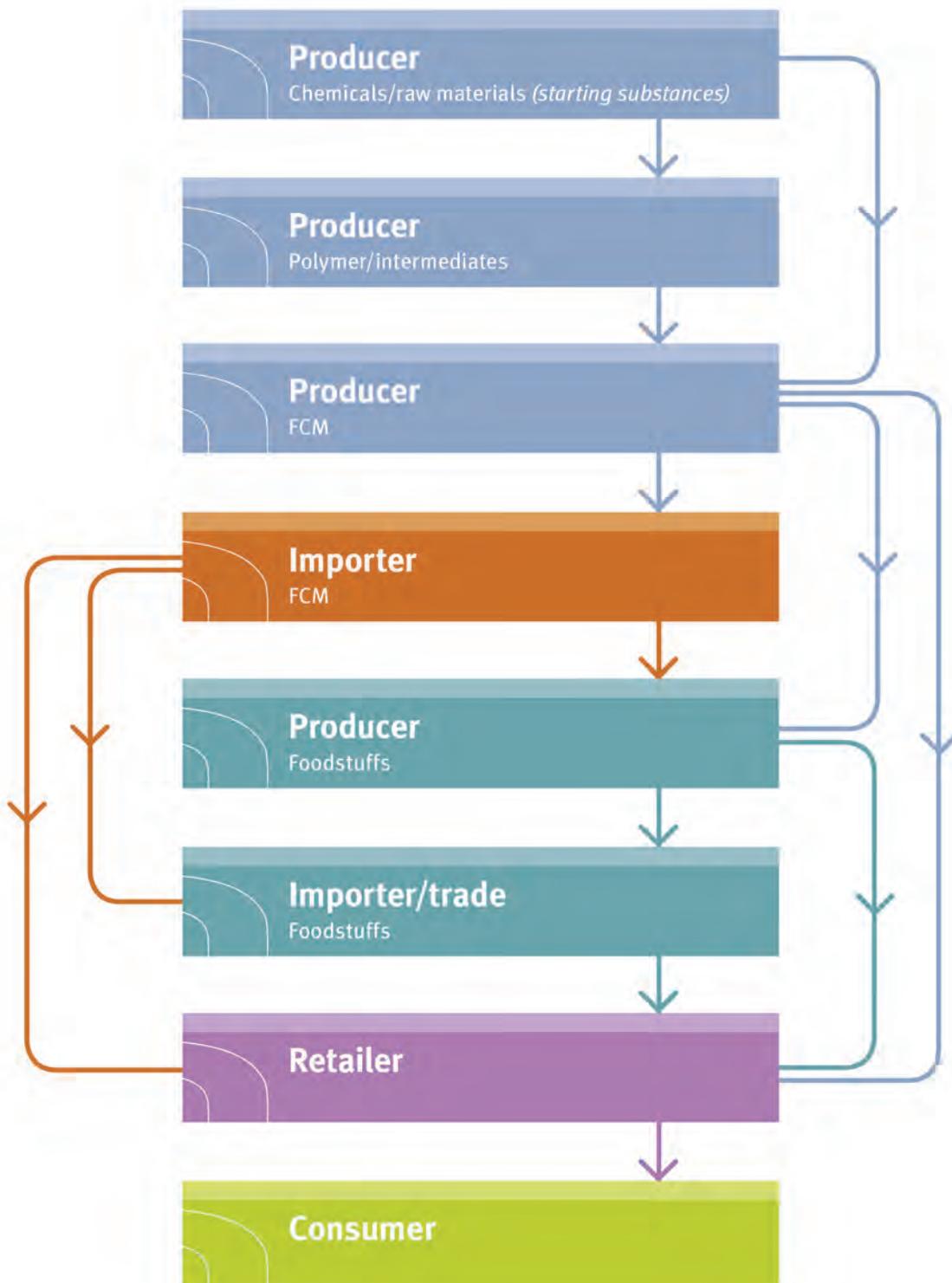


Food contact materials and articles: Printing Inks

Check lists for compliance in industry and trade and control by food inspection





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Preface

Food contact materials (abbreviated FCM in the following) are a potential source of contaminants in all types of foods. Food is normally in contact with one or several types of FCM, e.g. as in process equipment and packaging, including printed multilayer materials.

In-house control based on declaration of compliance and supporting documentation at the producers and importers are important prerequisites for the limitation of this contamination and to ensure compliance with the legislation. This is a general element of quality assurance, even though the European legislation does not specifically regulate printing inks.

The Nordic countries – Denmark, Finland, Iceland, Norway and Sweden – have had trade agreements and have co-operated within numerous areas for many years. Official opinions and public debate within one Nordic country will, in many cases, give rise to questions and debates in the other countries. Frequently, the call for uniform guidance and interpretations is brought forward, especially when the decisions and opinions within a certain area deviate from one other. This could become the case in areas where for instance guidelines for, and control of, in-house declaration of compliance and supporting documentation of FCM were following different paths in the various Nordic countries.

In principle, the establishment of in-house documentation, including declaration of compliance on FCM does not differ from the establishment of documentation on compliance in the in-house documentation of other areas under the food law.¹ However, the FCM area is sometimes regarded as more complicated to deal with.

Some may regard an FCM as being even more complicated, if including printing inks. This is likely due to an extensive lack of risk assessments compiled by international experts, e.g. in the European Food Safety Authority. EFSA (European Food Safety Authority) has assessed few of the chemicals used in printing inks, and risk assessments created by ink producers are often absent.

¹ EU Regulation no. 178/2004.

Industry and trade have an obligation to have

- Methods to ensure knowledge on materials, including critical point in their production
- Documentation
- Declaration of compliance and
- When needed, supporting documentation on compliance of FCM. This would include data on printing inks, their possible migration and test methods for analysis of migration, critical control points in the printing processes and the potential risk from set-off

Guidance on FCM has been given for years from authorities in the Nordic countries, both from the individual countries and from joint work with check lists in the Nordic Council of Ministers, including provision of check lists.

The Nordic countries have a long tradition of co-operation in the area of FCM and guidance for in-house control in the FCM area. Furthermore, these countries have similar legislation in major parts of the area of food packaging. With Denmark, Finland and Sweden being members of the European Union, and Iceland and Norway being associated through the European Economic Agreement (the EEA agreement), the subject of in-house documentation and declarations of compliance for food packaging was dealt with in a project group under the Nordic Council of Ministers.

The project group consisted of the following persons:

Denmark	<i>Bente Fabech</i> (chairperson) Danish Veterinary and Food Administration, <i>Gitte Alsing Pedersen</i> , Technical University of Denmark, DTU, National Food Institute
Finland	<i>Liisa Rajakangas</i> , Ministry of Agriculture and Forestry <i>Pirkko Kostamo</i> ; Finnish Food Safety Authority Evira
Iceland	<i>Grimur Olafsson</i> , Public Health Authority of Hafnarfjörður and Kópavogur
Norway	<i>Erlend Carlson</i> , Norwegian Food Safety Authority
Sweden	<i>Susanne Ekroth</i> , <i>Åsa Lagersted Nordström</i> and <i>Reggie Vaz</i> , National Food Agency

The Nordic Committee for Nutrition and Toxicology adopted the project which was sponsored by the Nordic Committee of Senior Officials for Food Issues under the Nordic Council of Ministers.

The project group would like to give special thanks to Paul Hunt, representing EuPIA, the European Printing Inks Association and Walter Quasigroch, Federal Ministry of Food, Agriculture and Consumer Protection, Germany, who provided their valuable contribution and knowledge in elaborating this project.

Summary

In-house control and the documentation of it is the basis for the assurance of compliance with legislation, both in the food area and in the area of food contact materials (called FCM).

Safe FCM is a complicated area for printing inks, also due to the critical control points in the printing process. It is therefore useful to have more precise check lists on printing inks as guidance to industry and trade, both in the Nordic countries and in EU.²

One of the goals for this check list is to contribute to the development of more uniform control and requirements for in-house control of FCM, both for products produced in EU and for those in third countries producing FCM for import into EU.

A further goal for the project was that check lists could be used as basic guidance for industry, trade and for the food inspectors in the Nordic Countries in their work in controlling in-house declaration of compliance of printing inks and printing processes.

The legal requirements in EU with relevance for FCM are found in different regulations and directives. The legal basis for the requirements of declaration of compliance is covered by several part of the EU legislation, like the Food Law,³ the Control regulation,⁴ the Hygiene regulation⁵ and the regulation on FCM. This includes the FCM framework regulation no. 1935/2004 and the GMP regulation no. 2023/2006 that covers all types of materials,⁶ and the production of them.

Printing inks used in FCM are regulated by these general requirements and some uses are addressed more specifically,⁷ and as there is no specific legislation in the area in EU yet, the responsibility of compliance could benefit from more guidance and risk assessments.

With this work on printing inks, the Nordic Food Authorities have continued previous work on elaboration of check lists with the minimum requirements for documentation, especially the declaration of compli-

² This check list on printing inks is a supplement to the general check list for all types of FCM. Nordic report, TemaNord 2008:517 (long and short version, see <http://www.norden.org/da/publikationer/publikationer/2008:517>)

³ Food Law no. 178/2002

⁴ Control regulation no.882/2004

⁵ EU hygiene regulation no. 852/2004 (*especially* art. 5, Annex II, chapter X).

⁶ The GMP regulation does not cover, e.g. stones and leather.

⁷ EU regulation no. 1935/2004, EU regulation no. 2023/2006 and national legislation e.g. on declaration of compliance.

ance needed to comply with the legal requirements for the in-house documentation of industry and trade.

The report has a short introduction to printing processes and some of the critical points in these processes. Such knowledge is regarded as useful in the control and quality assurance.

