EUROPEAN CARTON MAKERS ASSOCIATION

FERA Visit 23 04 2024

ECMA participation

Graphic packaging : Mathilde Gros, Annika Schrimpf
Mayr Melnhof Packaging : Caroline Seguin
WestRock : Elaine Murray, Eliza Konecka-Matyjek
ECMA : Jan Cardon

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1. Introduction European Carton Makers Association.
2. FCM legislation
3. ECMA GMP Version 2.1
4. Recent public food safety positions.
5. Testing conditions
6. Items to cover in the discussion

1. Introduction
European Carton Makers Association

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Association

Represents over 650 carton producers

14 national associations

Suppliers to the carton industry

Activity

Carton manufacturing mainly for product packaging (first or second layer)

Board Inks Adhesives	→	Sheetfed Offset printing	→	Die cutting and creasing	→	Folding and gluing	→	Flat delivery

Sector turnover > 15 000 mln €

Membership : over 80% sector turnover

60 000 employees

ECMA Food Safety Committee

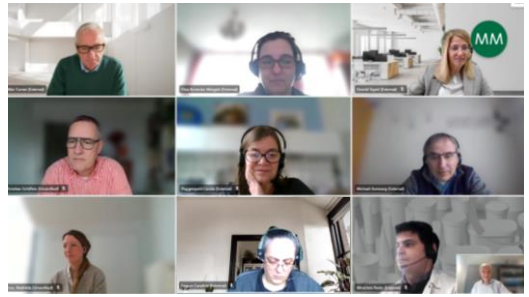
Chairmen

- ECMA
  Mike Turner
- SEDA
  Carmine Iuvone

FS Committee Members

- FFI German Folding Carton Association
  Christian Schiffers
- Graphic Packaging International
  Mathilde Gros
- Mayr Melnhof Packaging
  Sigrid Gerold, Carola Poggenpohl, Caroline Seguin
- Metsä Group
  Helena Moring Vepsalainen
- SEDA
  Paolo Minichini
- Van Genechten Packaging
  Michael Avemarg
- Westrock:
  Elaine Murray, Eliza Konecka-Matyjek
- ECMA
  Jan Cardon

Developed GMP
Delivers food safety guidance for the membership
Defines external FCM positions



2. FCM Legislation

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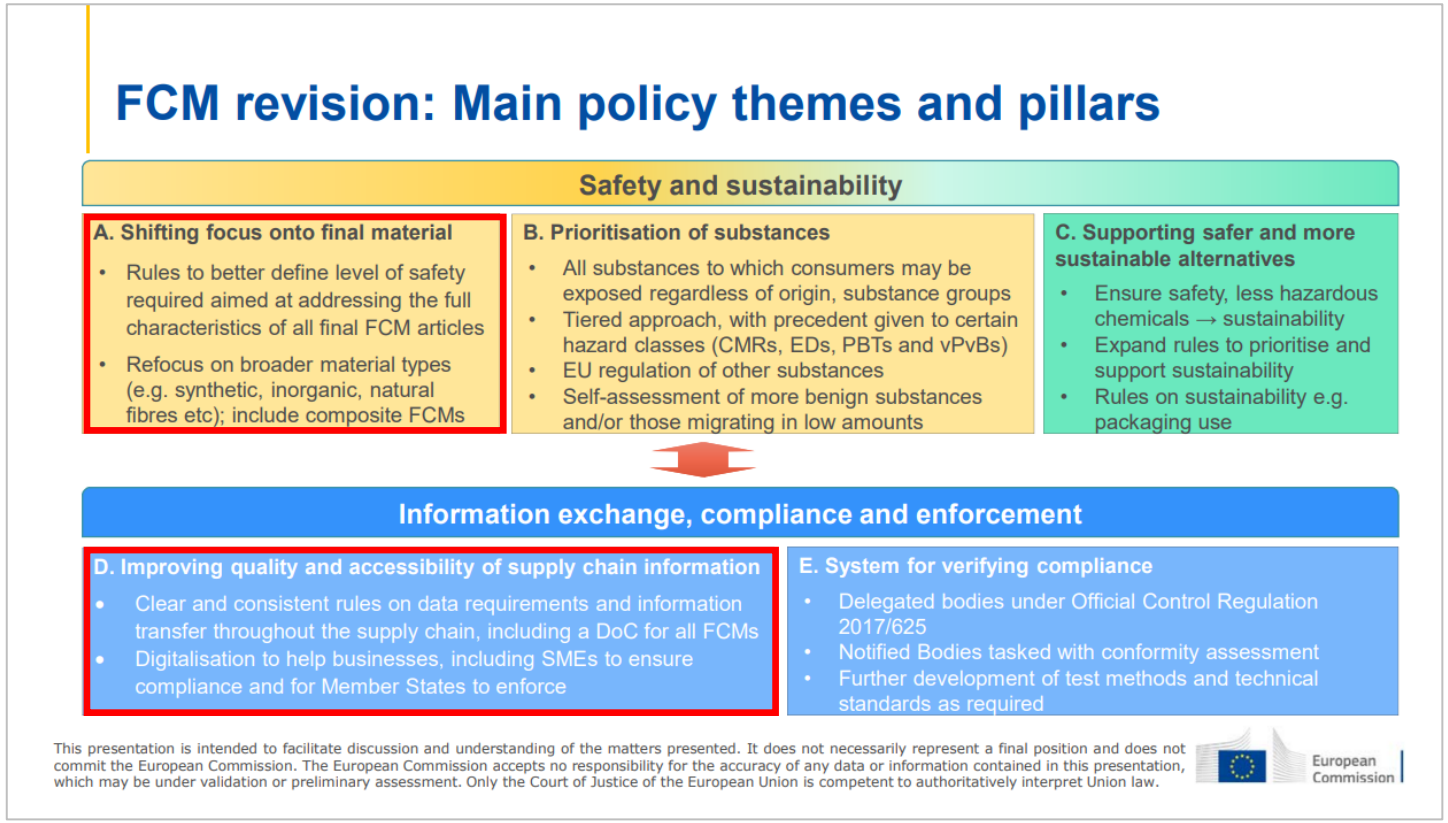
ECMA is closely following the review of the FCM legislation.



