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White Paper

Why food safety is critical for carton and corrugated inkjet machines

Prepared for: Koenig & Bauer Durst

KOENIG & BAUER | durst

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0. Executive summary

The Koenig & Bauer Durst joint venture was set up to supply high performance inkjet print engines for corrugated postprint and cartons. As the majority of the global printed packaging market is for food and beverage, the company is focussed on ensuring that their offering is fully compliant with food safety legislation throughout the world and complies with the most demanding brand requirements.

Packaging fulfils several functions, to contain and protect the product from manufacture through the distribution chain to retailer and in use, before it is disposed of at the end of life. The pack may provide information about the contents or a brand, in the case of an e-commerce transit pack. Packs may promote the product and/or the brand. There may be security features. Digitally printed packaging may be versioned or customised for a recipient, and it may have links to the on-line world that provide engagement and experience for the consumer. Food packaging has these functions, and it is important that there is no contamination from any ink or coating components that could affect the product, or potentially cause harm to a consumer. The trend toward living well and healthy eating is important to consumers, so brands take this responsibility seriously and legislators have drafted a range of laws and ordinances covering the safe limits of materials that could be used.

Analytical chemistry techniques are continually developing to detect very small amounts of contaminants down to levels of parts per ten billion, while new instruments are capable of detecting even lower amounts. Across the world the regulations vary on which materials are covered at which allowable levels. The Swiss Ordinance on Materials and Articles in Contact with Food (SR 817.023.21) is currently the most comprehensive set of regulations while several large multi-national brands have their own requirements. These proscribe certain chemical components from being used in inks and coatings and making sure that the packaging is produced following food safe best practice methods. Nestlé regularly updates its' "Quality Requirements for Vendors of Raw and Packaging Materials", that audits potential packaging suppliers in terms of safety and good manufacturing process.

Brands are responsible for the safety of their products, if manufacturers of packaging for food contact do not comply with these requirements they may be liable to prosecution under the local legislation, and certainly risk losing the business.

1. Introduction

This white paper is aimed to provide guidance for carton and corrugated producers considering an investment in inkjet.

Smithers is a provider of information on packaging supply chains, and provides a broad range of support and analytical testing services for packaging providers and users, including food contact testing and training. Smithers provides testing to help companies with assessment or to prove food contact regulation compliance. Alistair Irvine, Senior Manager of the Food Contact Testing group within Smithers comments: “Food safety is a critical part of the go-to-market strategy for Brands and Retailers, as they compete to win the loyalty of consumers demanding total safety for their families in the food they consume. Providing suitable food contact inks and coatings is critical for suppliers of new inkjet printing systems for cartons and corrugated because food makes up the majority of all printed packaging. Smithers provides independent advice and consultancy, as well as the laboratory assessment of printed samples.”

2. Why Food Safety is important

In 2020 one of the key consumer trends is living well, and this is impacting all aspects of consumption. The global COVID-19 pandemic is reinforcing the demand for hygienic, safe produce. The basic desire is to live longer, healthier lives for individuals and their families. Fresh, locally produced food is popular but is not available for many urban dwellers and many brands have changed their products and associated packaging to provide these experiences. This is the case for the mega-brands as well as the “upstart” craft brands, and there is considerable activity being undertaken to prove the merit of the products. Nestlé, the world’s largest food producer, uses the strap line: “Good food, good life – that is what we stand for” as their key message.

An impact of COVID-19

One interesting factor is how consumer behaviour has been modified as the pandemic plays out, with food hygiene becoming a major priority. Early on coffee shops banned customers bringing their own cups for filling, going back to single use cardboard hygienic cup use again. Some supermarkets reduced their deli-counters and more food was pre-packed hygienically and this trend is forecast to continue. Ensuring the packaging is not a potential source of contamination will be even more important for the post-COVID consumer.

Providing safe, nutritional food products is the key for these companies, they are taking every precaution to manage and minimise potential risks of contamination that includes any packaging. There have been high-profile examples of ink and coatings migrating into food products, with product recalls and damage to the brand. The other impact has been to raise

the issue in consumer consciousness, and the consequential rise of governmental regulation on food safety that is defining the marketplace.