In-house documentation, including declarations of compliance with the legal requirements, supporting documentation for the declaration and request of other types of information, are based on the assumption, that each link in the chain ensures compliance. The links from producers of chemicals for FCM to the users of the final materials in the food industry and trade rely on each member of the supply chain taking responsibility for providing and communicating information critical to ensuring compliance of the final, packaged foodstuffs or the final material or article sold to the consumers. Furthermore, it is important for the food safety aspects that food industry and also consumers follow the instruction of use on the labels of the FCM sold directly to them.

The check lists for the control of compliance for printing inks set a specific frame with minimum requirements to all relevant links in the chain from producers or importers of chemicals and raw materials like additives to the users of the final FCM in the food industry and trade, including intracommunity trade in the EU and import from third countries.

The check lists are guidance with the aim to give a starting point for industry and trade when developing their in-house documentation and declaration of compliance. It can be used in present and future work on constructing in-house control documentation or work on improvements of the documentation in order to ensure compliance with the requirements in the legislation, especially the EU regulation no. 1935/2004. Industry and trade would in most cases face supplementary requirements to ensure the technical properties of the printed surfaces, but this type of requirements are not included in this report.

Definitions and abbreviations

The following definitions and abbreviations are used in this report.

BfR	Federal Institute for Risk Assessment, Germany
CEN	European Committee for Standardization (CEN): Organization for development of European Standards and other technical specifications
DOC	Declaration of compliance: A written declaration of compliance stating that FCM complies with the rules applicable to them. This is to strengthen the coordination and responsibility of the suppliers at each stage of manufacture, including that of the starting substances, that the responsible persons should document the compliance with the relevant rules in a DOC, which is made available to their customers
EFSA	European Food Safety Authority
EU	European Union
EuPIA	European Printing Ink Association, a division of CEPE, the European Council of the Paint, Printing Ink and Artists' Colours Industry. EuPIA represents the interests of the vast majority of the European manufacturers of printing inks
FCM	Food contact materials
FDA	Food and Drug Administration, USA
NIAS	Non-intentionally added substances (covering reaction products and degradation products of the ingoing starting substances)
PAA	Primary Aromatic Amines
PAH	Polycyclic aromatic hydrocarbons
PCB	Polychlorinated biphenyls.
Set-off	Transfer of printing ink components from a printed packaging material or article into food or food simulant may occur either directly as migration through the substrate, or via contact to the reverse side in the reel or stack, known as set-off migration, or by gas phase transfer
SML	Specific Migration Limit
Supporting documentation	Appropriate documentation to demonstrate that FCM from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those FCM comply with the requirements of Regulation no. 1935/2004 shall be made available by the business operator to the national competent authorities on request. That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance.

1. Printing inks and printing processes

Printing inks are used to print on to many different kinds of food packaging materials and articles (FCM). Printing inks are normally used on the outer layers of FCM, or between one of the outer layers of a multi-layer material.

The EU GMP regulation assumes that printing inks applied to the non-food contact side of a material or article should do as follows “The printed surfaces shall not come into direct contact with food”. Direct food contact inks are not commonly used in food packaging, but where they are the industry gives the information, that these inks are made under very onerous restrictions in terms of formulation and manufacturing assets.

More than five thousand different chemicals are used in the production of printing inks.⁸ A minor part of the substances are evaluated by EFSA and restricted by a Specific Migration Level (SML).⁹ In addition most of the printing ink chemicals on the industry inventory lists are not fully risk assessed and toxicological data may be sparse. However, industry and trade have the obligation to demonstrate safety in use, and the public food inspection has to control it.

1.1 Printing ink, general on composition

Inks can be either solvent based, water borne, oleoresinous or energy-curing system.

Packaging inks are complex mixtures manufactured from colorants (5–30 %), binders (15–60 %), solvents (20–70 %) and additives including plasticizers (1–10 %) (SNT, 2003).

⁸ The substances were listed on an inventory list given by industry (Council of Europe, 2007) and on a newly revised list by the Swiss authority (Swiss Confederation, 2009a) and also by the European professional organization EUPIA.

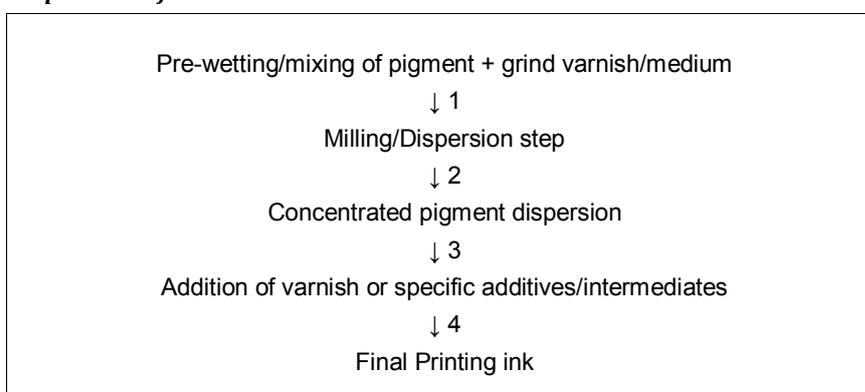
⁹ In the legislation on plastics, EU regulation 10/2010.

The *colorants* are the visible part of the inks and are categorized as either:

- Dispersions of *insoluble pigments* or
- *Solutions of dyes* (although such chemicals are not used extensively in modern food packaging inks)¹⁰

The steps in preparation of the ink formulations are given below.

Preparation of inks



In manufacturing of some inks (notably whites) the intermediate concentrate production (Step 2) can be avoided through adding all necessary additives prior to milling step 1, thus producing a finished ink in a single step.

Many pigments require milling to create the particle size required to create the maximum color possible from the pigments used. Some pigments do not need milling and can create color through simple high speed dispersion (e.g. production of white and black inks often does not require a full milling step).

A varnish, whether used in the grinding medium, as a so-called technology varnish (that is a varnish that contains a range of additives critical to final ink performance needs) or as an overprinting coating all contain a mixture of additives (polymeric or monomeric) and solvents. These are often created through simple blending on simple stirring/dispersing assets.

The number and categories of substances on the industry inventory list (transferred into the Swiss legislation of printing inks) used for manufacturing of packaging inks are given in *Annex I* together with a short description of the different substances.

¹⁰ Personal communication, Paul Hunt, Sun Chemical, November 2011)

1.2 Printing processes

Printing can be applied to the outer surface of a food packaging or in the middle of a multilayer packaging material or to the inside (the food contact side) of a FCM.

Different techniques can be used for the printing processes. In the production of printed food packaging the following listed are the most often used technologies for printing. A short introduction of the different techniques is given below.

- Offset
- Flexography
- Gravure printing
- Ink jet printing

Some critical points in formulation, production etc. is described in *Annex II*.

The ink producers are the responsible for the initial ink composition as delivered in the form of mixtures of varnish, additives and colorants to the printing company. However, it is possible for printers to add further chemicals/components to inks prior to its application to substrate in the printing press.

After applying the ink formulation to the substrate (FCM), drying of solvent and binder takes place. Depending of the field of application printing inks have different mechanisms of drying such as *evaporation, absorption into substrate, oxidative drying or curing* by supply of irradiated energy, e.g. in UV systems.

The energy-curing printing inks require special presses to ensure suitably effective cure, however, they are printed on to substrate using one of the 4 printing processes listed above.

1.2.1 *Offset printing*

This technique is the most used technique for printing paper and cardboard FCM (Richter et al. 2009). In *offset inks* the solvents are non-volatile and traditionally they are mineral oils or vegetable oils with boiling points in the area of 210–300 C (Silverberg, 1995). Drying of the system is achieved by absorption of solvents into the paper. The amount of oils in off-set print constitutes approximately 25 % of the printing ink formula (Silverberg, 1995).

Alkyl benzenes, with alkyl chain of C₁₀–C₁₃, have been found in off-set printed paper board and in the packed food (Aurela *et al.*, 2001) and contamination of recycled paper with aromatic and linear hydrocarbons from printing inks have recently been reported in different studies including Biederman M. and Grob K., 2010.

Currently new inks are being developed for paper and board with the use of novel fatty acid esters to substitute for mineral oils and reduce the risk of migration of hydrocarbons (Richter *et al.*, 2009).

Binders of alkyd resins are commonly used in offset printing. Linseed oil was historically a commonly used binder in offset print and may still be a part of the alkyd binder (Silverberg, 1995). The subsequent drying of the binder (after drying of solvents) is achieved by oxidation from reaction with air. Oxidative drying is a rather slow process compared to the drying of volatile solvent but can be accelerated by the use of heat (Silverberg, 1995). The drying process depends on many factors such as the applied amount of ink, water content in the paper and surroundings and the availability of air to every part of the substrate (Silverberg, 1995). Even after several days, the drying of offset printing may not be fully completed. The supply of heat may stimulate chemical reactions of the substances in the ink (Silverberg, 1995).

Today UV curing inks are used in many packaging segments in which offset printing are applied; this includes the printing of labels (personal communication from Flint Group Denmark).

1.2.2 Flexographic printing

The flexographic technique is considered a more modern technique. It has a growing market share and is now the most used technique for food packaging materials (SNT, 2003). *Flexographic printing* can be applied to all kinds of materials including food packaging based on plastic, paper, board and metal.

Flexographic inks have a lower viscosity than offset inks and are based on volatile solvents as e.g. ethyl acetate and alcohol (Silverberg, 1995). Flexographic inks are used for printing on flexible films and laminates (MST, 1999) and drying of the print is mainly achieved by evaporation of the solvents.

Water borne inks are used as an alternative to solvents in flexographic package printing. In this case a supply of high volume, warm air is usually needed in the printing process to supplement ink drying through absorption in to the paper.