DG Sante Working Group on Food Contact Materials
9-10 February 2022

Keller & Heckman Report (Dec 2022)
The final product needs to be compliant, but responsibility is shared.

FCM Legislation

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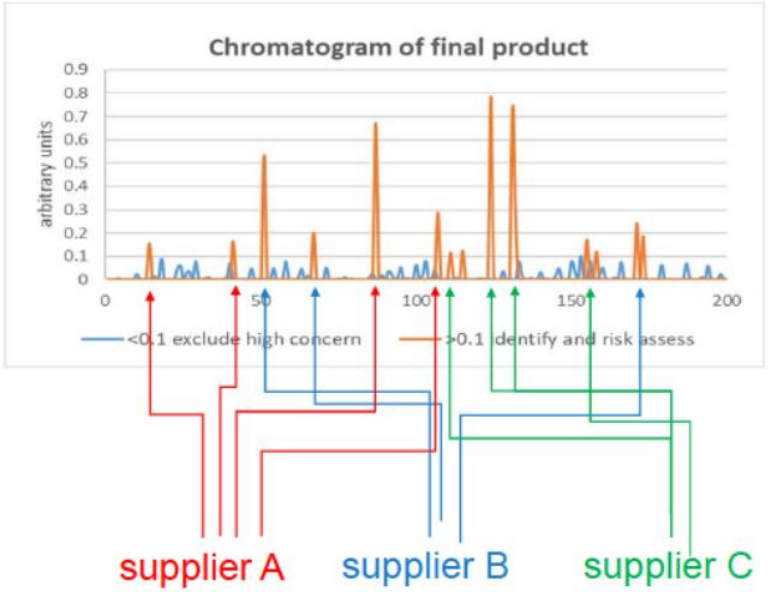
A: In practice

- **If** the **final** producer were to make a 'forest of peaks' style chromatogram:
- They would need to be able to explain all peaks give rise to safe migration level
- Information can't come from (present) analytical techniques **(→F)**
- Information to come from suppliers as shown on right→



European Commission

Information needs to come from the upstream suppliers.

ECMA Survey on information exchange (Status 03/2022)

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- Information obtained from different supplier categories (inks & varnishes, adhesives, cardboard) ?
- Replies for 52 production sites.