Market statistics showing importance of food within packaging market

Smithers sizes the global packaging market at $917 billion in 2019, food and beverage accounting for just under 38.0% of this total. The printed packaging and labels portion totals some $440.5 billion and printed food and beverage packaging in 2019 is valued at $262 billion, accounting for 61.2% of all printed packaging by value. The higher proportion of printed food and beverage packaging reflects the importance of packaging in food supply chains and more corrugated is becoming customer facing, with secondary shelf-ready packaging and subscription boxes growing strongly, as are coffee cup sleeves and produce trays, etc.

Table 1: World packaging (including non-printed) market splits by value in 2019

by value	2019
Food packaging	28.4%
Drinks packaging	9.6%
Healthcare packaging	3.9%
Cosmetics packaging	3.0%
Other consumer packaging	11.7%
Industrial/transport/other packaging	43.3%
All packaging	100.0%

Source: Smithers Information

The proportion of food and beverage printed packaging varies across the world, but is just under half of all printed packaging in Eastern Europe which is the lowest regional market share. In Latin America and Asia there are still many non-packaged foods sold in markets, and in Asia packaging manufactured goods for export is a larger proportion of packaging than in North America and Western Europe. Globally food and beverage packaging of all types accounts for well over half of the total global value of printed packaging, the proportion is higher in Western Europe and North America.

Table 2: Regional food and beverage packaging share of all printed packaging and labels by value in 2019

Region	Food and beverage share
Western Europe	62.9%
North America	71.2%
Asia	55.8%
Latin America	54.4%
Eastern Europe	49.0%
Middle East	72.3%
Africa	61.7%
Australasia	62.8%
World	61.2%

Source: Smithers Information

Food packaging is growing at a faster rate than the overall packaging market from 2019 to 2024. So, in 2019 61.2% of all packaging is for food and beverages, and converters serving these markets must follow the regulatory and brand requirements. In choosing to use a digital printing system (and inkjet is the fastest growing print process because it helps converters respond to the rapidly changing consumer preferences and brand requirements) converters will need to demonstrate compliance to the regulations if food packaging is produced. The ink formulation (including any primers and post-print coatings and varnish) is the major potential source of product contamination, with materials able to migrate from wet and dried ink-films by a variety of methods.

If a company selects an inkjet machine that does not meet the requirements it should not be used to manufacture food or beverage packaging. It will preclude converters from entering these markets during the lifetime of the machine unless the ink formulation and drying mechanism is changed. While the food sector has the highest profile it is not the only one that requires special measures. Tobacco, personal care, baby-care, pharma, tissues/hygiene products and petfood may have particular requirements – certainly from some of the brands who will select the suppliers they use. The bottom line is that using a printing system that provides safe printed packaging means companies can compete across a much larger potential market than systems unable to deliver such products. If converters do not use a printing method that can deliver food-safe packaging this market is closed to them.

Mechanisms of potential product contamination

There are three mechanisms of transferring ink/coating components into products unintentionally. Contamination is from by migration of components in printed material, through methods of:

- diffusion,
- set-off from a printed surface or
- gas phase migration in use, particularly cooking at high temperature.

Food-safe low-migration ink or coating will release levels below the accepted levels of contamination when they are properly applied and dried after printing. Using the appropriate materials is important, and following good manufacturing processes to demonstrate compliance and minimise the risks is the direction the packaging industry is taking.

Food-safe inks are available in radiation curing, oil-based (largely mineral oil free), solvent and water-based forms, with the latter two accounting for much of the coating volumes. A significant trend is the move from solvent to water-based coatings in many applications as the technology improves.