UV-curing systems are considered a good way to eliminate the use of solvents and again are used in a range of applications which includes printing of labels (Flint Group Denmark, Kipphan, 2010). The number of different pigments that can be used in flexographic inks is high, which facilitates its use in a broader set of print applications (Kipphan, 2001).

1.2.3 Gravure printing

Gravure printing is an older printing technique. Gravure printing is capable of detailed printing of high quality but is generally more expensive than flexographic and offset printing. The substrate can be paper or plastic. Inks used for gravure printing are quite similar to those used with flexography and have their characteristic fluid nature, so called liquid inks.

Although gravure printing of UV cured inks is feasible, it is not commonly used to apply these types of ink (personal communication, Flint Group Denmark; Paul Hunt, Sunchemical, 2011).

1.2.4 Ink Jet printing

There is growing use of ink jet printing in the manufacture of FCM. Such technology produces point-of-sale information graphics (e.g. Bar Codes) and has become a common printing technology used in printing labels.

Ink jet inks can utilize water-based, solvent-based or energy-curing type inks in their application on packaging/labels (personal communication, Paul Hunt, Sunchemical, 2011).

Special note on Energy-curing ink technology and Use

A typical UV inks may consist of:

- Monomers and prepolymers (oligomers) of e.g. acrylates (50–75 %)
- Pigments 10–30 %
- Photoinitiator 5–20 %
- Additives 1–4 % as e.g. surface active substances, wax, silicones and curing inhibitors (eq. hydroquinone) (Kipphan, 2010; Grafisk Bar, 2000)

Monomers provide the solvent like properties in the ink and together with oligomers react chemically to form the binder system.

Pigments and additives: Colorants and additives used in UV-curing inks correspond approximately to those of other printing ink technologies (Kipphan, 2001).

Photoinitiators are activated by UV radiation (wavelength 100–380 nm). This makes the photoinitiators decompose to radicals and thereby release energetic species which can start the curing (polymerization) of the acryl-resin binder.

UV lamps with different intensity are used depending on the type of ink used (including type of photoinitiator), thickness of the print and rate and intensity of the printing process. It is important to select the kind of UV lamp with sufficient intensity for optimal curing of the given system (MST rapport, 1998). The lifetime of a UV lamp is between 1,000 and 2,000 hours as the intensity of the lamps will gradually decrease while they are used.

UV curing inks are not suitable for thick, porous materials such as certain untreated grades of paper and board because the inks penetrate deeply into such materials and make it difficult for the radiation to penetrate deeply enough to achieve sufficient curing of the inks (Sun Chemicals personal communication).

There are two types of UV curing mechanisms/chemistries used in printing:

- The *radical system*, where the curing is only active as long as the UV radiation is on. In this system residual levels of monomers (e.g. acrylamid, acrylic acid, methylacrylate) may be present in the final material after curing. Focus on optimizing the process is very important to keep the level of residual monomers and photoinitiators as low as possible
- The *cationic system*, where the curing is activated by UV radiation and can continue afterwards without radiation. However, the most used photoinitiator with this system, triarylsulphonium salt, can give rise to an undesirable by-product by generation of *benzene* on curing (personal communication to Sun Chemicals). The cationic system is only seldom used with FCM in Denmark (MST, 1998 and personal communication to Sun Chemicals). Due to the ongoing curing in cationic systems, the level of residual monomers in this system is much lower than with radical curing (MST; 1998)

It should be noted that drying by UV curing is a very quick process compared to the drying of water and solvent borne inks (MST, 1998).

In general the following parameters can affect the curing of UV inks:

- Intensity (effect) and age of the UV-lamps
- Type of reflector, type of substrate, thickness of the print
- Speed of printing process
- If drying between the different steps is included or not
(www.Sicpa.com)

It is important to consider residual levels of allergenic acrylate monomers and impurities in the raw materials used with UV inks as these substances are known to be potentially present (Grafisk Bar, 2000).

Migration of photoinitiators such as benzophenone and 4-methylbenzophenone into food has been shown in recent years to be a problem. In a German study on migration of the photoinitiator, 2-isopropylthioxanthone (ITX) into different kinds of food, the level of migration was above 50 microgram/kg in 10 % of the samples, with the highest levels at 357 microgram/kg in orange juice and 208 microgram/kg in baby food (Rothenbacher et al, 2006).

It is known that UV radiation may cause photodegradation of dyes and pigments in print (SNT, 2003). For instance 4,4-bis(dimethyl-: ami-

no)benzophenone (Michlers ketone) is a possible degradation product from violet dyes or pigments (Salafranca et al, 2000). Safe choice of colourants is clearly a critical part of formulating safe energy curing inks.

Today the introduction of a new curing system based on electron beam (EB inks) radiation is becoming gradually more popular in the printing industry. These EB inks have no need for the use of photoinitiators in their formulation (personal communication from Sun Chemicals).

Some further critical points in formulation, production etc. are described *in Annex II*.

2. EU legislation and national guidelines for printing inks

The EU legislation on FCM is briefly described below in relation to printing inks. In the European Union there is no specific regulation on printing inks and none of the Nordic countries have national legislation for printing inks. However, some countries in Europe have, or are preparing for specific legislation of inks in the FCM area (November, 2011).

2.1 EU regulations

Printing inks¹¹ are covered by the general requirements in the *EU Council Regulation no. 1935/2004* and in *EU regulation no. 2023/2006* on Good Manufacturing Practice.

The requirements in regulation no. 1935/2004, covered by article 3 are crucial in ensuring food safety. These general requirements state that FCM shall, under normal and foreseeable conditions of use, not transfer their constituents into foodstuffs in quantities, which could:

- Endanger human health
- Bring about an unacceptable change in the composition of the foodstuffs or
- Bring about deterioration in the organoleptic characteristics thereof.
- This regulation applies to all FCM, which in their finished state are:
 - Intended to be brought into contact with food; or
 - Already brought into contact with food and are intended for that purpose; or
 - Can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use

¹¹ Either on the outer surface of the package or included in the inner layer of a multilayer or on the inside (the food contact side) of a FCM material.

The EU Commission Regulation no. 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food is furthermore essential. This regulation has requirements for quality assurance in the production of FCM and the intermediates used in the FCM, like the printings inks.

The more detailed rules on GMP for printings inks on the non-food contact side state that

“Processes involving the application of printing inks to the non-food contact side of a material or article

1. Printing inks applied to the non food-contact side of materials and articles shall be formulated and/or applied in such a manner that substances from the printed surface are not transferred to the food-contact side:
 - a. through the substrate or;
 - b. by set-off in the stack or the reel, in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.
2. Printed materials and articles shall be handled and stored in their finished and semi-finished states in such a manner that substances from the printed surface are not transferred to the food-contact side:
 - a. through the substrate or;
 - b. by set-off in the stack or reel, in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.
3. The printed surfaces shall not come into direct contact with food.”

From the EU Standing Committee on Food and Animal Health, March 2009 (EU Commission, 2009), there was a majority decision on some of the most commonly used photoinitiators 4-methylbenzophenone and benzophenone, stating that in-house documentation shall demonstrate that migration of 4-methylbenzophenone and benzophenone, must be below 0.6 mg/kg.

According to the Regulation on Control no. 882/2004, Article 8, the public food inspection can request detailed information on e.g. composition, testing of migration and set-off etc. for printing inks.

2.1.1 Compliance and negative lists

Compliance with regulation no. 1935/2004 shall be based on risk assessments of the chemicals used in the composition of the printing ink, including evaluation of possible migration or set off of these chemicals into the food.

Negative lists are drafted by EuPIA on chemicals which should not be used in printing inks. Negative lists should be regarded as information to the printing inks producers and might be useful in the printing inks production.

However, negative lists are not relevant in documentation of compliance as negative lists do not give information on the compliance of chemicals used in the printing inks and the possible migration of these chemicals and thereby the safety of use of printing inks.

2.2 National regulations, in certain European countries.

In addition to the harmonised legislation in Europe, some countries have national legislation.

Legislation relevant for printing inks in FCM is as follows:

2.2.1 *The Nordic Countries: Denmark, Finland, Iceland, Norway and Sweden*

None of the Nordic countries have additional, national legislation on printing inks. However, there are other parts of the legislation as in the Danish,¹² Finnish¹³ and Norwegian¹⁴ request for declaration of compliance for all type of FCM, does also cover declaration of compliance of printing inks.

Denmark, Finland and Norway require FCM producers and importers/operators to be registered and these companies are subject to public control.

Denmark, Finland and Norway request declaration of compliance for all types of FCM.

2.2.2 *Some other European countries: Switzerland and Germany*

Legislation in Switzerland and Germany (draft), associated country to the EU and EU member state respectively, is described in the following.

Swiss regulation on printing ink

In Switzerland a new regulation for printing inks was issued in 2010. On the basis of the inventory list of substances given by EuPIA (EuPIA, 2009a) and Council of Europe (Council of Europe, 2007), the list is being regularly revised and a complete list of substances in use is provided.

¹² Danish Order on food contact materials nr 579 of 01/06/2011 (revision of former order with the same requirements).

¹³ Finnish Food Ac 23/2006, requirement of registration 21a§ change 643/2010.

¹⁴ Norwegian food contact regulation, § 4c, 1993-12-21 nr 1381: Forskrift om materialer og gjenstander i kontakt med næringsmidler (matkontaktforskriften); <http://lovdata.no/for/sf/ho/xo-19931221-1381.html>

The substances are classified into a list A of evaluated substances and a list B of non evaluated substances (see Annex I). In the latest published list of authorized substances List A covered 1,116 substances and List B covered 4,608 non-assessed substances.