Sections in the survey

Confirmation of compliance : reference legislations, sector guidelines, certification schemes and standards
Intentionally used substances
- for which further compliance work needs to be performed by the converter
- Information on all present restricted substances
- self evaluated substances

Non intentionally added substances
Use instructions
Other useful information

ECMA Survey on information exchange (Status 03/2022)

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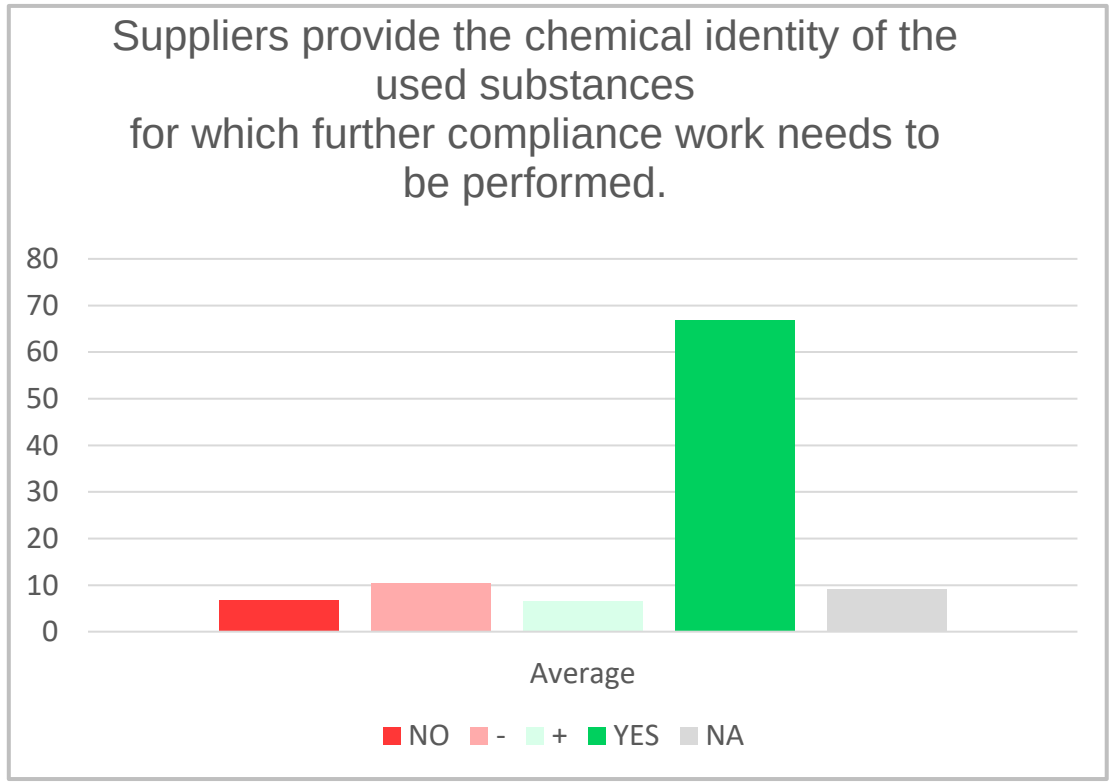
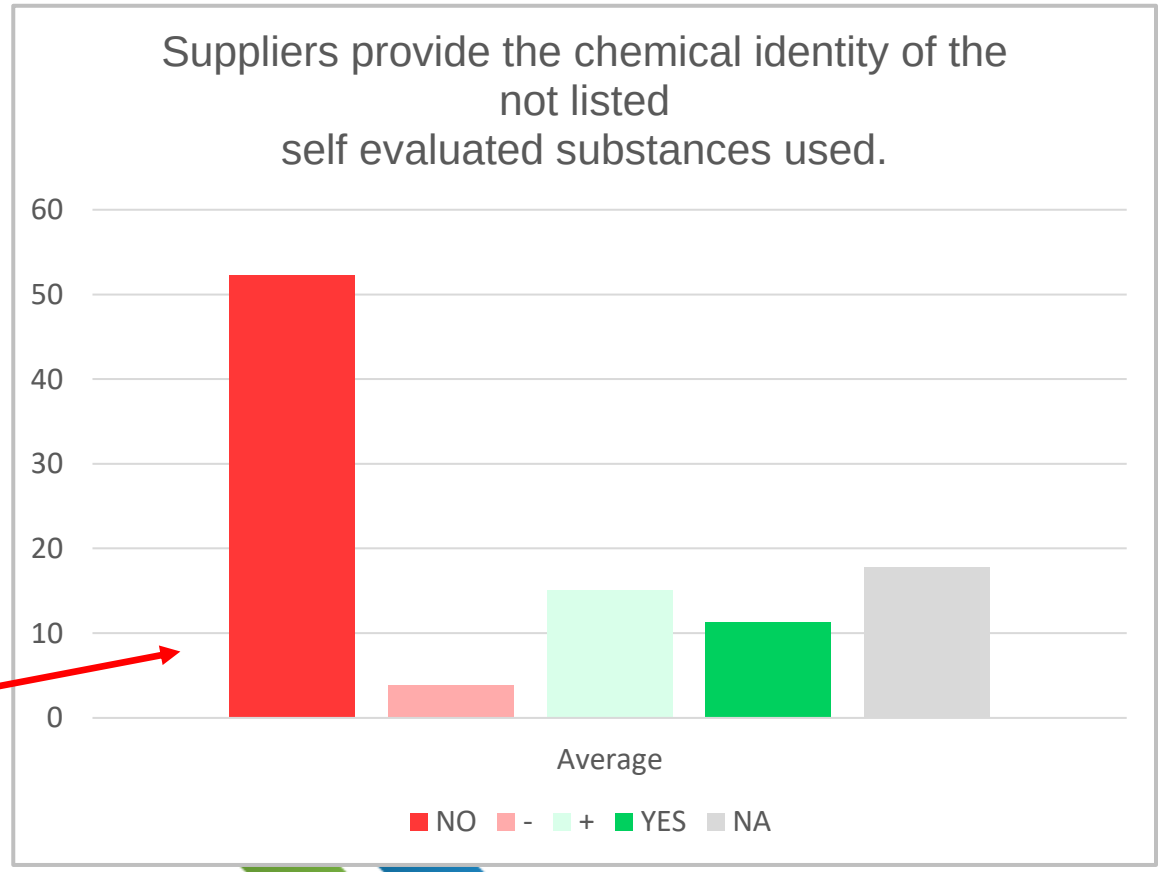
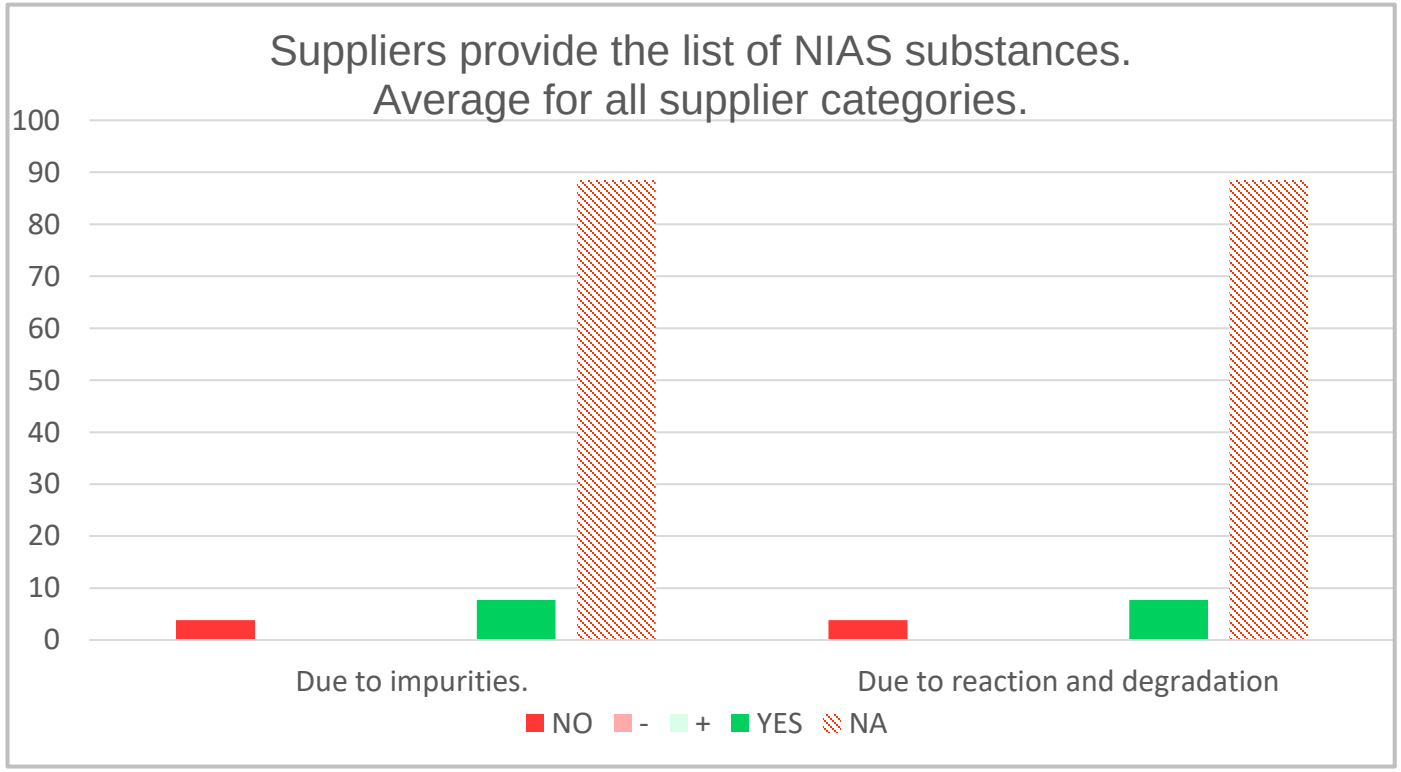