Food contact materials

Equipment and ink suppliers have talked about providing systems that deliver “Low Migration” results, as being suitable for food production. However, low migration is not a measurable definition, the measure is relative to other types of ink and coatings. The packaging sector is moving away from the term, using the terminology of *food contact materials* (FCM). Inks and coating for FCM are inks that, if correctly applied and cured and with the right choice of packaging concept, the legal migration levels can be met. In 2020 in Europe the legal migration limits are:

- 60ppm (parts per million) global migration for substances,
- Specific migration limits for evaluated substances
- 10 ppb (parts per billion) as a baselinefor nonevaluated substances, although lower limits can be applied when there are concerns of genotoxicity.

Good manufacturing practice (GMP)

Using suitable FCM inks is only part of the method of producing food-safe packaging. They must be used in the correct methodology to minimise the risk. To prove their capabilities many converters are using Good Manufacturing Practice (GMP) techniques that involve reasonable control processes and establish appropriate quality systems.

Some brands demand their suppliers follow such procedures and will audit the operations before they become an approved supplier. Suppliers will use standard manufacturing processes using a documented, measurable approach. GMP techniques comprise a set of consistent control and production of components followed by ink and substrate manufacturers, printing and converting. The European Commission GMP Regulation (EC) No 2023/2062 lays down rules to be followed by ink manufacturers and converters, specifying that quality assurance and control systems are established and implemented.

GMP broadly states that printing inks and varnishes applied to the non-food 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:

- through the substrate or
- 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.

Finally, GMP states that a printed surface shall never come into direct contact with the food.

3. Legislation developments

The broad principle that any packaging should not adversely affect the contents is followed everywhere, with varying degrees of testing in place. Regional government and individual countries have different legislation in place, there are some signs of more harmonisation in requirements being developed but potential corrective and litigation actions also differ regionally. Important regulations include:

- EU Regulation 1935/2004
- Swiss Ordinance
- US FDA indirect food additive guidelines (21 CFR 170 – 190)
- China National Health and Family Planning Commission, Standard GB 9685-2008
- FSANZ Food Standards Australia New Zealand Act 1991

Many countries and trading regions are applying their own regulations, for example in Nigeria the National Agency for Food and Drug Administration and Control (NAFDAC) uses sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act Cap NI Laws of the Federation of Nigeria (LFN) 2004 and all powers enabling it in that behalf.

The latest developments in analytical chemistry are capable of measuring ever smaller amounts of contaminants. Demonstrating the presence of materials in such very low quantities may be one of the factors behind the "Arms Race" of safety legislation between countries and regions.

Food safety has been a regulatory issue since medieval times, with severe penalties meted out to providers of contaminated or adulterated food. German Reinheitsgebot (pure beer) laws date back to 1487 when Albert IV, Duke of Bavaria, specified only three ingredients – water, barley malt and hops – could be used to brew beer (this was before yeast's discovery). The trend spread, and in 1516 standards for the sale of beer were added (some scholars say the intention was bread protection rather than beer protection, to stop the use of wheat and rye grain in brewing, saving these for bread making). Whatever the intent the concept of controlling food safety stuck and spread, remaining important and legislators across the world are continuing to make strides in ensuring the safety of their populations.

EU Regulation 1935/2004

In Europe the EU Regulation 1935/2004 covers food packaging, this requires that materials do not:

- Release their constituents into food at levels harmful to human health
- Change food composition, taste and odour in an unacceptable way

Regulation (EC) No 2023/2006 ensures that the manufacturing process is well controlled, so that the specifications for FCMs remain in conformity with the legislation. Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

There are no continent-wide mandatory requirements for inks or coatings (and substrates, adhesives, laminates or foils). There is today no specific EU legislation on ink for food packaging. The main regulation is EU 10/2011 (and amendments) that covers "Plastic materials and articles intended to come into contact with foodstuffs". It provides a migration limit of 60mg/kg food, with specific migration limits for individual substances. The regulation contains a comprehensive positive list of materials that can be used in plastics formulations, but this list does not include ink constituents, apart from those which also have uses in plastics.

The EuPIA publishes various guidelines and provides assistance in ensuring inks and coatings comply with the changing requirements. The document *EuPIA Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles* is

regularly updated and it provides detailed recommendations as to how to formulate inks that will comply with European regulations.

