GOOD MANUFACTURING PRACTICE GUIDE 2.1

A management tool for folding carton companies - guiding their policies on food safety

EUROPEAN CARTON MAKERS ASSOCIATION

GOOD MANUFACTURING PRACTICE GUIDE 2.1

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1. INTRODUCTION

Consumer health and safety is a top priority for the folding carton industry. Safe packaging is essential to meet the requirements and expectations set by legislators, brand-owners, retailers and consumers.

As the representative body for the folding carton industry, the European Carton Makers Association (ECMA), published the first version of its Good Manufacturing Practice Guide for food safety in 2011, (which was updated in 2013). At that time there was a clear need to improve awareness and provide general food safety descriptive guidance.

In the years since then, the public certification schemes recognised by the Global Food Safety Initiative (GFSI), e.g. BRCGS, FSSC 22000, are widely used in the packaging sectors. With their external auditing systems, they have become the standard for quality systems in food safety, combined with the GMP guide for the folding carton industry.

In 2020 the decision was taken to update the ECMA GMP. The objective was to address the folding carton industry specifics, that were not covered in detail within the GFSI schemes. In March 2021, ECMA released the updated GMP (Version 2.0) which was focused on complying with the sectors most widely used scheme - BRCGS Global Standard for Packaging Materials (Issue 6).

This updated Version 2.1 extends the ECMA GMP with guidance on FSSC 22000.

The tables included in the paragraphs 2.1 and 3.1 indicate which sections in BRCGS and FSSC 22000 were identified as areas requiring extra attention and significant sector specific guidance.
For all sections marked in green, detailed guidance and examples are given in the document.

The document avoids duplication between the text included in the legislation, in the GFSI schemes and in the GMP.
We are confident that this publication is helpful for both larger and smaller folding carton companies in managing their food safety policies and compliance with the EU regulations. Using the ECMA GMP requires a GFSI recognised certification.
This new GMP Version 2.1 was developed in the ECMA Food Safety Committee, with the involvement of Geers FCM Consultancy.

Mike Turner,
Managing Director - ECMA

2. BRC GLOBAL STANDARD PACKAGING AND PACKAGING MATERIALS

2.1 IDENTIFIED BRCGS CLAUSES

For all sections marked in green, detailed guidance and examples are given in this document.

Check the BRCGS website for the original document.
Go to: www.brcgs.com – Store – Global Standard Packaging Materials Issue 6 – free PDF

BRCGS Packaging Materials
Issue 6 - Part 2 Requirements

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2.2 HAZARD AND RISK MANAGEMENT

BRCGS Clause	ECMA Guidance
2.2.1	This description of scope is different from the scope on the certificate. This is to identify what type of risks need to be considered. Typically the scope of the risk assessment is for cartons to be used in contact with food, and with the non printed side possibly in direct contact with food. Risks need to be assessed for defects that may affect the health of the final consumer, but may also include the risk of reject by the direct customer, the food packer. When considering the scope, attention may also be given to the risk of breach of regulatory requirements that may lead to product recall. For example exceeding a specific migration limit for a chemical substance will probably not induce any direct effect to the final consumer, so may be rated low risk within that scope, but it does equally imply that the product will breach a regulatory requirement and could be subject of a recall induced by a national authority in food safety.

Example to BRCGS Clause 2.2.1
"The Scope of the HARA is to assess all risks that may be occurring in the manufacturing process of folding cartons, including the raw materials, process aids and equipment used. The risks are to be rated for the safety of final food consumers as well as the adherence of relevant regulatory demands."

BRCGS Clause	ECMA Guidance
2.2.2	Different sources are valuable to maintain awareness of safety hazards, guidelines, best practices and legislative developments. ECMA is regularly circulating updates in its Food Contact e-mail network and those updates are also made available to all members in the Members Only section of the website. On a number of topics more basic information is included in the Fact Sheets and Headlines part of the ECMA Sales Toolkit. Aside ECMA there are many other important sources for obtaining information : the National Carton Makers Associations, specific customer requirements, specialised laboratories and scientific publications.

Example to BRCGS Clause 2.2.2
The ECMA Food Contact update mails contained in recent years e.g. many times background information on developments regarding mineral oils, phthalates, PFAS, BPA, ... **Go to: www.ecma.org – Member Login – Members Only – ECMA Food Contact Network Update** The following Food Safety Factsheets - General overview Food Safety, FoodWatch (mineral oils), ECMA GMP Guide, Recommendation Adhesives, Fluorinated Substances - and Headlines - Food Contact Materials Regulation, German Mineral Oil Regulation and German Draft Ink Regulation - are available in the Sales Toolkit. **Go to: www.ecma.org – Member Login – Members Only – ECMA Sales Toolkit - ECMA Fact Sheets – Food Safety**

BRCGS Clause	ECMA Guidance
2.2.3	Description of the product: Consider direct or indirect contact, virgin vs recycled board. Presence of barrier layer , or laminate, presence of window, metallic foil, any printing on reverse, conventional vs UV, intended use may be frozen food, ambient dry food long term storage, short term hot food with fatty content (fast food), microwave or conventional oven cooking. The intended use of the carton needs to be discussed in detail with the customer.

Example to BRCGS Clause 2.2.3

"A Folding carton made from virgin fibre board printed in sheetfed offset and coated with a water based emulsion varnish. The product is side seam glued with a water based adhesive. The carton is intended for direct contact packing of chocolates, to be stored in ambient or cooler temperatures for up to 6 months. The product is destined for the EU market. Consumers targeted are adults, but may include children of age 3 upwards." A checklist to use with customers is available from the ECMA website. This checklist covers questions regarding the packed food, the intended use, the legal background and the materials used.

Go to: www.ecma.org – Member Login – Members Only – ECMA GMP – ECMA GMP Checklist (PDF)

BRCGS Clause	ECMA Guidance
2.2.4	A process flow diagram as requested here is intended to be serving as a guide to perform step by step risk assessment. Therefore the process flow needs to follow the product from raw material to finished product, step by step, and include the use of additives and / or process aids where relevant.

Example to BRCGS Clause 2.2.4

See general process flow chart in **Annex 1: Process flow – General GMP Requirements** on page 18. Companies manufacturing different types of products, may need to develop aside a general process flow with more specific diagrams. Paper cups will for instance require a more complex deeper process flow description. Companies with different plants and different printing technologies may also require separate diagrams.

BRCGS Clause	ECMA Guidance
2.2.5	Note that annual verification of the flow chart is a new requirement in BRC packaging version 6. It may be convenient to include this in the annual management review planning.

BRCGS Clause	ECMA Guidance
2.2.6	When assessing risks, all categories as requested in the BRCGS Packaging 6 standard need to be considered. Note that new additions of categories include the potential for raw material fraud. This seems to be a topic of growing concern in the food industry, transferred to the packaging standard. It can be assumed that these risks are expected to be low or remote in the carton industry. The risk of microbiology is usually low when packaging is intended for frozen use, or ambient dry foods. Chemical contamination is very relevant in printing processes, and or use of adhesives. The potential for unintended migration is included in the chemical risk. Although the likelihood of migration or other chemical contamination may be probable, the severity of the effect is often overrated. Practically always, there will be no noticeable effect to the final consumer. Concentrations are typically very low, and only over length of time and structural consumption might result in an adverse effect. Chemical contamination must be pretty severe to result in a taint & odour effect on packed food. However, what is a higher risk to the carton manufacturer is that exceeding limits of migration will mean a breach of regulatory compliance, and a product recall may be commissioned by the control authority. The foreign objects category is usually pretty well understood, and may comprise any physical form of contaminant such as glass pieces, jewellery, metal sharps, any small particle from equipment such as nuts and bolts etc. Potential problems arising from the use of recycled materials is if any relevance, relating back to unintended migration of substances. The carton industry knows very well that recycled based papers can be suitable to pack a few specific forms of dry foods, but in most cases a functional barrier needs to be applied by the packer or packaging designer. The choices offered by the carton manufacturer have to be correctly assessed by the final customer. Foreseeable misuse by consumer is probably not that relevant. Small toddlers might try to eat the packaging instead of the content, or use empty packaging as a toy. Defects critical to consumer safety could be imagined if for example a section of the packaging text containing nutritional information or allergen warning is mis printed or missing due to an error in printing. Loss of functional integrity may be related to pour spouts and tear strips either not working or being cut through. In case of cut through the packaging may show leakage and exposure to contamination, but may also ‘collapse’ in distribution leading to complaints for damage. The potential for malicious intervention is mostly a remote risk for the packaging company.

Example to BRCGS Clause 2.2.6
Chemical contamination may have considerable consequences. More background on the types of migration, the different contamination sources and the influencing parameters can be found in **Annex 2: Chemical contaminations** on page 20.