Not providing information means responsibility.



Not listed self evaluated substances : identity, self derived restrictions, applied RA and concentration most often not given.

ECMA Survey on information exchange (Status 03/2022)



Known impurities in the raw materials and components used ?
Based on the known carton manufacturing process which substances may appear ?

Clear separate lists are needed : IAS (restricted and NLS), NIAS and dual use substances.

ECMA Survey on information exchange (Status 03/2022)

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Identified weaknesses in existing supply chain information exchange :

- IAS : Important to obtain concentrations.
- Self evaluated substances.
- NIAS : Lists of known NIAS and knowledge sharing.
- Use instructions : Maximum quantity around 1kg of food to remain compliant. Knowledge sharing and recommendations (food in pack treatment, substances to avoid, storage). Support needed (SME companies)!
- Information to the carton maker, prior to any change in the formulations.

Based on outcome the ECMA supplier questionnaire templates were updated. (June 2023)

3. ECMA GMP Version 2.1

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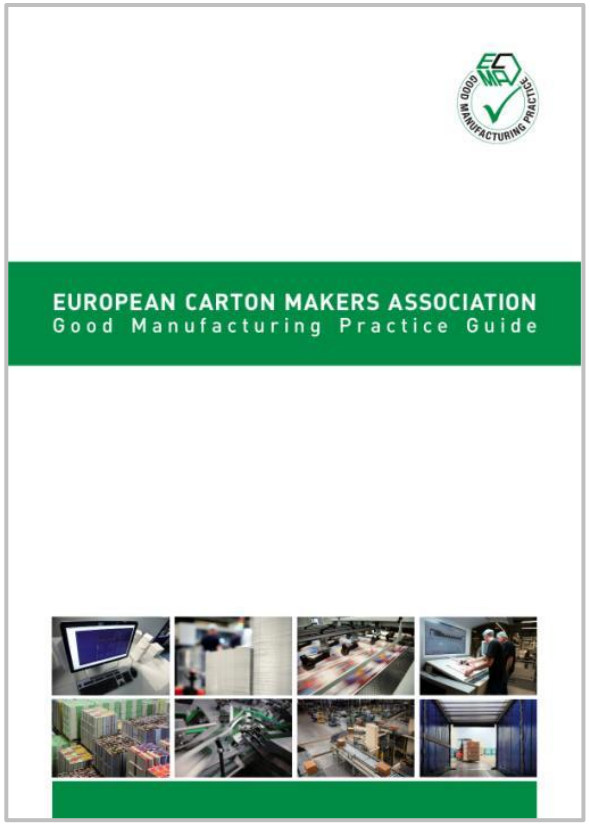
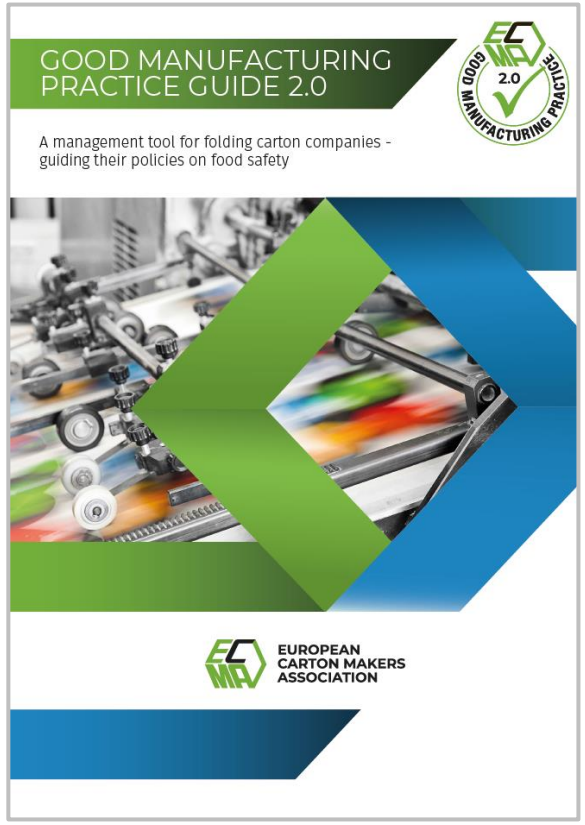