According to the Swiss regulation, substances may only be used for food printing inks provided that they meet the following requirements:

- Substances on list A have to comply with the restrictions (SML's from the EU Plastic Regulation) given for the individual substance
- Substances on list B may be used for manufacturing of packaging inks if no transfer of these substances to foodstuffs or food stimulants can be detected with a detection limit of 10 microgram/kg (including the analytical tolerance)

German regulation on printing ink (proposal)

In Germany, a proposal for national legislation on printing inks is drafted (personal communication, Walter Quasigroch, November 2011). The draft regulation will include a list of substances which are approved (due to evaluations by EFSA, JECFA and BfR) for use in printing ink formulations for FCM. The starting point for this is the Swiss regulation on printing inks.

In addition to this, chemicals which have not been risk assessed are listed but are not included in the legislation. The non-regulated substances might be used if the migration is not detectable (detection limit 10 microgram per kg food) and the substances are not classified as neither carcinogenic, mutagenic nor reprotoxic.

Toxicological risk assessment and an authorization procedure for chemicals used in printing ink will be a part of the proposed activity in Germany.

2.3 Guidelines from the European organization on printing inks EuPIA

The European Trade Association for printing ink makers, EuPIA, has published guidance documents and other information for their member companies; see an overview on

- http://www.eupia.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=10008E&eas:dat_im=05048E

Some point from this guidance is mentioned *in Annex III* (version 2009).

3. Check lists for drafting declaration of compliance

Printing inks used in FCM, are a potential source of contamination of the packed food. The final material shall comply with the legislation, including requirements on migration and set-off. Adequate in-house control in industry at every step of production is a tool to prevent violation of this legislation.

The responsibility for evaluation of the migration and risk assessment of transfer of chemicals in the printed FCM is on the producer, user and importer of FCM ensuring that the migration of all substances is within the official SML's (when found, e.g. in the EU Plastics Regulation) and/or without endanger to human health. The basis for the correct use of printing inks must derive from instructions of use from the producers of printing inks and it is the responsibility of the user of the inks to follow the instructions of use (normally in the form of a Technical Data Sheet "TDS" or declaration of compliance).

The check lists in this chapter are meant as guidance in developing declaration of compliance at each link of the chain from producer of the chemicals used in printing inks via the producers of final food contact material to the users of the final, printed packaging.

The check lists focus on critical steps in production, from selection of the starting substances (the chemicals) used in printing inks through to printing of the FCM and the use of the final FCM in the food industry. Risk assessment of chemicals and possible migration or set-off is requested at appropriate steps. Some critical control points in the processing are listed in Annex II.

3.1 Instructions of use

As a part of compliance declaration the printing ink producer is responsible for giving instructions of use of the inks, when this is needed.

However, if at the printers, extra solvents or additives are added by the printer (if required) before the ink is applied to the substrate, e.g. the surface of a plastic material, then the risk assessment for the extra solvents or additives should also be taken in to account in the risk assessment. This should be done either by the ink producer (if they advise the addition) or by the printer. The type of additives and solvent that can be used should at least be discussed with the ink maker prior to its use on press.

3.2 Supporting documentation

The supporting documentation for declarations of compliance is the background documentation, including details on e.g. recipes, analytical methods, migration testing and evaluation of migration results.

Supporting documentation shall be available for authorities on request, and within a short timeframe, e.g. 1–2 weeks.

3.3 Check lists as guidance for DoC in-house control

In house control of printing inks and printed FCM shall fulfill the regulations of 1935/2004 and 2023/2006 (GMP regulation).

The checklist below is meant to be used as guidance for establishing necessary in-house control and standard procedures by the industry.

The check lists are in addition meant to be used by the public food inspectors as a tool for verifying that the required information is present in the declaration of compliance.

Check list 1: General requirements and guidance for in-house control of all types of FCM

- *Legislation:* Requirements in EU legislation and national legislation on FCM, including EU regulation no. 1935/2004 and regulation no. 2023/2004 have to be met. The documentation of this should be part of the in-house quality assurance and documented in declaration of compliance and the supporting documentation
- *Updating:* The declaration of compliance shall always be updated when there are changes such as changes in the legislation or if changes are made in the composition or production of the FCM (including intermediates). In general, the documentation shall be re-viewed and revised periodically e.g. this could be once a year
- *Language:* The in-house declaration of compliance and documentation shall be written in a language understood by industry and trade and the national public food inspection
- *Supporting documentation:* Shall be available for the public food inspection on request, and within 1-2 weeks
- *Knowledge of suppliers and customers:* All links in the chain should have knowledge of the legal frame under which their suppliers and customers work. A dialog between the stakeholders is demanded
- *Analysis:* There are two general points:
 - Sampling of printed FCM for analysis shall take place at critical points, like start of a new production, after drying or curing of the ink, etc.
 - Analysis should in general follow a standardised or validated method by accredited laboratories

Check list: 2 Producers of chemicals and raw materials

Chemical substances and other raw materials produced and sold for the production of FCM shall have documentation for compliance with the requirements set in the EU regulation 1935/2004 and specific measures on the area.

The term “Producers” covers the national producers, producers in EU and importers into EU from third countries.

The declaration of compliance to the customer should include the following information:

Minimum requirements to suppliers of printing ink chemicals and raw materials:

- Chemical name and CAS-number for all substances used, including pigments and colorants
- EFSA opinion of the chemical substances (if available) *or*
- Producers risk assessment and documentation on toxicological test-ing (in-vitro and in-vivo) in accordance with the EFSA requirements for chemicals to be used in FCM) *or*
- Risk assessment of chemical substances from other countries following guidelines and data requirements equivalent to the EFSA requirements, like BfR or FDA
- Restrictions in other legislations, e.g. if the chemicals are regulated as food additives, including the requirements for purity and identity
- If non-evaluated chemicals are sold for FCM uses, these chemicals should not be mutagenic, carcinogenic or repro-toxic and be used only behind an appropriate functional barrier.

Please, see also the check list 1 general requirements.

Check list 3: Producers of printing ink formulations

Producers of intermediates such as formulations of printing inks etc. have the responsibility of selecting chemicals, for which a risk assessment is available, and to produce products, which will comply with the legislation when used in accordance with guidance or instructions of use given to the user. In this section, producers cover the national producers, producers in the EU and importers into EU from third countries.

Minimum requirements to suppliers of printing chemicals and raw materials:

- Name and address of the supplier
- Traceability
- Chemical name and CAS-number on all substances used; including pigments and colorants for substances
- EFSA opinion of the chemical substances (if available) or
- Producers risk assessment and documentation on toxicological testing (in-vitro and in-vivo) in accordance with the EFSA requirements for chemicals to be used in FCM) or
- Risk assessment of chemical substances done by other countries following guidelines and data requirements equivalent to the EFSA requirements, like BfR or FDA
- Restrictions in other legislations, e.g. if the chemicals are regulated as food additives, including the requirements for purity and identity
- If non-evaluated chemicals are sold for FCM uses, these chemicals should not be mutagenic, carcinogenic or repro-toxic and be used only behind an appropriate functional barrier
- Provide adequate information to the manufacturer of printed FCM, covering critical points in the printing process (e.g. drying, curing of ink formulation on the substrate and instructions of use of the ink, e.g. the need for use in combination with a functional barrier)

Please, see also the check list 1 general requirements.

Check list 4: Producers: Final FCM

Producers of final FCM are producing the FCM from the chemical raw materials and/or from intermediates. Some materials can be suitable for contact with a wide variety of foods under many different conditions of use, while others would have a limited area of use. Producers cover the national producers, producers in EU and importers into EU from third countries.

Minimum requirements to producers of inks formulations:

- Name and address of the ink supplier
- Traceability
- Declaration of compliance and documentation on risk assessment of the chemicals in the FCM
 - Are the chemicals e.g., additives on positive lists in the legislation
 - EFSA assessment, including report no.
 - Industry risk assessment conducted in accordance with EFSA guidelines
 - Risk assessment of chemical substances done by other countries following guidelines and data requirements equivalent to the EFSA requirements, like BfR or FDA.
- Information on analysis of migration of the FCM, including specific test conditions, simulants used or analysis in foods, duration of the test etc. Compliance with migration limits can be demonstrated by calculations based on recipes, on modelling and on chemical analysis.
- For dual-use additives, specifications on purity and identity and quantitative content and information on quantitative content in the FCM
- Information on quantitative content of substances functioning as surface active biocide
- Migration below the general “detection limit” of 10 ppb for non evaluated substances – given that these are not mutagenic, toxic to reproduction or carcinogenic (see producer of print formulations)
- Advice on conditions and restrictions of use of the final FCM., including instructions of use of the printing inks in combination with e.g. surface coatings like lacquers
- Provide adequate information to the manufacturer of FCM including instructions of use, covering critical points in the production (e.g. drying, curing of ink formulation on the substrate and the need for use in combination with a functional barrier)

Please, see also the check list 1 general requirements.

Declaration of compliance and documentation to the customers shall fulfil the demands of the customer, to enable the customer to take adequate measures to ensure correct use of the printing inks.

Contamination from printing inks into the food can be evaluated and tested in different manners, see Annex V for a short introduction.

Check list 5: Food producers: Users of final FCM

Food producers are users of the final FCM. Some materials can be suitable for contact with a wide variety of foods under many different conditions of use, while others would have a limited area of use. Such information should be taken into account by the user of the FCM.

Food producers cover the national producers, producers in EU and importers into EU from third countries.