BRCGS Clause	ECMA Guidance
2.2.7	According to HACCP principles, control measures can be divided into three levels. The basic level are prerequisites or PRP's, these can be interpreted as the 'must haves' and are defined in the BRCGS standard in chapters 4,5,6. The assumption is that these control measures have to be implemented anyway, even before you begin to think about risks. In previous versions of the BRCGS packaging standard an exemption clause was included, by which it was possible for a company to avoid some PRP's defined by BRCGS, if these were not relating to any significant risk for the specific process. Sadly this option has been deleted form version 6. The second and third level of control measure are called 'operational prerequisite (OPRP), or general control measure, and 'Critical control point' (CCP) These controls are specific to the company process, and follow as a result of the risk assessment process. The risk assessment is commonly a rating of likelihood of occurrence of a risk, with a rating say 1 to 5, multiplied with the severity of the consequence of the risk also rated say 1 to 5. So the risk multiplication will lead to a table of scores ranging from 1 to 25. Within this score range the company can define a threshold level for what risk is relevant. Any risk value below means that the risk is minor and no additional controls need to be implemented, any risk value above means the company needs to do something to control the risk and reduce it. So, either OPRP or CCP.

Example to BRCGS Clause 2.2.7

With reference to the process flow (2.2.4), the following relevant control points can be identified: Order processing: Identification of packed food and intended use, legal aspects (market of destination). Product development: Selection of suitable board, inks and varnishes, adhesives, plastic film for windows. Maximum acceptable application of volumes for ink, varnish and adhesive layers. Accurate clear approved product specifications. Material buying from cleared suppliers, based on certificates, audits or questionnaires, with a detailed declaration of compliance and approved by the food safety compliance director. Incoming goods control: check of documents, conditions on delivery, sensory check raw materials. Printing: Monitoring of drying/curing. Cleaning of machines with appropriate wash agents and in accordance with the established procedures. Ventilation of printed piles. Storage of raw materials, work in progress and finished goods: avoid contact between raw materials, products and dirt, exhaust gases and vapours. Covering of piles during intermediate storage. Traceability of products and materials used and manufactured. Avoid mixing. Personnel hygiene and response to hygiene incidents. Equipment: Excellent conditions of all machines used. Contact points between machine and product (lubricants). Aside those general relevant control points, customers are sometimes introducing own specific risks for which the health risk may not be high, but which are perceived by the customer as important for the product and brand value. Those risks need to be addressed as Pre Requisite Programs specified by the customer.

BRCGS Clause	ECMA Guidance
2.2.8	Classic HACCP theory often introduced the 'decision tree' process to determine whether a control point should be critical or not. The decision tree leads the user through a workflow based on yes/no questions to point to a certain outcome. So for each hazard that is identified to be relevant according to the previous section, this process has to be followed. Often for packaging processes the outcome is that no CCP's are to be implemented. Metal detection is sometimes mentioned as a CCP in carton manufacturing. Metal detection is however not usual in carton plants, and is present at other levels in the supply chain, in the way materials are specified and depending on the customer categories further down with the end users. Mixing is a hazard that may be considered as a critical control point. The mixing of products leading to, for instance, missing information on the present ingredients and present allergens may be very critical. The use of the decision tree system may sometimes lead to a difficult or incorrect judgement. The easier alternative, which is acceptable for packaging processes is to simply define a second threshold level in the risk matrix to create differentiation into three levels low, medium and high. Low is then an accepted risk, medium requires control through OPRP, high risk requires control through CCP.

Example to BRCGS Clause 2.2.8

Practical example of a HACCP safety hazard assessment.

See Annex 3: Practical example of a safety hazard assessment on page 22.

BRCGS Clause	ECMA Guidance
2.2.9	Critical limits for a CCP are to be defined. The limits are usually defined by the equipment supplier. Relevant is that the limits are in accordance with what the market is accepting. For mixing, there are no limits accepted by the market, there is no tolerance. The easiest way to control, is to find technical solutions by bar code reading at the gluing station or measures at the die cutting. Without technical solutions it is more difficult to secure.

BRCGS Clause	ECMA Guidance
2.2.10	Monitoring of a CCP means regular testing to verify the working of the control, and recording the results.

BRCGS Clause	ECMA Guidance
2.2.11	This clause may imply that the produced stock needs to be staying within the control of the packaging company for the timespan that the verification is recorded. A positive release system may be specified in the order. A positive release for final products is exceptional in carton manufacturing, only in highly sensitive cases or in view of consecutive problems. Within the company between the different process steps there is however a positive release. The ink needs to be well dried before the next production step.

BRCGS Clause	ECMA Guidance
2.2.12	An annual review is the minimum, some companies are revisiting the hazard and risk management system twice a year. Significant incidents may include for example changes in equipment, changes in raw material supply or a serious customer complaint involving product withdrawal or recall.

2.3 PRODUCT SAFETY AND QUALITY MANAGEMENT

BRCGS Clause	ECMA Guidance
3.4	Product specifications are commonly the result of negotiations between supplier and customer. In many cases in the carton industry, the specification ownership will be with the customer and the carton manufacturer role is to reproduce a design for which the customer is providing the reference materials and approved reference. Typically, the record of approval is documented with the 'approval to print' confirmation. It may be important for operators to verify how a formal agreement is documented in case of a web-based exchange of print reference materials. In case the customer is requesting the carton manufacturer to issue product specifications, a typical specification document is based on a cad drawing of the flat carton, and the information contained mentions dimensions, type of cartonboard used, addition of type of printing, coating and optionally adhesive. Multiple print designs are usually combined under one product specification, for which separate design drawings can be added. Details may be added as required on product weight, content of recycled fibre (post consumer if known), recyclability, gloss, friction, bending resistance, compression strength and so on. Along with the product technical specifications, for packaging destined for food a Declaration of Compliance (DoC) is to be provided. This document formally confirms the packaging products legal status and level of suitability in direct contact with food. A template reference document DoC is available from ECMA. Important considerations when writing a DoC are: The intended use, and foreseeable non intended use, as well as restrictions of use (e.g. not suitable for oven heating). Another parameter to be considered is the packaging surface to product volume ratio. (How much weight of food product is filled in one packaging item, and how many dm2 of packaging is used in that item. In an EU legal context often is assumed that 6dm2 of packaging surface equals 1 kilo of filling goods. In most carton applications a carton of 6 dm2 dimensions will contain less than a kilo of product. The implication is that the concentrations of migratable restricted substances in the carton should also be less. In addition to the specifications and the declaration of compliance, sometimes also "Acceptable quality levels AQL" are discussed with the customer. Such an attachment to the specifications provides a list with typical small quality defects. In an industrial process, complaints concerning about 3 or 4 boxes on a total delivery of a million pieces don't make sense. In an AQL it is stated how defects up to a certain level are accepted. The principles to AQL are explained in ISO standard 2859.

Example to BRCGS Clause 3.4

The Checklist to use with customers (available from the Members Only section of the ECMA website) offers an appropriate frame for discussing and defining the appropriate product specifications.

Go to: www.ecma.org – Member Login – Members Only – ECMA GMP – ECMA GMP Checklist (PDF)

The ECMA website provides also Technical Guidelines for the creation and exchange of artwork files **(go to: www.ecma.org – Publications – ECMA Technical Guidelines (PDF)** and in case the carton maker is issuing the product specifications the intellectual and industrial property rights are in general covered in the ECMA Sales conditions (section 5).

Go to: www.ecma.org – Member Login – Members Only – ECMA Sales Toolkit – ECMA Support Tools – ECMA Terms and Conditions of Sale (PDF)

Another document the ECMA members can download from the Members Only section of the ECMA website is a Food Contact Status Declaration template.

Go to: www.ecma.org – Member Login – Members Only – ECMA GMP - Food Contact Status Declaration (Word)

This template covers general information, a general description of the pack, the confirmation of the intended use, the declarations obtained from the raw material suppliers , the performed risk assessment and the required further compliance work.
AQL is based on sampling of lots and verification of the sample to either approve or reject the lot. Starting from the lot size, the sample sizes and number of acceptable defects are based on tables such as shown in **Annex 4: Practical example of an Acceptable Quality Level (AQL) table** on page 24.

As depicted in the table three general inspection levels are mentioned, as well as four special inspection levels. What general inspection level is applicable is to be negotiated and agreed between customer and supplier. The special inspection levels are used to follow up re-production of a lot after a reject or customer compliant on a previous lot of the same product. Obviously customer and supplier can agree on deviating samples and accepted levels and agree specific for the customer.

BRCGS Clause	ECMA Guidance
3.7	It is an obvious key element in GMP that the carton company is working with good reliable suppliers supplying materials that are consistent and suitable for purpose, especially regarding food contact safety assurance. Supplier approval procedures will likely have been implemented already as it has been a common requirement for many years in food safety certification as well as quality management system certification. Approvals can be based on the certification level of the supplier, a supplier audit or questionnaire reply score. Certification of the supplier or to have a supplier audited are the preferred options to approve suppliers but if not possible or practical a questionnaire is acceptable too. Just make sure though that relevant food safety control questions are incorporated and the questionnaire contents are not just covering quality or environmental topics. If a supplier is certified according to a GFSI scheme, no further effort in auditing or questionnaire is needed. Differences exist across Europe, in the UK the approval of suppliers will be more based on certification, as BRCGS (and other types of certification) are more widespread also upstream, while for instance in Germany carton makers are more used to working with their own audits. It is most important that there is assurance of the consistency of the supplied product and that the supplier is well able to monitor the composition and stability of the material and its suitability for use in food contact. Also in relation to this BRCGS clause, it is important to take in account the specific requirements of the customer and what he is asking for! If customers are really looking after specific substances, there is no other option other than checking with the supplier, they know their products best and what they are putting in. For a carton company there will be situations where the customer has already validated certain materials, and defines to the carton company which material suppliers are to be used. In such case these suppliers will be approved by default and no need for the carton company to make efforts in supplier approval. It is relevant though to have the approval reason well documented. Supplier performance monitoring is pretty straightforward and may be based on defined performance criteria of which the cost is not the least important. Typical further criteria may include the product quality, complaints, delivery performance, service level and so on.