2011 Updated 2013



March 2021 (Guidance on BRC)

November 2022 (Guidance on BRC & FSSC 22000)

ECMA GMP Version 2.1

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BRC GLOBAL STANDARD PACKAGING AND PACKAGING MATERIALS

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
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
3.5	Internal audits
3.6	Corrective and preventive action
3.7	Supplier approval and performance monitoring
3.8	Product authenticity, claims and chain of custody
3.9	Management of subcontracted activities and outsourced processes
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]
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
5.7	Control of non-conforming product
5.8	Incoming goods
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

GMP publication provides sector specific guidance for clauses marked in green.

ECMA GMP Version 2.1

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ECMA Guidance

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.

BRCGS Clause
3.7 Supplier approval and performance monitoring.

ECMA GMP Version 2.1

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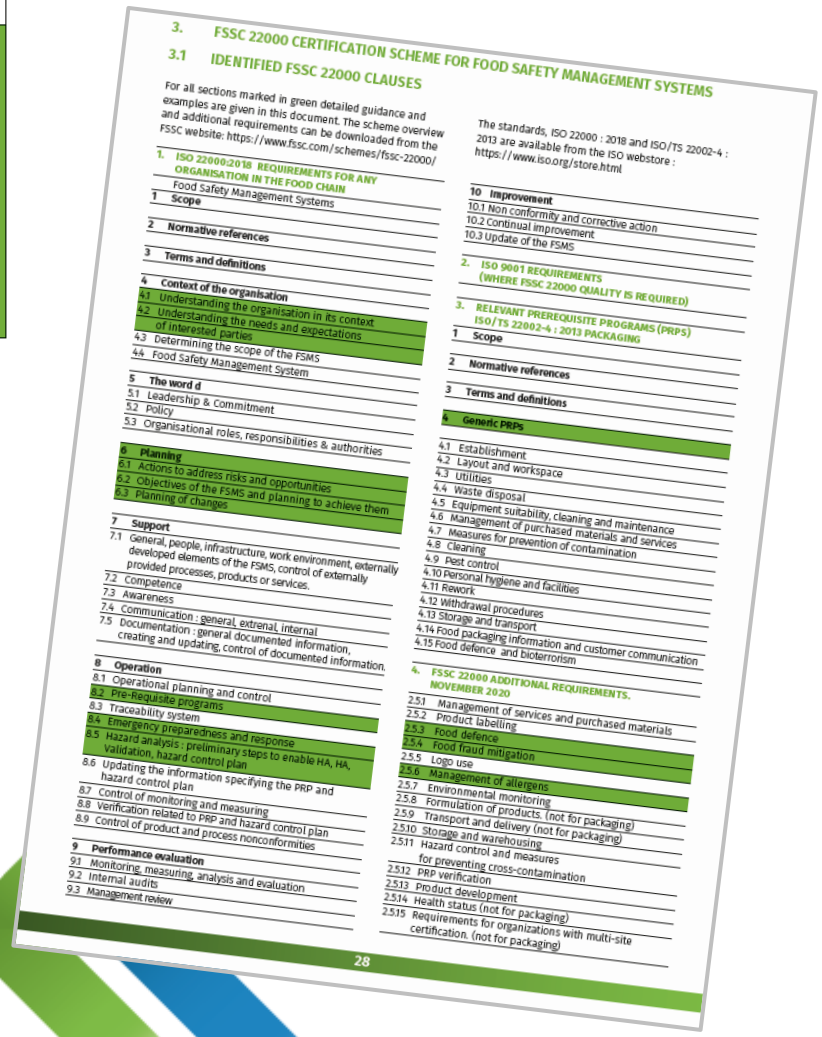
Example to BRCGS Clause 3.7

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)

FSSC 22000 CERTIFICATION SCHEME FOR FOOD SAFETY MANAGEMENT SYSTEMS


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)

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4. Recent public food safety positions.