Minimum requirements to the supplier of printed FCM:

- Name and address of the supplier
- Traceability
- Declaration of compliance and documentation on risk assessment of the chemical in the FCM
 - Are the chemicals e.g., monomers and additives on positive lists in the legislation
 - EFSA assessment, including report no.
 - Industry risk assessment conducted in accordance with EFSA guidelines
 - Risk assessment of chemical substances done by other countries following guidelines and data requirements equivalent to the EFSA requirements, like BfR or FDA
- Risk assessed of potential migration includes the intended use, like food types in contact, temperatures, contact time surface-volume ratio etc.
- Information on analysis of migration, including specific test conditions, simulants used or analysis in foods, duration of the test etc. Compliance with migration limits can be demonstrated by calculations based on recipes, on modelling and on chemical analysis
- For dual-use additives, declaration of compliance and documentation on specifications on purity and identity and quantitative content and information on quantitative content in the FCM
- Information on quantitative content of substances functioning as surface active biocide
- Migration below the general detection limit of less than 10 ppb of non-assessed substances
- Non-evaluated chemicals should not be mutagenic, carcinogenic or reprotoxic
- Advice on conditions and restrictions of use of the final FCM., including instructions of use of the printing inks in combination with e.g. surface coating like lacquers and/or functional barriers and specification of such barrier
- Provide adequate instructions of use, covering critical points in the production (e.g. drying and curing of ink formulation on the substrate)

Please, see also the check list 1 general requirements.

4. Recommendations

The establishment of appropriate in-house declaration of compliance and documentation for FCM is an ongoing process. The EU (and national risk assessments of chemicals and raw materials are in progress, industry is improving guidelines and advise and the EU legislation is evolving, both in the area of FCM and in other related areas.

Knowledge is still missing on different areas, e.g., test methods and test conditions for different materials as well as guidelines in trade, industry, national food administration and food inspection on what can be regarded as sufficient in-house declaration of compliance and supporting documentation.

The recommendations given in this chapter reflects questions and needs raised during the work within this project. The responsibility to start work on the areas mentioned is not only that of the Nordic countries, the EU Member States or the Commission, but especially the responsibility of several involved stakeholders.

Recommendations for future work

- More harmonized EU/ESA legislation on FCM, including printing inks – internationally e.g. in EU and in Codex Alimentarius
- The EU Commission should be encouraged to arrange for a workshop with Member States on in-house documentation on FCM, including printed FCM
- Training courses or workshops in developing declaration of compliance where the whole chain – from producers of chemicals, intermediates and FCM to food industry – are participating could be an activity to improve compliance
- Seminars addressing the Nordic and EU/ESA industries and other responsible companies on documentation and declaration of compliance. This should including the critical points in processing e.g. of processing and use of printed FCM. The authority's participants should include the whole spectra of knowledge from chemists, toxicologists and food inspectors
- Industrial organizations should continue their efforts on the development of compliance declarations on specific materials and articles
- Research and development of test methods should be prioritized in order to facilitate less costly industry or in-house testing
- Joint Nordic networking e.g. on efforts in the food inspection, including coordinated Nordic control campaigns of in-house documentation and declaration of compliance

- Market and share the Nordic report on printing inks with colleagues e.g., in the EU and Council of Europe. Work together and support the international corporation, e.g., in EU or in Council Europe when developing a resolution on printing inks

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Sammenfatning

Egenkontrol kontrol og dokumentation af kontrollen er grundlaget for sikring af overensstemmelse med lovgivning, både på fødevarerområdet og inden for fødevarerkontaktmaterialer (kaldet FKM).

Sikring af FKM er et kompliceret område, specielt for trykfarver, også på grund af de kritiske kontrolpunkter i trykprocessen. Derfor kan det være nyttigt at bruge tjeklister om trykfarver som vejledning til industri og handel, både i de nordiske lande og i EU.

Et af målene for disse tjeklister er at bidrage til udviklingen af en mere ensartet kontrol og krav til egenkontrol af FKM, både for produkter produceret i EU, og for dem i tredjelande, der producerer FKM til import til EU.

Endnu et mål for projektet var, at udarbejde tjeklister til bruges som vejledning i industri, handel og i fødevarerkontrol i de nordiske lande i deres arbejde med kontrol af overensstemmelseserklæringer i egenkontrollen for trykfarver og trykprocesser.

De krav i EU lovgivningen, som har relevans for FKM, findes i forskellige forordninger og direktiver. Det juridiske grundlag for krav til overensstemmelseserklæring er i flere dele af EU-lovgivningen, så som fødevarerlovlovgivningen, kontrolforordningen, hygiejneforordningen og forordningen om FKM. Rammeforordning nr. 935/2004 og GMP-forordningen. 2023/2006 dækker alle typer af materialer og produktionen af dem.

Trykfarver, der anvendes i FKM, er reguleret af disse generelle krav, og nogle få anvendelser er mere specifikt reguleret. Da der generelt ikke er specifikke lovgivning på området i EU endnu, kan de ansvarlige for overholdelse af lovgivningen have behov for vejledning og risikovurderinger.

Med dette arbejde på trykfarver, har de nordiske fødevarermyndigheder fortsat tidligere arbejde om udarbejdelse af tjeklister med minimumskrav til dokumentation, især overensstemmelseserklæringer, som er nødvendige for at overholde de lovmæssige krav, der stilles til egenkontrol og dokumentation i industri og handel.

Rapporten har en kort introduktion til trykprocesser og nogle af de kritiske punkter i disse processer. En sådan viden anses for nyttige i kontrol og kvalitetssikring.

Egenkontrol og dokumentation, herunder overensstemmelseserklæringer med de lovmæssige krav, baggrundsdokumentation og anmodning af andre typer oplysninger, er baseret på den antagelse, at hvert led i kæden sikrer overholdelse af gældende regler. Leddene i produktions- og forsyningskæden fra producenter af kemikalier til FKM til brugerne af

de færdige materialer i fødevareindustrien og handel skal kunne stole på, at hvert led tager ansvar for at tilvejebringe og formidle informationer, som er vigtige for at sikre overholdelse af lovkrav til færdigt pakke- de fødevarer eller de færdige FKM, som sælges til forbrugerne. Desuden er det vigtigt for fødevaresikkerheden, at fødevareindustrien samt forbrugerne følger brugsanvisninger for FKM, som sælges direkte til dem.

Tjeklisterne til kontrol af overholdelse af regler for trykfarver sætter en ramme med minimumskrav til alle relevante led i kæden fra producenter eller importører af kemikalier og råvarer, fx additiver til brugerne af den endelige FKM i fødevareindustrien og handel, herunder samhandel inden for EU og import fra tredjelande.

Tjeklisterne er vejledning givet med det formål at give et udgangspunkt til industri og handel, til brug for etablering af egenkontroldokumentation og overensstemmelseserklæringer. Vejledningen kan bruges i arbejdet, nu og fremtiden – med at opstille egenkontrol dokumentation eller arbejde med forbedringer af eksisterende dokumentation, for at sikre overholdelse af kravene i lovgivningen, især EU-forordningen nr. 1935/2004.

Industri og handel vil i de fleste tilfælde også stå overfor supplerende krav for at sikre de tekniske egenskaber af de trykte overflader, men denne type krav er ikke medtaget i denne rapport.

Yhteenveto

Lainsäädännön noudattamisen varmistaminen perustuu omavalvontaan ja sen dokumentointiin. Tämä koskee sekä elintarvikkeita että elintarvikkeiden kanssa kosketukseen joutuvia materiaaleja ja tarvikkeita (elintarvikekontaktimateriaaleja, Food Contact Materials, FCM).

Elintarvikkeiden kanssa kosketukseen joutuvien materiaalien ja tarvikkeiden turvallisuus on painovärien osalta monimutkainen, osin painoprosessiin sisältyvien kriittisten valvontapisteiden takia. Siksi on hyödyllistä laatia teollisuudelle ja kaupalle ohjeeksi tarkempi tarkistuslista painovärejä varten, sekä Pohjoismaissa että EU:ssa.¹⁵

Yksi tämän tarkistuslistan tavoitteista on edistää yhtenäisemmän valvonnan ja vaatimusten kehittämistä elintarvikkeiden kanssa kosketukseen joutuvien materiaalien ja tarvikkeiden omavalvontaan koskien sekä EU:n alueella tuotettuja että kolmansissa maissa EU-tuontiin tuotettuja tuotteita.

Lisäksi hankkeen tavoitteena oli, että tarkistuslistoja voitaisiin käyttää perusohjeena teollisuudelle ja kaupalle sekä pohjoismaisille elintarvike-tarkastajille heidän valvoessaan yritysten omavalvonnannassa painovärien vaatimustenmukaisuusilmoituksia ja painoprosesseja.

Elintarvikkeiden kanssa kosketukseen joutuvia materiaaleja ja tarvikkeita koskevista vaatimuksissa on EU:ssa säädetty eri asetuksissa ja direktiiveissä. Säännösten noudattamista koskevien vaatimustenmukaisuusilmoitusten säädösperusta on useissa eri kohdissa EU-lainsäädäntöä, kuten yleisessä elintarvikeasetuksessa,¹⁶ valvonta-asetuksessa,¹⁷ yleisessä elintarvikehygieniasetuksessa¹⁸ ja elintarvikkeiden kanssa kosketukseen joutuvia materiaaleja ja tarvikkeita koskevissa asetuksissa. Näitä ovat elintarvikkeiden kanssa kosketukseen joutuvia materiaaleja ja tarvikkeita koskeva puiteasetus N:o 1935/2004 ja asetus elintarvikkeiden kanssa kosketukseen joutuvien materiaalien ja tarvikkeiden hyvistä tuotantotavoista N:o 2023/2006, joka kattaa kaikentyyppiset materiaalit¹⁹ sekä niiden valmistuksen.