Example to BRCGS Clause 3.7

A supplier questionnaire is available per FCM used (board, inks and varnishes, adhesives and plastic). The confirmed compliance with reference legislation (EU/national) and sector specific guidelines provides an indication on the reliability of suppliers. Especially the level of detail included in the obtained Declarations of compliance, the information on the used restricted substances, the not listed self evaluated substances, the dual use substances and the NIAS, as well as the given use restrictions, are a further indication the production process and monitoring are accurate.

Go to: www.ecma.org – Member Login – Members Only – ECMA Food Safety Committee – 2020 - ECMA GMP Supplier Questionnaire - 17 September 2020 (PDF)

BRCGS Clause	ECMA Guidance
3.8	The carton producer should have a process in place to access information on historical and developing threats to the supply chain that might lead to the supply of fraudulent materials. This issue is an important topic in the food industry and from a continuous improvement perspective, it is useful to look into. Aside other sources, the ECMA membership assures regular supply of email updates that keep members well informed. In the carton industry it is generally accepted that threats will be low. Potential frauds that should be considered is the supply of non-low migration ink where low migration ink is purchased, or the addition of (bleached) recycled fibre in a virgin carton. Common claims not related to food safety but very relevant to carton industry are related to the sustainability of the wood used to make cartonboard with claims as FSC and PEFC. Sourcing paper and board from traders may represent a risk in view of compliance with the Timber Regulation. A company also has to document a 'vulnerability assessment' now on all (groups of) raw materials to assess the potential risk of substitution. In other words: does the company receive the material they ordered. A vulnerability assessment can be built as a model with points scored on a series of attributes. Parameters to consider for example are History of fraud, economic benefit, geographic origin, complexity of supply chain, ease of access, physical consistency of the material (liquid, solid, bulk), testing methods, existing controls. Examples of a structured assessment approach can be found on the internet. Check for example the 'International Food Safety and Quality Network' (IFSQN). The expectation for carton industry is non the less that the document assessment is to confirm that the supply chain is reliable and the vulnerability to fraud is low.

Example to BRCGS Clause 3.8
International Food Safety & Quality Network: www.IFSQN.com. Example of a vulnerability assessment from the food industry, see **Annex 5: Example of a vulnerability assessment for a food ingredient "Rapeseed Oil"** on page 25. Another very advanced vulnerability assessment approach is available from www.ssafe-food.org. A useful free tool is available and can be downloaded, with a decision tree, a detailed questionnaire and spiderweb assessment templates.

BRCGS Clause	ECMA Guidance
3.9	In case of subcontracting or outsourcing the carton company needs to make proper arrangements with the contractor in order to ensure the products are treated with the same food safety and hygiene standards as the carton company itself. The easiest approach is to select contractors who themselves are also certified companies to a recognized food (packaging) safety management system. If not, the contractor needs to be validated as included in the supplier approval procedure through auditing, or documented questionnaire. The carton company needs to monitor its contractors regularly to ensure reliability to meet the requirements. Specifications for the contracted or outsourced work should be in place and agreed. This does not refer to the product specification but to the way the products are to be handled by the contractor and what operation the contractor does to the products. The final release remains a responsibility of the carton company. This can be ensured by having the products physically returned for inspection and approval. It may also be organized by having the contractor send a set of samples to the carton company to assess and approve and then allow delivery of the goods directly to the customer.

2.4 SITE STANDARDS

BRCGS Clause	ECMA Guidance
4.6	Requirements on equipment state that equipment shall be designed for the intended purpose and shall minimize the risk of contamination. The equipment used in carton manufacture is usually not designed with food contamination prevention in mind so the options to influence design are limited. The carton company is normally not the designer of equipment and has to work with equipment as offered by the manufacturer. It can be concluded that this type of equipment is 'fit for purpose' as a general term. In cases where the carton company is designing its own equipment or equipment modifications there are more possibilities to consider concerning suitable design. The use of wood should be avoided, if possible, on items like stacking boards for palletisation of products. Arguably the use of wooden boards can be suitable as the risk of product contamination is limited, but equally when equipment has to be replaced this is the opportunity for the company to be showing the 'hygienic design mindset' as a supplier to the food industry. Elevated walkways that cross over products should be designed not to cause contamination, so no open mesh floors. Introduce glass protection and other features that may contribute to avoid the contamination of the product. Aside the design of the equipment, the inappropriate use of equipment is an important source of contaminations.

Example to BRCGS Clause 4.6

Appropriate use of the equipment. A guideline developed in the Packaging Ink Joint Industry Taskforce on the use of printing inks for paper and board packaging used for food contact, provides background for correct cleaning, ink drying and change overs from normal to low migration printing. H1 lubricants need to be used.

See **Annex 6 - Appropriate use of equipment** on page 26.

2.5 PRODUCT AND PROCESS CONTROL

BRCGS Clause	ECMA Guidance
5.2	The responsibility for graphic design and the liabilities that go with it are important topics to document with the order acceptance process. In most cases the customer placing an order will have the ownership of the graphic design and provide digital files to be printed. The carton company takes custody of the data and has to ensure that the files are well stored and protected. Carton companies may also have the expertise in house to make designs upon request of a customer, in which case rigid approval procedures have to be ensured before production. When preparing a job for printing, the carton company will use the approved files and uses these to make up possibly a multiplication of an item to suit the capacity of the print press (i.e. the design fits 4,6, 9, or so, times on a print sheet). Also elements like EAN Barcode, FSC logo with printer code, other logos (recycling, sustainability) from the marketing perspective, codes for item recognition and such may be added. Whatever happens to the file, the customer must approve the final artwork, the responsibility is with the customer and this includes aspects such as the text readability and font height. ECMA members need to manufacture in accordance with what was approved. Once the print is on press, all items should be checked for being correct before the actual printing can start. Approvals to be documented as part of the process controls. All this does not mean carton makers can just print whatever is requested For example it is not permitted to print both PEFC and FSC logos on the same pack.

Example to BRCGS Clause 5.2
A Technical Guideline for the creation and exchange of artwork files is available from the ECMA website. This publication covers, the die-line, the requirements on the text and graphic elements and the varnish, file formats, data structure and file names, means of data transfer, proof documents, digital proofs, the division of responsibilities and the data handling. **Go to: www.ecma.org – Publications – ECMA Technical Guidelines (PDF)**