Swiss Ordinance on Materials and Articles in Contact with Food (SR 817.023.21)

The Swiss Federal Department of Home Affairs (FDHA) issued a revised version of the Ordinance on Materials and Articles in Contact with Food (SR 817.023.21), which came into force on 1st May 2017. This provides a positive list of ingredients approved as ink ingredients on the non-food contact surface of food packaging, but not direct food contact. Part A contains over 1,000 materials, including pigments, resins, monomers and additives that have been toxicologically evaluated to be safe for humans. These are listed with their maximum SMLs (where there is no SML, an overall migration limit of 60ppm applies). Part B lists chemical substances that have not been toxicologically evaluated but are still allowed to be used in ink formulations with the default migration limit set at 0.01 mg/kg (10 ppb) for food or food simulant. Substances not listed may not be used in any part of a food packaging ink formulation.

Much of the Ordinance is contained in the Nestlé guidelines for its packaging in all regions and in the absence of well-established legislation has also gained widespread acceptance as a working standard outside Switzerland. Many leading inkmakers follow these requirements for their raw materials worldwide. All Koenig & Bauer Durst formulations comply with the Swiss Ordinance requirements, ingredients used are in the approved lists and are manufactured following GMP throughout the supply chain.

USA FDA regulation

In the US the key regulatory body is the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services. It has broad regulatory authority and while many packaging providers and suppliers to the industry claim they have FDA approval there really is no such approval.

The FDA regulates food additives and consider food contact materials to be a potential source of additives. Food contact materials are therefore considered to be secondary food additives and printed packaging remains subject to the more general non contamination requirements of the Federal Food Drugs and Cosmetics Act. There are specific regulatory bodies active in individual states, for example the California Office of Environmental Health Hazard Assessment issues the Proposition 65 List that identifies chemicals potentially harmful to humans. Food manufacturers should identify the presence of any chemicals on the list which is updated annually, and most will avoid these in food packaging.

Other regional and national regulations

Across the world there are many different sets of rules and regulations covering food packaging safety, with some covering general issues including exclusion lists and migration limits for packaging, and in some cases specifically for inks.

Japan

In Japan the Food Sanitation Law demands that food packaging must be inert. Packaging with toxic or harmful substances that provide a risk to human health, or have a harmful effect on food, is banned. The Japanese Printing Ink Manufacturers Association (JPIMA) has issued its Voluntary Regulations Concerning Printing Inks, with a negative list of materials not to be used.

India

In India the Food Safety and Standards Authority of India (FSSAI) is responsible for protecting and promoting public health through the regulation and supervision of food safety. It has introduced overall migration limits (as those in the EU) and/or positive lists of authorised substances for the 10 plastic types (but not for printed layers), with maximum concentration limits.

The voluntary Indian Standard IS 15495:2004 “Printing Ink for food packaging – Code of practice” prescribes guidelines for printing inks for use on food packages.

The exclusion list in Annex A comprises pigments and compounds based on antimony, arsenic, cadmium, chromium (VI), lead, mercury and selenium, as well as several dye colourants, solvents, plasticisers, and other compounds (e.g. dioxins, nitrosamines and others). It is less demanding than the JPIMA and EuPIA exclusion lists – in particular, phthalate ester plasticisers usable in solvent-based inks are not banned. With regard to converter’s obligations, in the case of immediate food wrappings, printing inks must be applied only on the outside of the wrapper, and are to be printed in such a manner as to avoid set-off.

China

In China food safety is a very hot topic, with growing consumer awareness in most cities following several major incidents. The governing body is the National Health and Family Planning Commission. There have been several revisions to the Guobiao (GB) standards in operation. Food contact materials and articles are regulated by Standard GB 9685-2016 “Uses of Additives in Food Contact Materials and their Products”. The range of permitted food contact additives has been widened, the list is being expanded to include more

authorised substances, whose toxicological assessment and migration management principles are largely based on the European model of Regulation (EU) No 10/2011.