¹⁵ Tämä painovärien tarkistuslista täydentää kaikentyyppisiä elintarvikkeiden kanssa kosketuksiin joutuvien materiaalien yleistä tarkistuslistaa. Nordic report, TemaNord 2008:517 (lyhyt ja pitkä versio, ks. <http://www.norden.org/da/publikationer/publikationer/2008-517>)

¹⁶ Yleinen elintarvikeasetus N:o 178/2002

¹⁷ Valvonta-asetus N:o 882/2004

¹⁸ EU:n yleinen elintarvikehygieniasetus N:o 852 (erityisesti 5 artikla, liite II, X luku)

¹⁹ Hyviä tuotantotapoja koskeva asetus ei kata esim. kiviä ja nahkaa.

Näissä yleisissä vaatimuksissa säädetään elintarvikkeiden kanssa kosketukseen joutuvissa materiaaleissa ja tarvikkeissa käytettävistä painoväreistä. Tiettyjä käyttötapoja koskevista vaatimuksista säädetään erikseen.²⁰ Koska EU:ssa ei vielä ole tätä alaa koskevaa erityislainsäädäntöä, säännösten noudattamisesta vastuussa olevat voisivat hyötyä lisäohjeistuksesta ja riskinarvioinneista.

Tämä painovärejä koskeva työ jatkaa Pohjoismaiden elintarvikkeviranomaisien aiempaa työtä tarkistuslistojen laatimiseksi. Tässä esitetään vaatimustenmukaisuusilmoituksia koskevat minimivaatimukset, jotka täyttäisivät lainsäädännön vaatimukset teollisuuden ja kaupan sisäisessä omavalvonnassa.

Raportissa esitellään lyhyesti painoprosessit sekä joitain näiden prosessien kriittisiä pisteitä. Näitä tietoja pidetään hyödyllisinä valvonnassa ja laadunvarmistuksessa.

Omavalvonnan dokumentointi, mukaan lukien vaatimustenmukaisuusilmoitukset, niitä tukevat asiakirjat ja muut tietopyynnöt, perustuu oletukseen, että säännösten noudattaminen varmistetaan ketjun jokaisessa vaiheessa. Yhteydet elintarvikkeiden kanssa kosketukseen joutuvissa materiaaleissa ja tarvikkeissa käytettyjen kemikaalien tuottajista aina materiaalien ja tarvikkeiden loppukäyttäjiin elintarviketeollisuudessa ja -kaupassa perustuvat siihen, että kukin tarjontaketjun jäsen ottaa vastuun kuluttajalle myydyn lopullisen, pakatun elintarvikkeen tai lopullisen materiaalin tai tarvikkeen säännösten mukaisuuden varmistamisen kannalta kriittisen tiedon tarjoamisesta ja välittämisestä. Lisäksi elintarviketurvallisuuden kannalta on tärkeää, että elintarviketeollisuus ja kuluttajat noudattavat heille suoraan myydyissä elintarvikkeiden kanssa kosketukseen joutuvien materiaalien ja tarvikkeiden pakkausmerkinnöissä annettuja käyttöohjeita.

Painovärejä koskevat säännösten noudattamisen valvonnan tarkistuslistat minimivaatimuksineen määrittävät tietyt puitteet kaikille tuotantoketjun oleellisille vaiheille kemikaalien ja raaka-aineiden kuten lisäaineiden tuottajista tai maahantuojista aina elintarvikkeiden kanssa kosketukseen joutuvien materiaalien ja tarvikkeiden loppukäyttäjiin elintarviketeollisuudessa ja kaupassa, mukaan lukien EU:n sisämarkkinakauppa ja tuonti kolmansista maista.

²⁰ EU asetus N:o 1935/2004, EU asetus N:o 2023/2006 ja kansallinen lainsäädäntö koskien esim. vaatimustenmukaisuusilmoitusta.

Tarkistuslistat ovat ohjeistusta, joka tarjoaa teollisuudelle ja kaupalle lähtökohdat omavalvonnan dokumentoinnin ja säännösten noudattamista koskevien vakuutusten kehittämiseen. Niitä voidaan käyttää nykyisessä ja tulevassa työssä omavalvonnan dokumentoinnin rakentamisessa tai parantamisessa, millä varmistetaan laissa säädettyjen vaatimusten noudattaminen, erityisesti EU-asetuksen N:o 1935/2004.

Useimmissa tapauksissa teollisuuden ja kaupan on noudatettava tiettyjä lisävaatimuksia painopintojen teknisten ominaisuuksien varmistamiseksi, mutta tällaisia vaatimuksia ei ole sisällytetty tähän raporttiin.

5. Annex I Chemicals used in printing inks

In this Annex the groups of chemicals used are briefly described.

Table: Substances on industry inventory list for printing inks (Swiss Confederation, 2009b). The list is currently being updated

	Evaluated substances, list A	Non-evaluated substances, list B
Monomers	292	1205
Solvents and energy curing monomers	29	256
Additives	705	2878
Photoinitiators	24	72
Colorants	66	197
Total number	1116	4608

5.1 Colorants (pigments and dyes)

Colorants include insoluble particles of *pigments* or solutions of *dyes* in a varnish or vehicle. The particles of pigments are usually within a size of 0.01–2 micrometer and dispersion agent must be added to ensure that they do not agglomerate. (SNT, 2003; Kipphan, 2001). The industry inventory list of colorants includes 263 different substances. Most of these are pigments which are the mainly used type of coloring agent, whereas dyes represent only a minor proportion of the total. None of the colorants on the inventory list has been evaluated by EFSA. Pigments are inorganic or organic based and different categories of these are mentioned below.

5.1.1 *In-organic pigments*

Among all colorants for plastics the two inorganic pigments of titanium dioxide (white pigment) and carbon black are the most used (SNT, 2003). Trace amounts of polycyclic aromatic hydrocarbons (PAH) may be present in carbon black. This is an impurity of special toxicological interest and therefore purity requirements for these pigments with respect to PAH are given the EU regulation on plastics no 10/2011 and in several national regulations/recommendations as e.g. in BfR recommendations (SNT, 2003).

Heavy metals and trace elements including e.g. cobalt, chromium, lead, and nickel can be present in inorganic pigments. The concentration of heavy metals in colorants for food packaging is restricted by several national regulations (SNT, 2003).

5.1.2 Organic pigments

Most of the colorants used for food packaging printing inks are organic pigments. One of the most abundant group is the azo pigments characterized by the azo functional group (-N=N-). This covers yellow, red and orange pigments. Primary aromatic amines, PAA, are often used as starting substance for production of the organic azo pigments and residual levels of PAA may therefore be present in the final print as monomer impurities with the risk of migration (SNT, 2003). Several national regulations have included a limit of 0.05 % for acid extractable aromatic amines in colorants (SNT, 2003).

Among the non-azo organic pigments, the phthalocyanine pigments seem to be the most abundant (SNT, 2003). The phthalocyanine pigments are typically used for green, blue and violet colors but include also some red and yellow ones. The green pigments of phthalocyanine may be contaminated with PCB's (polychlorinated biphenyls) due to chemical reactions in the production (SNT, 2003).

5.2 Binders

Binders are polymeric resins and the film forming component of an ink in which the coloring material is finely dispersed or dissolved. In conventional inks the binders are referred to as resins, these are often viscous liquids of polymeric materials consisting of pre-polymers or final polymers. They can derive from sources such as natural resins from trees, asphalt from crude oil, alkyd resins and chemically modified cellulose or fully synthetic resins as acrylic resins, polyamide resins, polyurethane resins and epoxy resins (Silverberg 1995; SNT 2003; EuPIA 2009a; personal communication with Sun Chemicals). Linseed oils have previously been widely used in offset printing as they form a firm elastic material from reaction of the oil with oxygen in the air. But other binders as e.g. the alkyd resins are now more common used. A growing interest has also been towards the non-drying vegetable oils as e.g. rape (seed) oil and soya-bean oil (Silverberg, 1995).

After drying of the printing ink by evaporation of solvent or oxidation, the main function of the binder is to fix the ink film to the printed substrate and contribute to functional properties and resistant. It is important that the amount of binder is sufficient to match the amount of pigments to avoid set-off/rub-off of pigment substances (personal communication to Eva Wallstrøm, 2010). This point would be regarded as a critical control point and should be addressed in instructions of use.

In the energy curing systems the polymerization of the binder takes places via irradiative energy (e.g. ultra violet (UV) curing or electron beam (EB) curing) during the printing process at the printing companies. With UV curing inks, binders of acryl resins are most often used

(Silverberg, 1995). The ultraviolet curing is initiated by a photo-catalyst (photoinitiator) absorbing distinct light energies from the UV beam radiation source after the ink has been applied to the substrate (SNT, 2003). Optimization of the process is important to reduce residual levels of starting monomers. The time for fully hardening, including chemical cross reactions of the polymer chains depends on the UV ink system (personal communication to Eva Walstrøm and Sun Chemicals, 2010). This point would be regarded as a critical control point and should be addressed in instructions of use.

The curing systems are solvent free as the reactive monomers provide solvent-like properties with appropriate viscosity for application of the ink. Many different acrylic esters are available as can be seen from the inventory list (A and B) of substances. UV inks are mostly used on board and labels however, UV cured coatings may be used on the top side of many different materials to provide protection (personal communication to Sun Chemicals). EB curing does not require a photoinitiator for free radical initiation but is started by excitation of electrons.

In water borne inks, an aqueous dispersion of acryl polymers is most often used as binder. However, other kinds of binders can be used. According to literature acryl resins (Silfverberg 1995, Chen L. et al., 2004), modified rosins (e.g. modified with fumaric acid) (Xia T.D. et al, 2008; Silfverberg, 1995) and polyurethane based resins (Fang C-Q., et al, 2009) are used as binders in water borne printing inks.