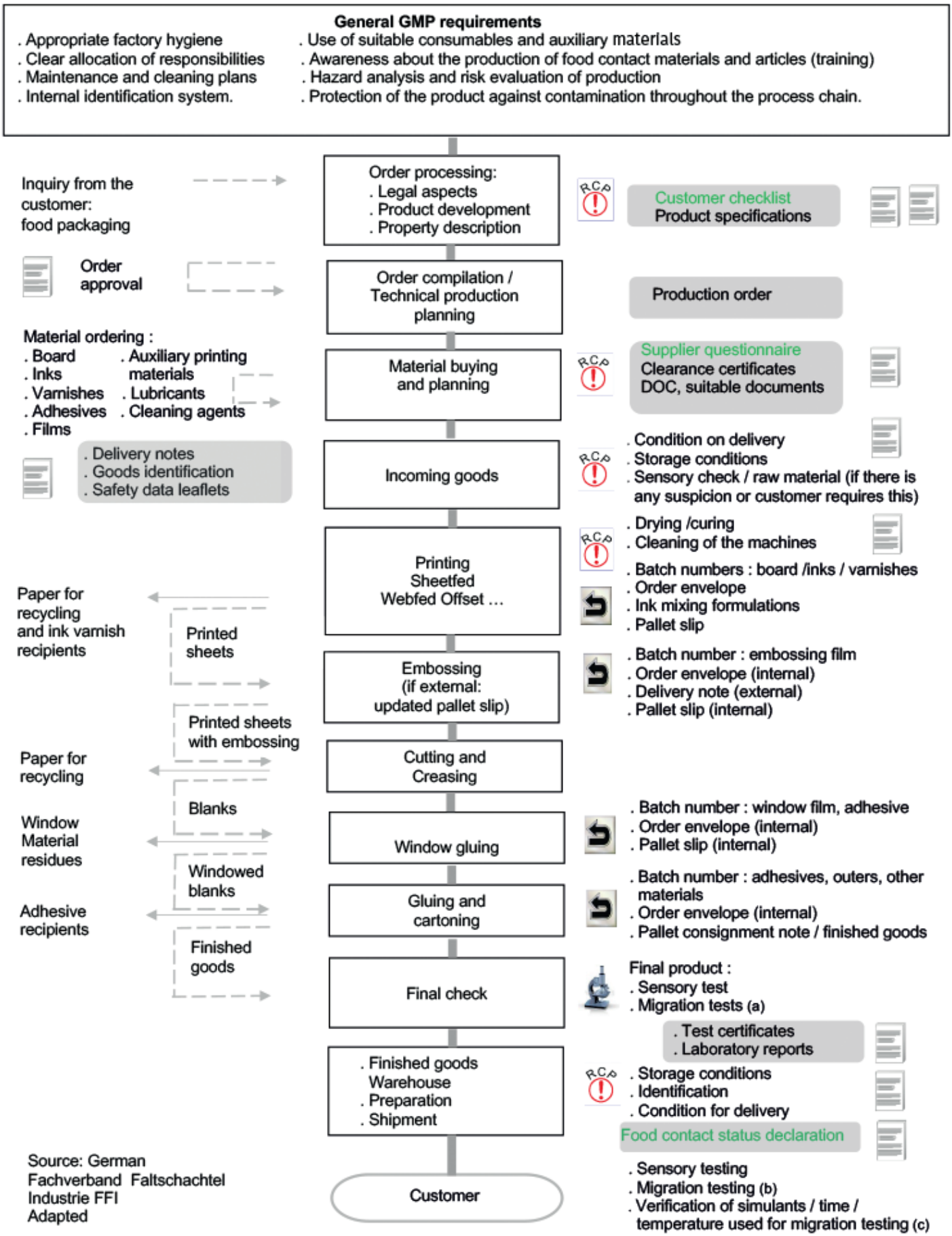
BRCGS Clause	ECMA Guidance
5.6	Depending on the contents of product specification and requests by customers, various product tests to technical attributes can be included in the order. Material related weight and calliper, bending resistance and the related crease efficiency, colour measurement, barcode readability, coefficient of friction, gloss are all measurable attributes that could be tested if this would be relevant or agreed with the customer. Testing for compliance with legal requirements is another dimension. One requirement is that the packaging should not have any negative taint & odour effect on the packed product. This is a quite subjective requirement. A carton company might be able to set up a testing panel to test for taint & odour, a commonly applied method referred here is the Robinson test. But this test is designed with chocolate as a tasting medium and is only really meaningful when testing carton packaging intended for chocolate or a similar product. As carton packaging has many variable applications it is always wise to have the customer evaluate the packaging with their product and have them approve. The second legal requirement is the chemical purity. The packaging may not have an effect on the packed product that could induce a health risk, or even what could be considered 'an unacceptable change of composition' of the packed product. Here comes in to play that for the scope of plastic packaging, the listings of chemicals are defined in EU legislation, a lot of them with restrictions in maximum levels considered safe in food. These plastics regulations are not directly applicable to cartons for cartons are not plastic, but taking account the general requirement of no unacceptable change of composition, they can still be used to apply the same limitations to carton packaging. Aside the requirements originating from food safety authorities, as indicated in 3.4, certain customers are also coming with their own substances at their own specific levels which they want to have checked in test conditions. The starting point for chemical compliance verification is always a risk assessment. In certain cases no further verification will be required, e.g. in case a functional barrier is present. The testing for substances is done by migration testing and requires specialist knowledge and equipment. Therefore this type of testing is usually done in third party laboratories. Since these type of tests are time consuming and expensive, the carton company should develop a wisely chosen plan of sampling and periodic testing, in order to build data and knowledge over time. It needs to be highlighted that monitoring and demonstrating compliance with the relevant restrictions can however be achieved by other means such as using worst-case calculations or mathematical modelling or by using available data on worst case samples or test results in more severe migration test conditions.

Example to BRCGS Clause 5.6
A listing of laboratories that can provide chemical testing is available from the ECMA members website. **Go to www.ecma.org – Member Login – Members Only – List of migration specialised laboratories (PDF)** The CEPI/CITPA Food Contact Guidelines for the compliance of paper & board materials and articles" provides valuable information on the recommended testing for paper and board materials and articles. **Go to: www.cepi.org – Policy Areas – Product Safety - Food Contact Guidelines for the Compliance of Paper and Board Materials (PDF)**

BRCGS Clause	ECMA Guidance
5.8	A carton company should check incoming deliveries of materials to assess that the materials can safely be used to produce food packaging. The delivery should be assessed for being the correct product in the correct quantity which can be done by assessing product labelling to be consistent with order papers / system documentation. Next the products should be delivered without physical contamination and with its packaging being undamaged. This type of inspection is typically performed by the employees in logistics that are unloading the materials. Good practice would expect a formal recording to confirm that the materials have been inspected and approved for delivery. When deemed appropriate, it is optional that the carton company samples deliveries for analysis to confirm the technical attributes are as agreed per specification. For carton board this can include a check of grammage, caliper and bending resistance. It is also common practice to demand the supplier to issue a certificate of analysis with the deliveries, so that a review of the testing data from the supplier can be used as an alternative to product sampling. Also on incoming deliveries it is relevant to assess for taint and odour, in order to ensure there will no issue once the materials are used in the process. The taint and odour assessment in this stage would be limited to a general awareness observation by the employees in the incoming goods area. It may be applicable to both the delivery vehicle as well as the goods delivered. Based on risk assessment (complaints, historical data ...) it is possible to bring down the level of control for the incoming goods from the regular suppliers. The level of control can't be lowered for the new suppliers and in case of previous complaints.

2.6 ANNEXES

Annex 1: Process flow – General GMP Requirements



a Testing can only be done on the finished food contact material. In case the customer adds another layer or material for example (inner bag), migration testing must be done on the combination of the inner layer AND the printed carton. In principle, the printer needs to perform testing only on the printed material/article for which he is responsible. However, if an inner bag is used for example, it is for the customer of the printer to evaluate the combined printed carton with the inner bag.
Note that migration testing can be avoided when other ways can be used to demonstrate compliance (modelling, worst case calculations, using results of other samples/more severe conditions)

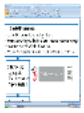
b Migration testing needs to be done by the customer in case the customer places an additional layer or material between the printed material and the food (an inner bag as the first example or a bottle that is placed between the printed carton/paper and the food).

c The customer needs to verify that the migration testing performed by the producer of the printed carton/paper is sufficient and adequate for the food he is intending to place in the packaging. Tables with simulants that need to be selected and that are for example included in the Regulation on Plastics can be used as a guidance. However, it is the responsibility of the customer to verify whether this guidance is appropriate for his food.

Relevant control point
Control and documentation are required here in order to guarantee the legal marketability of the product.

Traceability
Steps need to be taken here to make sure that the products are identified clearly. It must be possible to demonstrate the origin and/or destination of the materials used.

Testing
At these control points, it is advisable to make internal tests to check the packaging or to have tests carried out by independent, certified laboratories.



Documentation
Control points that have to be documented adequately and have to be signed by staff responsible. Processes are made transparent via appropriate documentation.

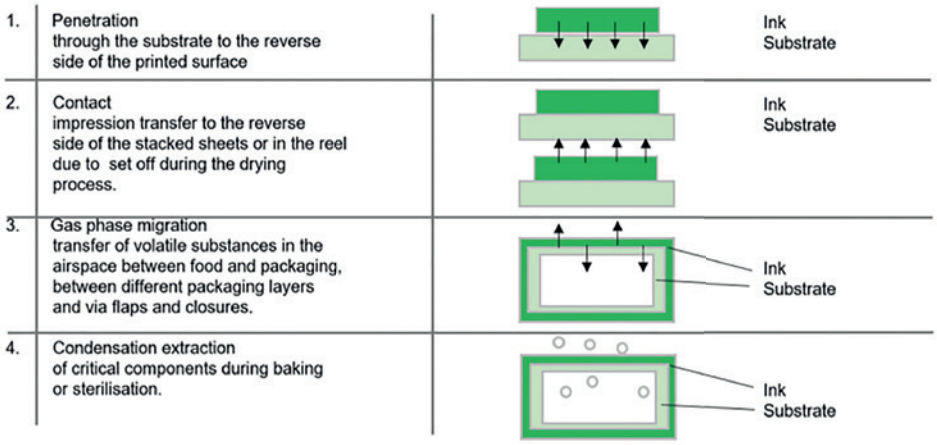
Annex 2: Chemical contaminations

Ink migration

Migration of a constituent is the transfer of the constituent into food through the packaging material. Specific regulations determine the migration limits for certain substances. Migration above compliance limits can occur from different layers of packaging, unless there is a functional barrier in place.

There are four key ways in which migration occurs. The overview below covers inks as an example to explain the migration mechanisms.

As explained in the following paragraphs migration also happens from other sources.