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Mineral oils (New position paper March 23)

https://ecma.org/news/news-archive/position-paper-mineral-oil-hydrocarbons-in-food.html

Potential sources. Toolbox projects.

Folding carton industry supplies variety of solutions :

- inner layer or barrier coating on the reverse side
- inner or intermediate barrier bags
- cartonboard from recycled material with a functional adsorbent
- cartons made of virgin board

Information needed on compliance of barrier material (Council of Europe Resolution CM/res (2020)9

All materials used need to be taken into consideration.

SCoPAFF limits April/October 2022 (MOAH in food dry 0,5 mg/kg, fatty foods 1 mg, oils 2 mg/kg)

Close cooperation needed !
Cartonboard and folding carton manufacturers committed to support downstream operators.

Newest developments
EFSA risk assessment (09/23)
Commission intention Regulation MOAH
Recommendation MOSH monitoring and indicative levels.

Recent public food safety positions.

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Statement on direct food contact inks (June 2023)

https://ecma.org/news/news-archive/ecma-statement-on-direct-food-contact-inks.html

Existing confusion

- Annex GMP Regulation 2023/2006 : Rules for inks on the non-food contact side / substances should not be transferred by set off / does not mean other specific inks cannot be in direct contact.
  New German ink ordinance covers direct and indirect contact printing !
- Naming of certain ink series “Food Contact Material inks”

Different documents available from the European Ink Manufacturers Association (EuPIA) on DFC applications

<u>Presence overprint varnishes does not change the contact character.</u>

Ink classification for food contact (Source EuPIA)

FCM inks → Non-Direct Food Contact inks (non-DFC inks)
FCM inks → Direct Food Contact inks (DFC inks)

DFC categorization & examples	Intentional physical touching contact	Reasonably foreseeable physical touching contact
Long term	Inside printing trays fruits & vegetables	Teabags with cartonboard tags
Short term	Fast food clamshells with inside printing	Fast food and sandwich boxes outside printing

Recent public food safety positions.

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https://ecma.org/publications/ecma-statements.html

Statement on barriers (September 2023)

Opposing policy orientations (avoid unnecessary packaging ↔ extra barrier recommended)

Definitions absolute and functional barriers.

Sector

- Fully supports to avoid extra packaging layers and barriers applied on the reverse side which are not easily separable in the recycling process.
- Food Safety Expert Panels determine the migration levels to respect.

Open communication in the supply chain essential !

Type of food, processing, use … the overall packaging concept. Customer checklist available for the ECMA membership.

To facilitate the communication in the supply chain on other layers present in the packaging concept, reference is made to the tables of barrier films included in the (not published) draft

JRC Technical Guidelines for plastic compliance testing.

Recent public food safety positions.

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Functional barrier properties of various polymers.

Source: JRC Technical guidelines for compliance testing in the framework of Regulation (EU) No 10/2011 on plastic food contact materials. Draft for stakeholder consultation. Eddo Hoekstra. 2015

Table 9 Functional barrier layer thickness L^{FB} (in µm) of various polymers through which no migration can be expected at different contact conditions for four different molecular mass ranges

Polymer	time/Temp	FB layer thickness (µm)			
Molecular mass range of migrant (g/mol)		100-250	251-500	501-750	751-1500
LDPE, PP rubber	10 days at 60°C	no FB	no FB	7000	2600
	10 days at 40°C	no FB	8800	2640	1000
	10 days at 20°C	7000	3000	800	340
	2 hours at 100°C	no FB	10000	3240	1360
HDPE	10 days at 60°C	no FB	9000	3300	1080
	10 days at 40°C	8500	3000	960	400
	10 days at 20°C	2280	800	280	130
	2 hours at 100°C	no FB	6400	1800	700
PP homo/isotactic; random	10 days at 60°C	no FB	4600	1400	580
	10 days at 40°C	3900	1480	500	220
	10 days at 20°C	1080	440	160	70
	2 hours at 100°C	8000	3000	900	380
PET, PBT, PEN	10 days at 60°C	91	35	12	5
	10 days at 40°C	31	14	4	2
	10 days at 20°C	9	4	2	1
	2 hours at 100°C	61	23	7	3
PS	10 days at 60°C	127	49	16	6
	10 days at 40°C	46	18	6	3
	10 days at 20°C	17	7	3	1
	2 hours at 100°C	65	26	8	4
SBS	10 days at 60°C	no FB	no FB	4600	1900
	10 days at 40°C	no FB	5800	1750	700
	10 days at 20°C	5000	1900	600	280
	2 hours at 100°C	no FB	7600	3300	1000
PA 6	10 days at 60°C	210	82	25	10
	10 days at 40°C	80	32	11	5
	10 days at 20°C	26	11	4	2
	2 hours at 100°C	105	40	14	6

* In case of perfluorinated substances the maximum molecular mass should be 1500 g/mol due to the comparable lower molecular volume.