5.3 Solvents

5.3.1 *Solvents based systems*

The aim of the solvents is to keep the binders in a soluble state until the printing ink formulation is applied on to the substrate.

Solvents used in printing inks can either be volatile or non-volatile types

Amongst non-volatile solvents used would be mineral oils (hydrocarbons) of different kinds and with different boiling points (210–300 C). Traditionally non-volatile solvents are used in conventional offset printing techniques (Silverberg, 1995; Biedermann et al., 2010). Vegetable oils can be also be used as alternative solvents to mineral oils in offset printing and more recently, further solvents based on fatty acid ester have been introduced (Richter et al., 2009).

Volatile solvents such as toluene, xylene, alkyl benzenes, petroleum fractions have been used for flexo and gravure printing. Today other solvents as ethanol, ethyl acetate, longer chain alcohols and esters are the most used for flexo and gravure printing in Europe.

5.3.2 *Water borne systems*

As an alternative to organic solvents, water may in some cases be used fully or partially in flexographic printing (Silverberg, 1995). For technical reasons the water borne flexo inks area mainly used with porous materials such as paper and board (MST, 1999) and today flexo-inks on paper and board are mainly water borne (personal communication to Eva Wallström, 2010).

Special focus is put on surface tension properties when working with water borne inks on a polymeric substrate. To obtain a sufficient adhesion of the ink on the substrate, the surface tension of the ink need to be adjusted to the surface tension of the substrate (MST, 1998; personal communication to Eva Wallstrøm).

In total the water borne printing inks covers only a limited part of all printing on FCM today. However, industry is looking into the possibilities of extending the use of water born printing inks beyond paper and board and onto polymeric substrates (personal communication to Sun Chemicals and Flint Group, 2010).

5.4 Varnish

Varnish is a mixture of *binders and solvents*. Different kinds of varnish are produced according to the different kinds of printing processes: offset, flexo, gravure printing. In offset varnish the mixture is prepared with heat. This may stimulate chemical reactions of the substances in the solution (Silverberg, 1995). In other techniques no heat is involved in the processes.

5.5 Additives

A broad range of chemical additives are added to the printing inks for the achievement of different technical effects during the production process and/or in the final material.

These various additives include: Catalysts, antioxidants, adhesion promoters, amine stabilizers, antifoam agents, antimists, antistatics, biocides, chelating agents, dispersing agents, siccatives for optimized drying, flow agents, gallants, ink stabilizers, optical brighteners, photoinitiators, waxes, slip agent, suspension agent, thickener, UV stabilizers, wetting agent.

Plasticizers, e.g. phthalates or citric acid esters or polymeric based plasticizers are used to give flexibility in the printed surface. However, phthalates are not used any longer for FCM by the European printing ink industry (personal communication from Paul Hunt, November 2011).

6. Annex II Critical control points in formulation, production etc

6.1 Critical points

In support of the checklist for declaration of compliance (in Chapter 3) examples of critical points in the different steps of production of printed and use of FCM are given below.

6.1.1 *Critical control points*

Critical control points in the production and use of printing inks can be grouped into the following categories:

- composition of the inks
- printing process and instructions of use
- composition of the final FCM
- instructions of use to the packer, – the food producer, including instruction on whether a functional barrier is needed in the final, combined package

6.1.2 *Formulation of printing inks*

Whenever selecting a suitable ink system, the toxicology of the substances in the ink formulation and their migration must be risk assessed. This includes risk assessments of the raw material chemicals and information on the end use of the final FCM including possible barrier properties of the material in relation to

- Direct contact between FCM and food
- Potential transfer of substances by vapor phase transport
- Set-off during the processing and storing of the material. In addition to this, the critical control points in the printing process used shall be identified and respected in the quality assurance

6.1.3 The composition of the final material

Printing inks on the inventory list are often used on the outer side of a package. However they are also used in direct contact with the food, e.g., on printed plates, such articles need specific risk assessment, and such inks and coatings for direct food contact are normally only sold by specialist organizations that will have completed a higher level of assessment of all chemicals used.

Components in conventional printing inks can migrate from the outer side of a pack into the food in some cases, e.g. from the outside of printed board boxes. Instructions of use from the producer of printing inks should give guidance on the prevention of such contamination. Varnishes and coatings are often used as a surface layer outside the printed surface. One way of preventing migration is the use of a suitable functional barrier.

Functional barrier

A functional barrier may be considered to be a barrier consisting of one or more layers which either reduces the migration of authorized substances below their specific migration limit (SML) or reduces the migration of non-authorized substances into foods or food stimulants' to a not detectable level.

The concept of a functional barrier is included in regulations on plastic FCM where associated with the use of non-evaluated substances for plastic or recycled plastics for food packaging, However the concept has general relevance and may, in principle, be applied to any type of multi-layer structure.

To reduce migration of printing inks or their components, industry should take the use of a functional barrier into account, e.g. when printed paper is used for FCM as outer package in the food industry.

Any barrier layer will need to prevent/reduce chemical migration from one or more of the following sources:

- an adhesive used in a laminate
- a non-food contact plastic layer
- non-food contact paper/board layer
- a printing ink or
- coating applied to the non food contact surface of a packaging material

6.2 Examples of critical control points

The following lists are guidance on critical control points in the production of printing inks and use of printing inks in the in printing on FCM and packing of food.

6.2.1 *Critical control points: Producers of printing inks formulation*

- Sufficient knowledge of the chemical composition of the printing ink formulation (e.g. to avoid substances which are known or suspected to be carcinogenic, mutagenic and/or reprotoxic to human)
- Knowledge of the chemical and toxicological characteristic of chemicals in the ink formulation
- Purity of the printing inks chemicals, including residual monomers in pigments (PAH, metals, PCB and PAA) and impurities and NIAS²¹ in binder resins e.g. substances in natural resins and oils
- Alterations in the use of starting materials (focus on composition and purity of stating substances and formulations)
- Give instructions of use to the printer when needed. The instruction shall take into account the printing processes in which the inks are meant to be used. The printer is supposed to follow the instructions of use and both parties should have a dialogues based contact

6.2.2 *Critical control points: Printer*

The critical control points in the production of printed FCM differ depending of the printing process used, contact conditions and food types in contact. This should be part of information in “instruction of use” from the printing ink supplier.

- Follow the instructions of use from the ink supplier
- The level of knowledge and understanding in the printing companies should be adequate
- Training and education of personal (to ensure that they have the needed competences to carry out their responsibility)

²¹ NIAS is used for N=not, I= intentionally, A=added, S= substances and is covering reaction products and degradation products of ingoing starting substances.

6.2.3 Critical control points: Food producing industry (the packer)

- Follow the instructions of use from the printer
- Evaluate the suitability of the FCM of the specific food types temperatures involved in processing or storage and storage time
- Select an appropriate functional barrier, when needed
- Perform necessary migration tests on the final FCM

6.3 Good manufacturing practices, key points

6.3.1 Solvent or Water based printing

- Alterations in the production equipment and /or alterations in the production process (recording of process parameters), e.g. UV-lamps
- Adhesion, drying and curing of the print ink on FCM. Instruction of use shall ensure optimal end effective use and
- Drying must not start before application of the ink
- Ensure an optimal ratio between binder and pigment/dye to meet product resistance specifications (e.g. ISO standards) and to reduce migration of pigment/dyes
- Ensure complete drying or curing of the binder. Measure the degree of monomer curing in energy curing systems. Make control of drying temperature in the printing process of conventional inks
- Ensure necessary and optimal adhesion of the dried print to the substrate (including resistance to physical and chemical stress)
- Avoid set-off from storing and handling of the finished material in a stack or a reel. Exclude or reduce possible transfer of substances from the printed surface to the food e.g. by application of a functional barrier
- Monitor the residual level of solvents in the final product
- Test for contact side e.g. by application of a functional barrier. Follow the detailed rules on good manufacturing practice (Regulation (EC) 2023/2006)
- Register alterations in the application and use of the final materials (including the kind of foodstuffs, temperature and time of contact and surface/volume ratio in use)
- Test for pinholes in multilayer materials when printing is applied in the middle layer
- Migration of additives (including plasticizers), residual levels of monomers of binders and pigments, degradation products of starting substances, solvents and impurities

6.3.2 Water based printing

- Chemical and toxicological characteristics of the water borne inks. Substances in use may be irritating and allergic to human (MST, 1999), this include acryl resin monomers
- Adjustment of surface tension of the water borne ink to obtain good printability and full adhesion of pigments to the substrate

6.3.3 Offset-based printing

- Risk of migration of critical substances as aromatic and cyclic hydrocarbons from mineral oils used in offset printing
- Ensure optimized drying of binders to obtain fully adhesion of the pigments. This is especially of relevance for offset printing where the oxidative drying of non volatile solvents (oils) may be slow
- Ensure optimized drying/oxidation of the solvents and reduce residual solvents in the finished print
- Check for potential generation of reaction products of starting substances, especially with supply of heat in production of varnish for offset printing and in the drying of offset binders
- Presence of contaminants in solvents and binders with the potential to migrate from the final FCM
- Organoleptic properties: Residual levels of solvents in the final material can give rise to bad smell and/or taste of the packed food

6.3.4 Energy-curing systems

Ensure sufficient chemical and toxicological knowledge of the substances used in UV-cured inks. Substances known to be critical are:

- Residual levels of monomers and oligomers of reactive binders, e.g. acryl resins. Residue levels of e.g. acrylate monomers are to be expected as 100 % of curing is not attainable (MST, 1998), especially with *radical curing*. These substances may give rise to migration when the material is in contact with food. The acrylate monomers are allergic to human by contact (MST, 1998). It is important to monitor the level of curing of the final product by migration testing for acrylate monomers
- Other monomers as : PAA reaction products of isocyanate monomers in polyurethane resins; bisphenol A in epoxy resins
- Residual levels of photoinitiator catalysts
- Possible photodegradation products of dyes and pigments (due to radiation from e.g. an UV source)
- Ensure that UV-lamps are effective and with optimal intensity. The lifetime of UV lamps are 1,000–2,000 hours (MST rapport, 1998)

In general the following parameters can affect the curing of UV inks:

- Intensity (effect) and age of the UV-lamps
- type of reflector
- type of substrate
- thickness of the print (in thick materials of paper and board the inks can absorb too deeply into the material and thereby not be reached and cured by the radiation)
- speed of printing process and
- if drying between the different steps is included or not

Ensure organoleptic properties, as this is one of the general requirements in regulation no. 1935/2004, article 3, e.g. content of acrylates and photoinitiators (including impurities in these) in the final material may give rise to bad smell of the product (MST, 1998).