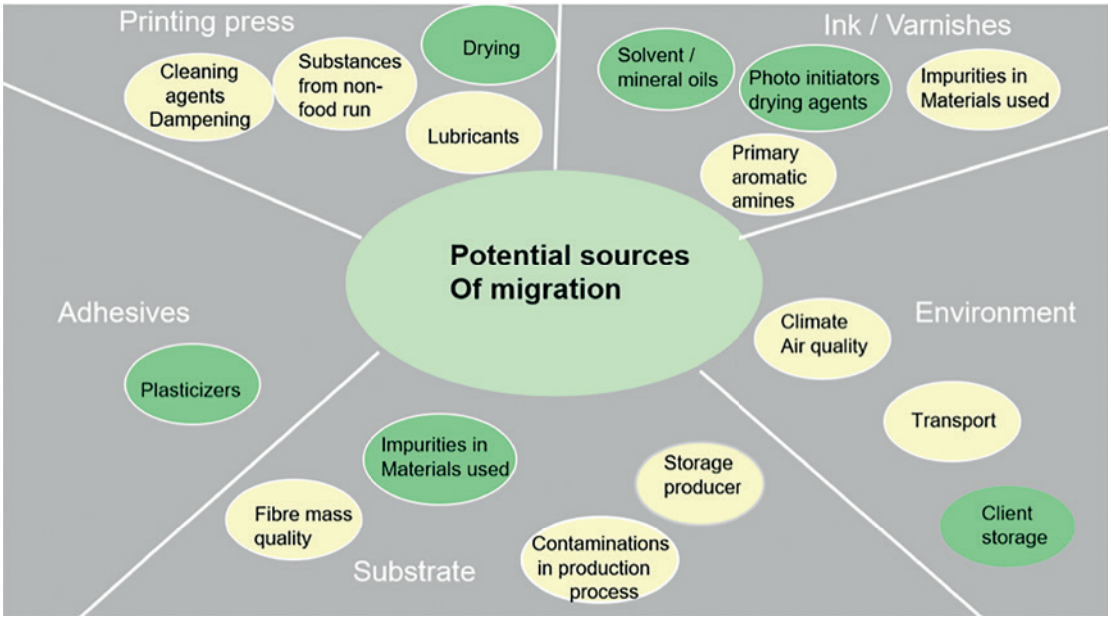


Source : Club MCAS Bonnes pratiques d'impression des fabricants de matériaux et objets en papiers cartons destinés à entrer au contact avec les denrées alimentaires. (adapted)

Visible set-off is caused by mechanical rub or by 'blocking' of a partially dried ink film and is generally regarded as a quality problem. Set-off of substances that are prone to migrate are usually invisible. Both types of set-off can lead to not compliant packaging from a food safety perspective.

Sources of contamination

Possible sources of contamination during manufacture of packaging, through different primary aspects (substrate, printing and conversion, ink and varnish composition, adhesives, environment) are identified in the diagram below:



Source : Club MCAS (adapted)

Migration influencing parameters

Subsequent transfer of substances originating from the printed and glued pack to the food contact side of packaging and subsequently to the food is dependent on many different parameters.

Composition and design of the packaging and its components (substrates, inks, varnishes, and adhesives), the size of the substance, the type of food, the surface/volume ratio, storage time and temperature, other storage conditions of the filled packaging, are only a shortlist of the most important parameters influencing possible transfer of substances into food.

Food contamination

Dual use substances require extra attention in risk assessments. Such substances are authorised as food additives and can also be part of the ink, varnish or adhesive formulation. It is important to check, overall compliance should take account of all sources.

Certain substances may also be already in the food by nature, or the food may be contaminated with unintentionally added substances from other sources.

Annex 3: Practical example of a safety hazard assessment

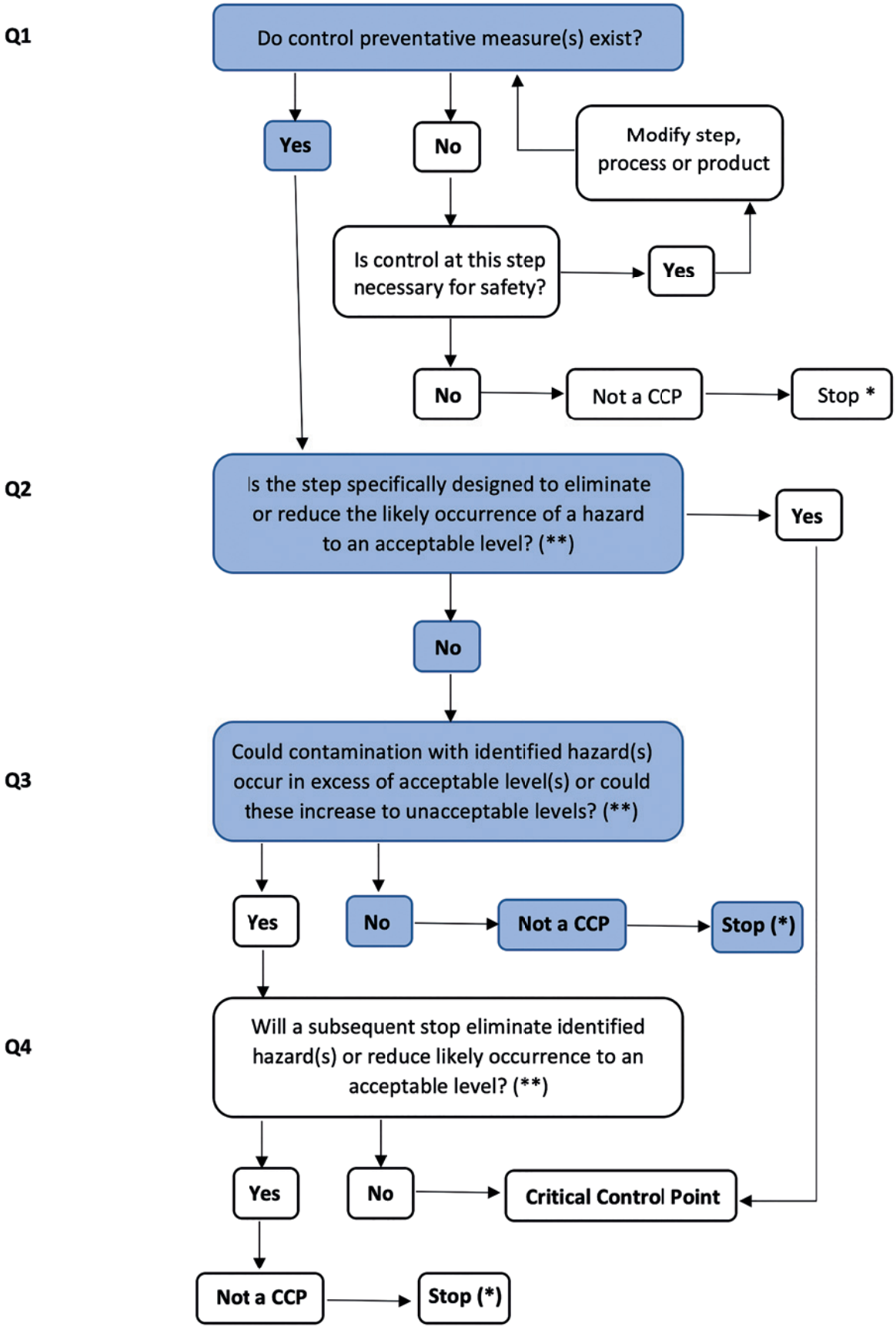
Within the guidance provided in relation to the clauses 2.2.7 and 2.2.8, is explained how a risk assessment process is leading to a classification of risks based on likelihood and severity. A threshold of acceptable risk is determined and if the risk score is above the threshold, the risk is perceived as relevant and needs to be controlled by an operational control measure or a critical control point.

The easiest and for packaging accepted way to make the split between OPRP and CCP is by defining a second threshold. As further background, below however also an example of the use of a decision tree as well established in HACCP.

HACCP example ECMA

Process step	Potential hazard(s)	Cause	Precentative measure(s)	CCPs	Critical Limit(s)	Monitoring procedure(s)	Corrective Action(s)	Record(s)
Cutting of sheets using compressed air	Chemical contamination of product	Contamination of air with lubricant residues	Use of food grade lubricant and regular maintenance of filters	No*	N/A	N/A	N/A	N/A

*As per decision tree:



Extract of CAC-RCP 1-1969, Rev4-2003 – Recommended International Code of Practice General Principles of Food Hygiene

Annex 4 - Practical example of an Acceptable Quality Level (AQL) table

AQL levels are discussed with the customer.
Typically, a table as below is indicating which level of small quality defects is accepted.

Reading of the tables:
If the lot size is 500 001 and a general inspection level I, is agreed with the customer the table is indicating a sample size code letter N.

The sample size is 500 and in case an acceptable quality level of 2,5 is agreed, this means the lot can still be accepted in case of 21 defects. 22 defects are leading to a rejection.