Australasia

The Food Standards Australia New Zealand (FSANZ) regulates food packaging safety. It is an independent statutory agency established by the Food Standards Australia New Zealand Act 1991. FSANZ is part of the Australian Government's Health portfolio. FSANZ develops standards that regulate the use of ingredients, processing aids, colourings, additives, vitamins and minerals.

4. Brand initiatives

The legislative pattern across the world is confusing, and not harmonised. Outside these regulatory frameworks a growing trend is actions taken by the major global food brands who are taking pre-emptive action to ensure their products are safe. These go beyond the use of food-safe inks and coatings, but cover the manufacturing steps involved in package production.

Food safety is an ever more important issue for consumers following several highly publicised contamination events, and brands know they could be severely damaged with significant financial penalties and harmful publicity. To combat the risk some major brands are taking control and setting their own stringent standards.

Kelloggs publishes a *Supplier Quality Requirements* document that is regularly updated. The document details the requirements for suppliers, including the acceptable levels of specific components. Probably the most comprehensive is the Nestlé approach, that details “Nestlé Quality Requirements for Vendors of Raw and Packaging Materials”, the latest update is January 2020. This audits potential packaging suppliers in terms of safety and good manufacturing process. Nestlé requires that packaging suppliers have knowledge of all components and materials that may contact the product, are aware of the current legislation on food safety, and have processes to capture updates. Converters will use processes for evaluating potential migration and are willing to share this

In 2005 Nestlé baby milk, packed in gable-end liquid cartons, was found to contain isothioxanthone (ITX), a photoinitiator used in UV curing inks on the outside of the cartons involved. ITX migrated onto inside of the pack when print was re-reeled before making up and filling the cartons. This high-profile scare led to 50,000l of milk being removed from shelves and much bad publicity for Nestlé. They then developed stringent procedures to ensure this never happens again, with the “Nestlé Guidance note for inks and coatings” used as best practice by many converters today.

information with Nestlé. Many other large brands, including General Mills, Mondelēz International and Kraft Heinz, follow similar principals and it is important that corrugated and carton producers can demonstrate their compliance if they wish to become suppliers to these major brands. Using FCM inks is an important part of obtaining these approvals.

They aim to prevent a future packaging safety and compliance incident (including a recall of product) due to safety and compliance failures that would greatly damage the brand. Technology developments – in the materials and printing methods, as well as in analytical chemistry techniques – will continue to change the landscape. The power of multinational brands means they will spread their required best practices for suppliers to all regions where they operate. There are many examples of companies pushing the European levels of safety wider afield.

For converters the requirement is to demonstrate compliance with the brand requirements, particularly when the change their processes, such as investing in a digital package printing machine. It is necessary to obtain certification from an approved independent testing facility, who themselves are accredited to ISO 17025 that confirms the competence, impartiality and consistent operation of laboratories.

5. Standards under development

Regulators are developing ever-more stringent legislation covering food-safe packaging because they are acting on behalf of their populations who are pushing for greater nutritional safety. The legislators are being guided by analytical chemists and toxicologists, to determine what should be tested and the permitted levels of contamination. There is currently a disconnect between what can be measured and its potential toxicological impact is some instances and future legislation covering the limits will take into account not just the sensitivity of analytical chemistry techniques but also the potential impact of a contaminant on human heath in determining safe levels.

The other trend will be greater harmonisation of regulations across the world, although there are political implications for many legislators. The current lack of harmonisation means what is OK in some countries may be not permitted in others. This situation is concerning for multi-national brands who need to comply with an ever-changing set of regulations. So many brands self-impose even more stringent requirements on their suppliers to ensure risks of migration of components are minimised.

6. The impact for the packaging converter

Managing and minimising risk is the responsibility of the converter. Corrugated and carton producers must ensure that every product sold is fit for purpose. The particular requirements for food packaging mean it is necessary to comply with the local regulations on food safety issues, and potentially more stringent regulations when printing on behalf of global brands. When a converter makes an investment in digital printing equipment to improve the levels of service they offer it is necessary to prove that the output is suitable for use. For food this means obtaining the necessary independent certifications proving the output meets the local regulatory and specific brands requirements. The first step in achieving this is to choose the appropriate equipment from a provider who will certify their inks and consumables will meet these standards in use.