7. Annex III EuPIA, Industry guideline

An industry guideline has been suggested for evaluation of a printed food contact material (EuPIA, 2009).

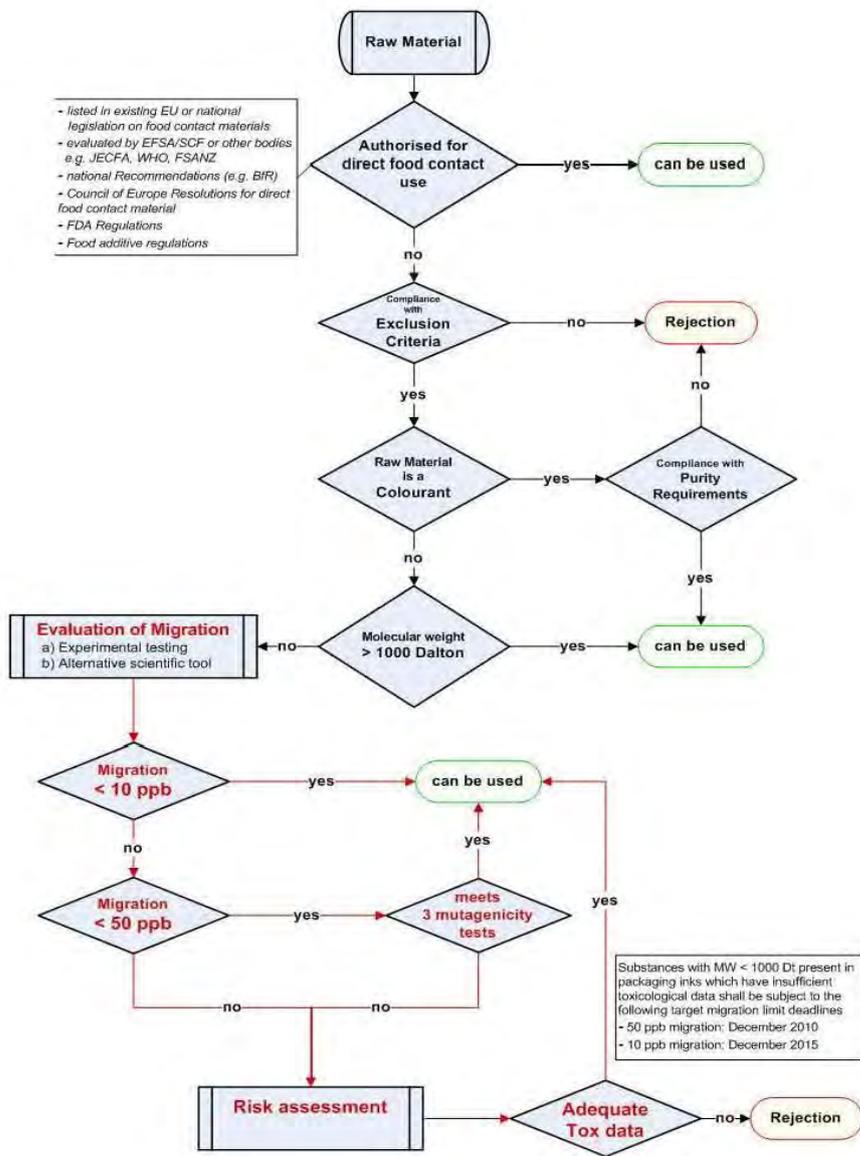
The scheme below is based on the guidance from the Council of Europe (Council of Europe, 2007) and has been further developed and updated. According to the industry guideline, substances used in food packaging inks with no formal SML/TDI shall be subject to the following target migration limits:

- 10 microgram/kg, in case of no or insufficient toxicological data (from December 2015)
- 50 microgram/kg if the substance is demonstrated not to be genotoxic (according to EFSA guideline)
- A value higher than 50 microgram/kg, if supported by favorable toxicological data and/or evaluation done in accordance with EFSA guidelines

Industry suggest that for packaging which does not currently meet these limits and data requirements, an action plan between the printing ink manufacturer, the converter and the other relevant members of the packaging chain should be generated.

In addition to the guideline, an exclusion list of substances (colorants, solvents, plasticizers and other compounds) that must be avoided in the production of printing inks is given in the industry guideline (EuPIA, 2009b).

An exclusion list may be a useful tool for the industry but cannot be used in demonstrating compliance.



Industry guideline, EuPIA 2009b

Comments to the above guideline on evaluation on printing inks

Guidance lists (“positive lists”) of substances that can legally be used in accordance with regulation no. 1935/2004 should be based on risk assessment of the substances used, and should include the chemical itself not only the potential impurities.

Substances with a molecule weight > 1,000 Dalton are without toxicological concern, only *provided* that they are materials of inert polymers that are not metabolized in humans.

The restriction of 10 microgram/kg is valid only for plastics and provided that the substance(s) are not classified as CMRM substance) (C= carcinogenic, M= mutagenic and R=damage of reproduction). Further development of GMP should improve the use of low-migrating substances in substitution of substances with a migration potential more than 50 microgram/kg (EuPIA guideline).

8. Annex IV Migration testing

To enable the migration testing of printing ink substances from printed FCM, information of the composition of the printing ink formulations shall be given from the producers of printing inks to the producer of printed FCM.²²

Sampling for migration testing shall be taken at critical points in the production and storing of printed food contact materials and packed food.

Analysis shall be done by official standard methods where possible or by in-house validated and qualified methods.

Verification of migration should be done by:

- Calculation of the maximum possible migration of known amounts of chemical substances in the printing inks into worst case food applications. This include knowledge of surface-volume ratio for the packaging; or
- worst case testing of intentionally and non-intentionally substances (NIAS) into solvents, or
- use of applicable and generally recognized diffusion models on known substances (transfer by set-off should be estimated separately), or
- migration testing according to the relevant technical EU directives and standard methods for plastic

Migration testing of printing ink substances

When testing for migration from printing inks, testing can be done in a stepwise manner e.g., for plastic, according to the draft CEN guide: Guide for examination of plastic food contact materials” (CEN, 1997).

A possible stepwise procedure is given below.

²² Disclosure of specific components in inks may require often the provision of confidentiality agreements between the various parties involved in assessing the risk (that is ink or coating maker, printer, analytical laboratory and possibly food packer if required).

If disclosure of migratable components to the partners in the supply chain is not possible due to complex confidentiality reasons for instance then the completion of a declaration of compliance (as set out above) would become the responsibility of the producers of the printing ink formulations. The migration data shall be made available to the food inspectors as part of the supporting documentation.

Extraction test for analysis of potential migrants

- Extraction testing according to the CEN guide (CEN 1997) with diethyl ether, or
- Alternative extraction testing with isooctane and/or 95 % ethanol
- Screening and identification of chemical substances in the solvent(s) is done by relevant techniques of GC and LC, included high resolution mass spectrometry (GC-HRMS and LC-HRMS) where needed
- When possible the identified substances are compared to pure standard substances
- The identified substances are compared to the inventory list for printing ink substances to check if the substance is evaluated by EFSA or not

Migration test

Printed plastic: Migration testing into stimulants' is done according to Regulation (EU) No 10/2011 on food contact materials and by the use of relevant CEN methods. The relevant fatty and/or aqueous food stimulant(s) are selected according to foreseeable use of the food contact material and worst case test temperature and time is selected in accordance with the regulation. Identification and quantification of specific substances in the test medium is done by relevant techniques of GC and LC, included high resolution mass spectrometry (GC-HRMS and LC-HRMS) where needed.

Printed paper and board: Migration testing can be done by the use of Tenax e.g. according to EN 14338 (CEN, 2003) and/or into solvents by EN 15519 (CEN, 2007). Identification and quantification of specific substances in the extracts is done by GC-MS and LC-MS/MS and where needed high resolution mass spectrometry (GC-HRMS and LC-HRMS).



Food contact materials and articles: Printing Inks

Check lists for compliance in industry and trade and control by food inspection

In-house control and the documentation of it is the basis for the assurance of compliance with legislation, in the food area and in the area of food contact materials (FCM).

Safe use of FCM is a complicated area, in general, and specifically the use of printing inks and the critical points in the printing process. One of the goals for this check list is to contribute to the development of more uniform control and requirements for in-house control.

Printing inks used in FCM are regulated by these general requirements and some uses are addressed more specifically, and as there is no specific legislation in the area in EU yet.

In-house documentation is based on the assumption, that each link in the supply chain ensures compliance. The check lists set a frame with minimum requirements to all relevant links in the supply chain from producers to food industry and trade.

The check lists are guidance to industry and trade in order to ensure compliance with the requirements in the FCM.