SAMPLE SIZE CODE LETTERS

Lot Size	General Inspection Levels			Special Inspection Levels			
	I	II	III	S1	S2	S3	S4
2 to 8	A	A	B	A	A	A	A
9 to 15	A	B	C	A	A	A	A
16 to 25	B	C	D	A	A	B	B
26 to 50	C	D	E	A	B	B	C
51 to 90	C	E	F	B	B	C	C
91 to 150	D	F	G	B	B	C	D
151 to 280	E	G	H	B	C	D	E
281 to 500	F	H	J	B	C	D	E
501 to 1200	G	J	K	C	C	E	F
1201 to 3200	H	K	L	C	D	E	G
3201 to 10000	J	L	M	C	D	F	G
10001 to 35000	K	M	N	C	D	F	H
35001 to 150000	L	N	P	D	E	G	J
150001 to 500000	M	P	Q	D	E	G	J
500001 and over	N	Q	R	D	E	H	K

ANSI/ASQ Standard Z1.4 - 2008

SINGLE SAMPLING PLANS FOR NORMAL INSPECTION

Sample Size Code Letter	Sample Size	Acceptable Quality Levels (Normal Inspection)																					
		0.065		0.10		0.15		0.25		0.40		0.65		1.0		1.5		2.5		4.0		6.5	
		Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re	Ac	Re
A	2																					0	1
B	3																			0	1	↑	
C	5																	0	1	↓			
D	8															0	1	↑		↑		1	2
E	13													0	1	↓		↑		1	2	2	3
F	20											0	1	↑		↑		1	2	2	3	3	4
G	32									0	1	↑		↓		1	2	2	3	3	4	5	6
H	50							0	1	↑		↓		1	2	2	3	3	4	5	6	7	8
J	80					0	1	↑		↓		1	2	2	3	3	4	5	6	7	8	10	11
K	125			0	1	↓		↓		1	2	2	3	3	4	5	6	7	8	10	11	14	15
L	200	0	1	↑		↓		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22
M	315	↑		↓		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑	
N	500	↓		1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑			
P	800	1	2	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑					
Q	1250	2	3	3	4	5	6	7	8	10	11	14	15	21	22	↑							
R	2000	3	4	5	6	7	8	10	11	14	15	21	22	↑									

↑ Use first sampling plan above arrow, if sample size equals or exceeds lot or batch size, do 100 percent inspection.
↓ Use first sampling plan below arrow AC : Acceptance number Re : Rejection number

Annex 5 - Example of a vulnerability assessment for a food ingredient “Rapeseed Oil”

available from IFSQN (www.IFSQN.com)

As explained in the guidance related to clause 3.8, vulnerability assessments are a well- established practice in the food industry, to minimize the risk of purchasing fraudulent raw materials.
Below an example from the food sector for a food ingredient, rapeseed oil:

Vulnerability Assessment

QS-Development
Quality is Dynamic
www.gsd.ie

	High: 1 / Medium: 3 / Low: 5					High: 1 / Medium: 3 / Low: 5		
Food Material	**Nature - Physical Form?**	**How is the historical evidence?**	**How is the economic factor?**	**How possible is the access in the SC?**	**Significance = Addition of ratines**	**Is the testing/detection sophisticated?**	**How likely can we detect? Measures in place?**	**PRN**
Rapeseed Oil	3	5	3	3	14	1	5	70
Details	Single liquid ingredient	Other oils (olive oil) have been adulterated before ...DETAILS	Other oils (peanut, coconut) are more expensive ...DETAILS	Short supply chain. No seals used on oil drums ...DETAILS	...DETAILS	High Know How ...DETAILS	No measures in place in-house	...DETAILS
					0			0
					0			0

Developed by QS-Development - Revision 2 - September 2015

The quotations for the different criteria (form, historical evidence, the economic advantage to substitute, the access in the supply chain) are added, and multiplied with control criteria (sophisticated testing, chance to be detected) ending in an overall score. The company needs to define a score level, above which monitoring is required.

Annex 6 - Appropriate use of equipment

Guidance on Inks and varnishes

Introduction
Inks and varnishes have been a prime source of food safety incidents. For this reason the Packaging Ink Joint Industry Task Force developed a "Guidance for the use of printing inks for paper and board packaging used for contact with food". The following selected content is based on this PIJITF guidance.

Cleaning
To prevent contamination always use clean equipment and tools.

- Rollers and blankets must not be contaminated.
- Thorough cleaning with a dedicated cleaning agent

Normal press washes can also be a potentially significant source of unwanted migration. They are by nature both liquid and prone to migration.
When a risk assessment indicates the need for a low migration press wash the ink supplier can recommend a suitable press wash and provide guidance for its use which should be followed.
A low migration press wash is unlikely to be as economic and efficient as a normal wash and great care must be taken to change procedures to take account of this.
It is best practice to wipe the rollers and blankets dry of solvent wash after cleaning to reduce the risk of migration.

Ink Drying
Conventional Ink Drying: When low-migration inks are used, the addition of driers or drying accelerators on the press is not allowed. Ink films must be completely dried after application. Pallets with printed sheets should not be stacked before an appropriate drying time.

UV Curing
Incomplete curing of UV ink layers greatly increases the risk of migration and also the possibility of organoleptic effects giving rise to odour. The following is the recommended good practice to obtain satisfactory curing:

- check necessary power is readily available
- ensure correct number of lamps of right power and intensity are used
- ensure regular maintenance of lamps and reflectors

A variety of factors influence the degree of curing – the type and energy of UV lamp output including condition of reflectors, the press speed, the time interval between printing and curing, and the substrate (particularly when printing on non- coated board surface in relation to the absorbency). This means it is essential to continuously monitor and document the curing quality and output. Verify that current printing speed corresponds to pre-validated conditions and run tests to check there is sufficient curing of ink film. Note that the addition of non-approved curing accelerators on the press is not allowed.

Changing from Normal to Low-Migration Printing

Ideally, the same ink type should be run continually on a press to avoid the need for costly clean-downs and to avoid potential contamination. However, in circumstances when such changeovers cannot be avoided the following (non-exhaustive) list provides the basis for a code of practice for the changeover:

- use inks from original containers
- empty all ink and coating, ducts and pipes
- for offset process, change fount to the one recommended by the ink supplier, cleaning mixing and storage tanks, filters and pipes as part of procedure
- clean all rollers and blankets
- **certain substances liable to migrate may remain in the system – a risk assessment should be used to determine an appropriate time period to ensure any non-low migration traces are removed completely from rubber blankets or rollers**
- for first print run, an adequate quantity of run-up sheets should be printed as a way of removing any last traces of 'non-low migration' materials

  As best practice or to validate the procedure of the press cleaning process, consider having compliance testing (migration testing) done on the initial sheets run after completion of the change-over. Ideally the converter should talk to the ink supplier of the non-food grade inks to assess what trace chemicals could be used to do targeted validation testing.
- if ink is supplied to the press from a drum ensure there is no contamination from normal inks by using a clean pump and pipes and if a 'bag' is used in lining the drum ensure that there is no contamination from plasticisers
- ensure all subsequent processes are free of the risk of migration from solvents, plasticisers, oils, greases and other potential migrants
- storage next to unsuitable ink can also lead to migration

3. FSSC 22000 CERTIFICATION SCHEME FOR FOOD SAFETY MANAGEMENT SYSTEMS

3.1 IDENTIFIED FSSC 22000 CLAUSES

For all sections marked in green detailed guidance and examples are given in this document. The scheme overview and additional requirements can be downloaded from the FSSC website: https://www.fssc.com/schemes/fssc-22000/

The standards, ISO 22000 : 2018 and ISO/TS 22002-4 : 2013 are available from the ISO webstore : https://www.iso.org/store.html

1.	**ISO 22000:2018 REQUIREMENTS FOR ANY ORGANISATION IN THE FOOD CHAIN**
	Food Safety Management Systems
1	**Scope**
2	**Normative references**
3	**Terms and definitions**
4	**Context of the organisation**
4.1	Understanding the organisation in its context
4.2	Understanding the needs and expectations of interested parties
4.3	Determining the scope of the FSMS
4.4	Food Safety Management System
5	**The word d**
5.1	Leadership & Commitment
5.2	Policy
5.3	Organisational roles, responsibilities & authorities
6	**Planning**
6.1	Actions to address risks and opportunities
6.2	Objectives of the FSMS and planning to achieve them
6.3	Planning of changes
7	**Support**
7.1	General, people, infrastructure, work environment, externally developed elements of the FSMS, control of externally provided processes, products or services.
7.2	Competence
7.3	Awareness
7.4	Communication : general, extrenal, internal
7.5	Documentation : general documented information, creating and updating, control of documented information.
8	**Operation**
8.1	Operational planning and control
8.2	Pre-Requisite programs
8.3	Traceability system
8.4	Emergency preparedness and response
8.5	Hazard analysis : preliminary steps to enable HA, HA, Validation, hazard control plan
8.6	Updating the information specifying the PRP and hazard control plan
8.7	Control of monitoring and measuring
8.8	Verification related to PRP and hazard control plan
8.9	Control of product and process nonconformities
9	**Performance evaluation**
9.1	Monitoring, measuring, analysis and evaluation
9.2	Internal audits
9.3	Management review
10	**Improvement**
10.1	Non conformity and corrective action
10.2	Continual improvement
10.3	Update of the FSMS

2.	**ISO 9001 REQUIREMENTS (WHERE FSSC 22000 QUALITY IS REQUIRED)**

3.	**RELEVANT PREREQUISITE PROGRAMS (PRPS) ISO/TS 22002-4 : 2013 PACKAGING**
1	**Scope**
2	**Normative references**
3	**Terms and definitions**
4	**Generic PRPs**
4.1	Establishment
4.2	Layout and workspace
4.3	Utilities
4.4	Waste disposal
4.5	Equipment suitability, cleaning and maintenance
4.6	Management of purchased materials and services
4.7	Measures for prevention of contamination
4.8	Cleaning
4.9	Pest control
4.10	Personal hygiene and facilities
4.11	Rework
4.12	Withdrawal procedures
4.13	Storage and transport
4.14	Food packaging information and customer communication
4.15	Food defence and bioterrorism