The requirements are way beyond the normal hygiene and cleanliness requirements of a food approved packaging provider. The converter must have a documented quality management system in place that can be externally audited, usually certified in accordance with EN ISO 9001 systems. The system should identify potential risks of contamination and identify measures to minimise those risks. This particularly covers the choice of inks, coatings and adhesives used in pack and label printing. It is the responsibility of the converter to demonstrate compliance with documented testing of samples conducted by an independent certified laboratory testing facility.

If a manufacturer of packaging for food contact does not comply with these requirements they may be liable to prosecution under the local legislation, and will risk losing the business from larger brands.

7. Koenig & Bauer Durst inks for packaging

In 2019 Koenig & Bauer and Durst formed a joint venture to combine their expertise focussed on high speed digital printing for corrugated and folding carton packaging applications. The new company has two presses for the corrugated segment , the SPC 130 and CorruJET 170 and is developing a seven colour digital press for folding cartons, the VariJET 106, which will be introduced to the market in 2021. All associated services and the ink business are included in the JV, Koenig & Bauer Durst AG.

Koenig & Bauer AG has long experience in packaging presses and is using this expertise in the new inkjet machines coming to market. This includes ensuring inks fully comply with regulatory and brand requirements. Beyond this there are options to use food-grade auxiliary materials such as lubricants and hydraulic fluids, etc., and to use suitable cleaning materials to reduce risk of food contamination further.

The parent companies also sell inkjet presses for labels, glass and plastics (as well as a strong portfolio of non-packaging machines). Each machine has inks tailored for optimal press performance that are suitable for the particular applications including food packaging.

In the Delta SPC 130 press for corrugated the ink system is the patented water-based ink with UV sealing functionality. These are functional water-based inks, with a UV curable component dispersed into water to produce a suitable ink viscosity without the need for low molecular weight monomers that could potentially migrate from the printed ink film if not wholly cured. The benefit of using water as a diluent in functional UV inks means that low molecular weight monomers that could migrate are not needed. The inks contain with high molecular weight oligomer molecules that are too large to migrate.

All Koenig & Bauer Durst inkjet inks for cartons and corrugated are formulated with materials that are listed in Annex A of the Swiss Ordinance. Inks are manufactured at GMP accredited facilities where there is full chain of custody on all raw materials to eliminate potential contamination from impure chemical ingredients.

UV curing inks dry through a photo-polymerisation chemical reaction. UV radiation causes the photo-initiator molecules to cleave, each part contains electrons (free radical) that react with monomers and oligomers in the ink vehicle. This reaction breaks a chemical bond in the pre-polymer leaving another free radical that reacts further, building up the polymer chain until all the ink has reacted. The reaction may be terminated by the presence of oxygen molecules, and there may be unreacted photo initiator and monomer if the UV lamp is aged and there is a possibility that incomplete cured material could migrate into the product in the pack.

Koenig & Bauer Durst Water Technology inks for food have been tested by an independent testing institute for its suitability for printing corrugated board and cardboard materials in the primary food packaging sector. In this context, a primary packaging is understood as a carton, box or other packaging made of

suitable corrugated or cardboard material to which the digital print is applied on the exterior, non-food-contact side. Food grade Koenig & Bauer Durst inkjet inks are manufactured under GMP-compliant production conditions (Regulation (EC) No. 2023/2006).