4.	**FSSC 22000 ADDITIONAL REQUIREMENTS. NOVEMBER 2020**
2.5.1	Management of services and purchased materials
2.5.2	Product labelling
2.5.3	Food defence
2.5.4	Food fraud mitigation
2.5.5	Logo use
2.5.6	Management of allergens
2.5.7	Environmental monitoring
2.5.8	Formulation of products. (not for packaging)
2.5.9	Transport and delivery (not for packaging)
2.5.10	Storage and warehousing
2.5.11	Hazard control and measures for preventing cross-contamination
2.5.12	PRP verification
2.5.13	Product development
2.5.14	Health status (not for packaging)
2.5.15	Requirements for organizations with multi-site certification. (not for packaging)

3.2 CONTEXT OF THE ORGANISATION

ISO 22000 Clause 4.1: Understanding the organisation in its context
ECMA Guidance
Requirements are related to what is known as higher level structure in a series of ISO management systems standards, 9001; 14001; 45001 etc. Any organisation that is already certified to one of these standards is familiar with defining its context. Understanding the context of the organisation is usually demonstrated by drafting a context analysis. An inventory of interested parties to which the organisation has a certain relationship, either as desired by the organisation, or as unavoidable non desirable effect. Examples of typical interested parties, or stakeholders, are : Shareholder; Head-office; Sister-site; Competitor; Customer; Consumer; General public; NGO; Neighbour; Employee; Supplier; Authority; Certification body; Trade association.

ISO 22000 Clause 4.2: Understanding the needs and expectations of interested parties
ECMA Guidance
Once the interested parties are defined, the next step is to identify for each of these what their needs and expectations are. There are some obvious generics which can be listed here as a guidance, however it is up to each organisation to make the effort to pick up on site specific themes from this generic guidance. Some typical examples: Shareholder expects revenue; Customer expects reliable supply at best price and great service; Consumer wants user-friendly convenient packaging; Authority demands regulatory compliance; NGO want sustainability and environmental protection; Employee expects safe and healthy work environment and prompt salary payment; and so on.

3.3 PLANNING

ISO 22000 Clause 6.1: Actions to address risks and opportunities
ECMA Guidance
The actions to address risks and opportunities should reflect back on the context analysis that has been established with clauses 4.1 and 4.2. Knowing the needs and expectations of the organisations stakeholders is subjected to a SWOT analysis. At best practice the organisation can determine for all stakeholders where the organisation is performing strong or weak in meeting defined expectations. And whether risks should be mitigated or opportunities are up for grabs. This insight will then be the source of selections of actions or objectives to be set. It will normally not be realistic to set actions or objectives to all of the risks and opportunities. It could be valid for the organisation to be selective on the priorities.

ISO 22000 Clause 6.2: Objectives of the FSMS and planning to achieve them
ECMA Guidance
Once objectives have been decided upon, the standard requires from the organisation a plan on how the objective is to be achieved. Also, this is equivalent to ISO 9001 standard and the like. This basically means that it will not be sufficient anymore just to set a target (KPI), monitor the results throughout the year, and at the end evaluate if the target is achieved or not, and if not justify the reasons why. Making a plan to achieve objectives now implies more of an improvement project-based approach. The organisation needs to develop a plan of activities that will be done in a defined period in order to ensure the objective will be achieved. Also, it needs to be determined who will be responsible for the follow up, and how the success will be evaluated. Obviously within the scope of ISO 22.000, here we need to deal with objectives relevant to the food (packaging) safety management system. By example, let's say stakeholder employees are complaining about hot working climate in the factory and the SWOT analysis identifies an opportunity to improve ventilation, but in order to maintain the building proofed against pests, flyscreens should be installed as well. So, the objective can be defined as 'fly screens to be installed at entrance doors, in order to allow ventilation in summer months' to be completed by x date, responsibility with faciliatory department. Measurement of success: improved employee satisfaction by 10% according to survey score xxxx, together with no increase in EFK (Electric Fly Killers) counts vs previous year.

ISO 22000 Clause 6.3: Planning of changes
ECMA Guidance
Planning of changes mainly requires for the organisation MoC procedure to include, the site food safety team to be notified in the planning stage of changes in process that may impact the food safety management system i.e., change of equipment, raw material supplier, external logistics etc. Approach not dissimilar to health and safety related pre work risk assessment, for the expert team to assess.

3.4 OPERATION

ISO 22000 Clause 8.2: Pre-Requisite programs

ECMA Guidance

The prerequisite program (PRP) is a set of control measures which are more or less regarded as the defaults that are expected when implementing a hygiene management system. This involves typically things like hand wash facilities, protective clothing, pest control etc.

These controls are considered as to be implemented anyway before the product safety team starts to perform a risk assessment to the process steps. Any residual risks are identified and require additional measures to the PRP program.

Under ISO 22.000 where this clause is mentioned an organisation implementing FSMS is free to choose what measures are applicable as PRP. Within the scope of FSSC 22.000 though this is easy, as FSSC demands that for packaging processes the PRP program is defined by TS 22002-4 (as listed here in this summary).

ISO 22000 Clause 8.4: Emergency preparedness and response

ECMA Guidance

This section is dealing with situations when product safety controls are out of limits.

Situations imaginable could be a pest infestation in the factory, a glass breakage incident, a major machine crash that could imply metal particles are lost in the products. A mal function of UV curing on a print press and such a like.

When an incident occurs in internal process, factory workers should be sufficiently trained to be able to identify the issue as a potential contamination incident and notify responsible persons who can then decide whether there is a need to scale up the incident to isolate and quarantine stock, or even a potential recall or withdrawal.

Within FSSC 22000 certification scheme this clause will logically evolve into section 4.12 Withdrawal procedures of TS 22002-4.

ISO 22000 Clause 8.5: Hazard analysis: preliminary steps to enable HA, HA, Validation, hazard

ECMA Guidance

The Hazard control section (8.5) is quite similar to the BRCGS standard section 2 on Hazard and risk management. For the following clauses covered in ISO 22000:2018 reference is made to the content provided in relation to BRCGS (G - Guidance / E - Example / Annexes):

- **8.5.1 Preliminary steps to enable hazard analysis**
  - 8.5.1.1 General: BRCGS Clause 2.2.1 (Scope) (E) & 2.2.2 (Maintain awareness) (G/E)
  - 8.5.1.2 Characteristics of raw materials, ingredients and product contact materials & 8.5.1.3 Characteristics of end products & 8.5.1.4 Intended use: BRCGS 2.2.3 (Description of the product, customer checklist) (G/E)
  - 8.5.1.5 Flow diagrams and description of processes: BRCGS 2.2.4 (Process flow diagram) (G/E/Annex 1) & 2.2.5 (Verification) (G)
- **8.5.2 Hazard analysis**
  - 8.5.2.2 Hazard identification and determination of acceptable levels: BRCGS 2.2.6 (Identification of potential product safety hazards) (G/E/Annex 2)
  - 8.5.2.3 Hazard assessment & 8.5.2.4 Selection and categorisation of control measure(s): BRCGS 2.2.7 (3 levels of control measures) (G/E) & 2.2.8 (Decision tree CCP) (G/E/Annex 3)
- **8.5.4 Hazard control plan (HACCP/OPRP plan) :**
  BRCGS 2.2.9 (Critical limits CCP) (G) &
  BRCGS 2.2.10 (Monitoring) (G) &
  BRCGS 2.2.11 (Procedure when limites not met) (G) &
  BRCGS 5.6 Product inspection, testing and measuring (G).

3.5 GENERIC PRP'S

ISO /TS 22002-4 Section 4 Generic PRPs
ECMA Guidance
For the following generic PRPs covered in ISO/TS 22002-4 reference is made to the content provided in relation to BRCGS (G - Guidance / E - Example / Annexes): • 4.5 Equipment suitability, cleaning and maintenance : BRCGS clause 4.6 Equipment (G/E/Annex 6) • 4.6.2 Selection and management of suppliers : BRCGS 3.7 Supplier approval and performance monitoring (G/E) • 4.6.3 Incoming raw materials : BRCGS 5.8 Incoming goods (G) • 4.14 Food packaging information and customer communication : BRCGS 3.4 Specifications (E)

3.6 ADDITIONAL REQUIREMENTS

FSSC 22000 Additional requirement 2.5.3: Food Defence

ECMA Guidance

Food Defence (i.e. Product defence for packaging producers) refers to a routine of:
a) assessing the risk of the site being attacked for idealistic motives.
b) implementing sufficient security measures to mitigate this risk to acceptable levels.

The risk assessment process is often referred as TACCP (Threat assessment critical control point) , or threat analysis. Commonly in Europe it can be assumed that political threat to a carton factory is negligible. For this type of risk, looking at likelihood and severity, the likelihood will be very low, the severity may be very high.

Whether or not that results in a level of risk that needs additional security measures is up to each company to decide. Security measures tend to be in place anyway for property protection reasons, and those should be sufficient. Mainstream operators in the food industry might require specific security measures as well from their suppliers.

If a company has difficulty to make a TACCP type risk assessment an alternative approach can be to make a gap analysis based on Security standard checklists that are available on the internet.

FSSC 22000 Additional requirement 2.5.4: Food Fraud Mitigation

ECMA Guidance

Food fraud (i.e. product fraud for packaging producers) is referring to the processes being susceptible to fraudulent act, which is different to the product defence in that fraud is financially motivated rather than politically motivated.

The organisation is to assess here whether its products or processes are vulnerable to fraud. Hence the term VACCP for vulnerability risk assessment. Vulnerability assessment is to include the supply of raw materials, and potential to fraud to those.

Examples of fraud to the sector may include the selling of regular inks as being low migration inks, of using regular carton board instead of FSC claim board from sustainable sources. Unlike food industry examples of fraud in packaging industry seem unknown.

So, the outcome of VACCP is likely to be that no source of fraud is significant to imply additional measures to prevent are required. Example of a vulnerability assessment : See BRCGS 3.8 Product auhtenticity, claims and chain of custody. (G/E/Annex 5)

FSSC 22000 Additional requirement 2.5.6: Management of Allergens

ECMA Guidance

Requirements to the management of allergens for a (carton) packaging company are usually low. There will be no allergens present in the processes or products. One potential identified source might be starch based anti set-off spray powder used in offset printing. A declaration from the supplier is sufficient to exclude allergen content in those.

Further mitigation is implemented by excluding food and drink to be brought into the production areas by workers. A suitable canteen facility away from production should be available with provisions to store home brought food. Handwashing after breaks is implemented as part of the PRP program.

Declarations of allergens as relevant to the packed food may be included in print designs provided by the customers. It is important here for the carton manufacturer to document (non-) liability for any errors in print design.

In further converting process it is key to avoid risk of mix up in general and most importantly if a product line contains both allergen and non-allergen variants.

For comments in relation to responsibility for the graphic design : See BRCGS 5.2 Graphic design and artwork control (G)

4. CROSS REFERENCES

4.1 BRCGS – FSSC 22000

BRCGS Packaging Materials *Issue 6 - Part 2 Requirements*	**FSSC 22000 : 2018 & ISO/TS 22002-4 : 2013**
1. Senior management commitment	
1.1 Senior management commitment and continual improvement	
1.2 Management review	
1.3 Organisational structure, responsibilities and management authority	
2. Hazard and risk management	
2.1 Hazard and risk management team	
2.2 Hazard analysis and risk assessment	8.5 Hazard control
3. Product safety and quality management	
3.1 Product safety and quality management system	
3.2 Document control	
3.3 Record-keeping	
3.4 Specifications	8.2 Pre-Requisite programs. TS 22002-4 4.14 Food packaging information and customer communication
3.5 Internal audits	
3.6 Corrective and preventive action	
3.7 Supplier approval and performance monitoring	8.2 Pre-Requisite programs. TS 22002-4 4.6.2 Selection and management of suppliers
3.8 Product authenticity, claims and chain of custody	Additional requirements 2.5.4 Food fraud mitigation
3.9 Management of subcontracted activities and outsourced processes	8.2 Pre-Requisite programs. TS 22002-4 4.6.1 Management purchased materials and services. General requirements
3.10 Management of suppliers of services	
3.11 Traceability	
3.12 Compliant-handling	
3.13 Management of product withdrawals, incidents and product recalls	
4. Site standards	
4.1 External standards	
4.2 Building fabric and interiors : raw materials handling, preparation, processing, packing and storage areas	
4.3 Utilities	
4.4 Site security and product defence	
4.5 Layout, product flow and segregation	
4.6 Equipment [Press cleaning]	8.2 Pre-Requisite programs. TS 22002-4 4.5 Equipment suitability, cleaning and maintenance.
4.7 Maintenance	
4.8 Housekeeping and cleaning	
4.9 Product contamination control	
4.10 Waste and waste disposal	
4.11 Pest management	

5. Product and process control	
5.1 Product development	
5.2 Graphic design and artwork control	
5.3 Packaging print control	
5.4 Process control	
5.5 Calibration and control of measuring of monitoring devises	
5.6 Product inspection, testing and measuring	8.5.4 Hazard control plan (HACCP/OPRP plan)
5.7 Control of non-conforming product	
5.8 Incoming goods	8.2 Pre-Requisite programs. TS 22002-4 4.6.3 Incoming raw materials.
5.9 Storage of all materials and intermediate and fished products	
5.10 Dispatch and transport	
6. Personnel	
6.1 Training and competence : raw materials handling , preparation, processing, packing and storage areas	
6.2 Personal hygiene : raw materials handling, preparation, processing, packing and storage areas	
6.3 Staff facilities	
6.4 Medical screening	
6.5 Protective clothing	
7. Requirements for traded products	
7.1 Approval and performance monitoring of manufacturers/packers of traded packaging products	
7.2 Specifications	
7.3 Product inspection and laboratory testing	
7.4 Product legality	
7.5 Traceability	

4.2 FSSC 22000 – BRCGS

FSSC 22000	BRCGS Packaging Materials Issue 6 Part 2 Requirements
1. ISO 22000:2018 REQUIREMENTS FOR ANY ORGANISATION IN THE FOOD CHAIN	
Food Safety Management Systems	
1 Scope	
2 Normative references	
3 Terms and definitions	
4 Context of the organisation	
4.1 Understanding the organisation in its context	
4.2 Understanding the needs and expectations of interested parties	
4.3 Determining the scope of the FSMS	
4.4 Food Safety Management System.	
5 The word d	
5.1 Leadership & Commitment	
5.2 Policy	
5.3 Organisational roles, responsibilities & authorities	
6 Planning	
6.1 Actions to address risks and opportunities	
6.2 Objectives of the FSMS and planning to achieve them	
6.3 Planning of changes	
7 Support	
7.1 General, people, infrastructure, work environment, externally developed elements of the FSMS, control of externally provided processes, products or services	
7.2 Competence	
7.3 Awareness	
7.4 Communication: general, extrenal, internal	
7.5 Documentation: general documented information, creating and updating, control of documented information	
8 Operation	
8.1 Operational planning and control	
8.2 Pre-Requisite programs	3.4 / 3.7 / 3.9 / 4.6 / 5.8 (See below under heading ISO/TS 22002-4)
8.3 Traceability system	
8.4 Emergency preparedness and response	
8.5 Hazard analysis : preliminary steps to enable HA, HA, Validation, hazard control plan	2.2 Hazard analysis and risk assessment. 5.6 Product inspection, testing and measuring.
8.6 Updating the information specifying the PRP and hazard control plan	
8.7 Control of monitoring and measuring	
8.8 Verification related to PRP and hazard control plan	
8.9 Control of product and process nonconformities	
9 Performance evaluation	
9.1 Monitoring, measuring, analysis and evaluation	
9.2 Internal audits	
9.3 Management review	
10 Improvement	
10.1 Non conformity and corrective action	
10.2 Continual improvement	
10.3 Update of the FSMS	

FSSC 22000	BRC Packaging Materials Issue 6
2. ISO 9001 requirements (where FSSC 22000 Quality is required)	**Part 2 Requirements**
3. Relevant prerequisite programs (PRPs) ISO/TS 22002-4 : 2013 Packaging	
1 Scope	
2 Normative references	
3 Terms and definitions	
4 Generic PRPs	
4.1 Establishment	
4.2 Layout and workspace	
4.3 Utilities	
4.4 Waste disposal	
4.5 Equipment suitability, cleaning and maintenance	4.6 Equipment
4.6 Management of purchased materials and services	3.7 Supplier approval and performance monitoring. 3.9 Management of subcontracted activities and outsourced processes. 5.8 Incoming goods.
4.7 Measures for prevention of contamination	
4.8 Cleaning	
4.9 Pest control	
4.10 Personal hygiene and facilities	
4.11 Rework	
4.12 Withdrawal procedures	
4.13 Storage and transport	
4.14 Food packaging information and customer communication	3.4 Specifications
4.15 Food defence and bioterrorism	
4. FSSC 22000 Additional requirements. November 2020	
2.5.1 Management of services and purchased materials	
2.5.2 Product labelling	
2.5.3 Food defence	
2.5.4 Food fraud mitigation	3.8 Product authenticity. claims and chain of custody
2.5.5 Logo use	
2.5.6 Management of allergens	
2.5.7 Environmental monitoring	
2.5.8 Formulation of products. (not for packaging)	
2.5.9 Transport and delivery (not for packaging)	
2.5.10 Storage and warehousing	
2.5.11 Hazard control and measures for preventing cross-contamination	
2.5.12 PRP verification	
2.5.13 Product development	
2.5.14 Health status (not for packaging)	
2.5.15 Requirements for organizations with multi-site certification. (not for packaging)	

EUROPEAN
CARTON MAKERS
ASSOCIATION

WWW.ECMA.ORG

ECMA
P.O. Box 85612
2508 CH The Hague
The Netherlands
+31 70 312 39 11
mail@ecma.org