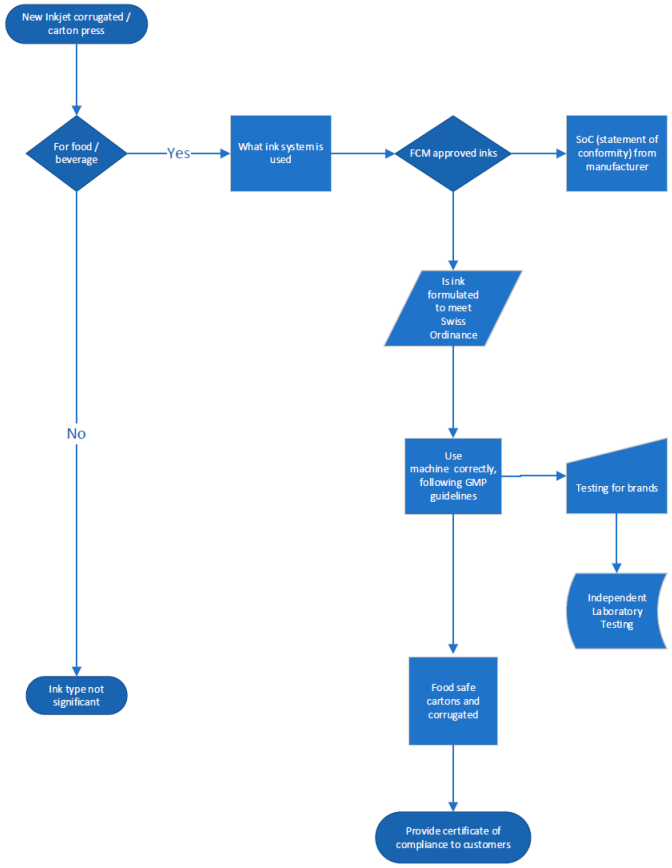
Koenig & Bauer Durst inkjet declares that their inks do not contain mineral oils, heavy metal-free organic pigments and contain no substances of animal origin. The inks (and associated consumables, e.g. flushing fluids) comply with the requirements of the currently applicable Swiss Ordinance, the current valid EuPIA guidelines and currently applicable Nestlé Guidance Note for Packaging Inks (as of September 2016).

8. Recommendation and tick list for converters to consider

When a company invests in new equipment there are always many factors that combine to make up the decision. When moving into a novel production method there will be new materials and processes that must be considered, outside their normal scope of operations. This will involve conducting a range of tests to demonstrate that the packaging is food safe. The converter should work with an independent laboratory to performing chemical analysis to demonstrate compliance with local regulatory requirements. The laboratory should operate in accordance with the ISO 17025 standard.

When deciding on a new investment the converter will consider the machine specifications, economics and workflow as part of the selection criteria. If the press will be used to print food and beverage packaging there are further criteria to consider to ensure compliance with local regulations and specific requirements of particular customers.

FIGURE 0.1 Schematic showing considerations for converters in deciding the type of inkjet printing machine for food and beverage cartons and corrugated



Source: Smithers Information

To print food and beverage cartons or corrugated converters will need to:

- Identify the local up-to-date regulations for food contact packaging (and any specific customer requirements) and make sure any new equipment is compliant
- Achieve a suitable food safety certification, e.g. GFSI Certification, to cover hygiene procedures in production and to ensure suitable protective clothing and washing facilities are available for staff and visitors
- There should be processes that ensure traceability of materials used in production, using suppliers who can document the materials comply with the regulations. Material safety data sheets (MSDS) should be available for inks, coatings and varnishes in use
- Only use inks and coatings that are suitable for food contact materials, and operate the printing and finishing equipment in accordance with recommended methods to minimise potential food contamination

- Conduct independent tests on packaging material sold on the equipment that will be used, to provide a certificate of compliance for the packaging material that states compliance with relevant local regulatory requirements
- Batches must be identified with material description or trade name; batch number; producer identifier; production date and shelf-life expiry date if applicable
- A documented procedure should cover a product recall in the event of a failure
- Storage locations must be clean, free from infestation, and maintained at a temperature and humidity appropriate for the material. The material must be adequately protected against water and other damages

The vendor of the equipment should provide advice and support to companies considering such an investment. The ability of the machine vendor to provide this support is becoming a critical differentiator as the market for digital packaging equipment is growing.

Increasingly many brands are demanding that their suppliers provide proof that they are minimising the risks of product contamination across their operations. Kellogg's publishes their "Supplier Quality Requirements" document, which states that they will pursue partnerships with suppliers and trade partners that:implement a robust Food Safety plan based on HACCP principles that identify and mitigate risk of physical, chemical and microbiological hazards

- meet the requirements of an approved benchmarked GFSI scheme
- demonstrate compliance with regulations in both the producing and destination markets
- have a continuous improvement mindset and close Kellogg and GFSI audit gaps on a timely basis
- maintain a documented quality management system which stays focused on product quality and consistency and
- agree to follow the Kellogg Supplier Code of Conduct which requires compliance with applicable labour standards and business ethics, as well as pertinent environmental, health and safety standards.

Choosing the appropriate equipment and ink combination is important.

Dr Stefan Kappaun, Executive Vice President Inks and Fluids at the Durst Group is keen to confirm that: "Our ink development always aims to be ahead of the regulatory framework and

suitable for the most demanding end users. Our development group has a deep understanding of market needs and engagement with the leading brands to make sure we provide equipment and consumables that exceed their requirements, helping our customers provide packaging with the lowest possible risks of food contamination".

9. Glossary

This section provides a brief explanation of many of the acronyms and technical terms used in this white paper and in the food safety sector.

BfR	Bundesinstitut ür Risikobewertung (German Federal Institute for Risk Assessment)
BMLEV	Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz (German Ministry of Nutrition, Agriculture and Consumer Safety)
BPA	bisphenol A, industrial chemical widely used in plastics and epoxy coatings, being replaced
Dalton	unit of molar mass, 1 Da = 1 g/mol, defines the size of a molecule, the EFSA assesses that material over 1,000 Da are not absorbed by the body and therefore may be excluded from any calculations of migration
CFR	code of Federal regulations (USA)
CoA	Certificate of Analysis
DoC	Declaration of compliance, issued by a supplier stating that it uses appropriate materials and processes to comply with the local food safety regulations
EB	Electron beam curing inks, radiation curing grades with no photoiniator
EFSA	European food safety authority
EuPIA	European Printing Ink Manufacturers Association
Exclusion list	group of chemicals specifically prohibited for use in an ink or coating formulation
FCM	food contact material
FCN	food contact notification
FCS	food contact substances
FDA	food and drug administration in the USA
FSMA	food safety modernization act in the USA
FSSAI	Food Safety and Standards Authority of India
GB	National Standard (China)

GFSI	Global Food Safety Initiative, a private organization that maintains a benchmark food safety standards scheme for manufacturers
GMP	good manufacturing practice
GRAS	generally recognised as safe
HACCP	hazard analysis and critical control points, a systematic preventive approach to food safety from biological, chemical and physical hazards
HARPC	hazard analysis and risk-based preventative controls (USA)
ITX	isopropyl thioxanthone, a photoinitiator formerly used in UV curing inks
JHOSPA	Japan hygienic olefin and styrene plastics association
MERCOSUR	Common Market of the South (South America)
Migration	transfer of material from packaging into the contents, often from inks or coatings. Low migration was widely used to describe inks with limited migration but is not a quantitative or scientific description and so has largely been superseded by the term “inks (or coatings) for food contact materials”
MOH	mineral oil hydrocarbon
Monomer	Low molecular weight component of UV curing inks, large component of the formulation to get the desired viscosity, risk of migration if ink is not fully cured
NIAS	non-intentionally added substance, chemical(s) present in a food contact material or article that have not been added for a technical reason during production
OEHHA	California Office of Environmental Health Hazard Assessment
Oligomer	UV curing ink ingredient consisting of repeating units, higher molecular weight material to give durability to the final ink film
Photoinitiator	Chemical used to initiate the free-radical polymerisation in UV curing inks, it breaks down int at least two highly reactive components that then react with oligomer and monomers to form the final ink film. Low molecular weight materials may remain in the final ink film and are a risk for migration
PIM	plastics implementation measure
PPM/PPB	parts per million, parts per billion
SML	specific migration limit
SoC	statement of composition, provided by the ink manufacturer providing information on the ink to converters enabling them to issue declarations of compliance
UV	radiation curing inks and varnishes dried by ultraviolet light
UV-LED	UV inks dried with ultraviolet light emitting diode technology