Table 10 Barrier films which act as a general FB in reducing any migration down to levels below of 10 ppb at test contact conditions of 10 d @ 60°C.

Table 11 Barrier films which act as a FB in reducing any migration down to levels below of 10 ppb when used for long term storage at room temperature.

5. Testing conditions.

Appropriate testing conditions for regular cartons LT storage at Room temperature.

Testing and other means of assessing compliance part of process flow producing food-safe cartons.

Efficient to develop packaging systems, combinations of well-defined substrate, ink and adhesive for type of application.

Misconception cartons should be tested according Plastics Regulation.

Intended use, properties and migration behaviour may differ greatly.

- Liquid simulants NOT appropriate for Paper and Board without a plastic layer.
- MPPO / in food / in infant powder as worst case type of food.

Which conditions to use ?

Plastics Regulation conditions LT RT : 10 days @ 60 °C

Covers storage above 6m at RT including hot filling and/or heating up to

2h at 70 °C - 15 min at 100 °C.

Not representative of use of cartons.

Testing conditions.

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ANNEX V

COMPLIANCE TESTING

For testing compliance of migration from plastic food contact materials and articles the following general rules apply.

CHAPTER 1

Testing for specific migration of materials and articles already in contact with food

2.1.4. ***Specific conditions for contact times above 30 days at room temperature and below***

For contact times above 30 days (long term) at room temperature and below, the specimen shall be tested in accelerated test conditions at elevated temperature for a maximum of 10 days at 60 °C ([7]).

(d) Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T-70)/10) minutes.

(e) For storage at room temperature the testing conditions can be reduced to 10 days at 40 °C if it is shown by scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.

Testing conditions.

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2.1.3. Conditions of contact when using food simulants

The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2.

By way of derogation to the conditions set out in Tables 1 and 2, the following rules apply:

(i) If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place;

Council of Europe Res CM/Res (2020)9 and TG paper and board.

Testing conditions : The worst foreseeable conditions of contact of the test specimen with food are to be chosen for testing + reference to JRC for liquid foods and beverages.

Testing conditions.

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Contacts with FEICA (European adhesives & sealant industry association)

Accelerated tests at elevated temperature

Certain sets of migration conditions as defined by the Plastics Regulation (EU) No 10/2011 apply elevated temperatures that do not reflect the real conditions of use but constitute an accelerated test.[12] For example, conditions of 60 °C for 10 days are often utilsed as an accelerated test for prolonged storage (> 6 months) conditions at room temperature.

Accelerated tests are a very useful tool to reduce testing time and provide migration results in a timely manner. Anytime accelerated test conditions lead to a change of the physical properties of the food contact material compared to the properties it exhibits in the actual food contact scenario, however, results should be evaluated with caution.

For certain types of adhesive applications, a change of physical properties will take place at temperatures of 60 °C. The observed migration at 60 °C will in such cases be substantially different from the real long-term migration at room temperature or even at 40 °C. In these cases, the migration results obtained may not be valid, and may be typically higher than the worst-case scenario at real contact conditions.

Migration testing of adhesives intended for food contact materials. (Version 10/05 2023)

...

Testing conditions.

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Hotmelt adhesives

Liquid simulants containing ethanol may re-dissolve large parts of hotmelt applications (e.g., tackifiers). In addition, elevated temperatures above 40 °C are likely to cause a softening of a hotmelt due to the low molecular weight fraction (e.g., waxes). In general, food simulants and conditions in Regulation (EU) No 10/2011 are not appropriate for this category of adhesive. Testing conditions should be defined on a case-by-case basis, depending on the adhesive and application type.

...

Contacts with EuPIA (European ink manufacturers association)

Recommended for LT @ RT
If contact temperature < 40 °C : 10 days @ 40 °C
> 40 °C : 10 days @ 60 °C

EuPIA Guidance on migration Test methods for the evaluation of substances in printing inks and varnishes for food contact materials. Version 03 05 2023

Testing conditions.

EUROPEAN CARTON MAKERS ASSOCIATION

4.4. Justified deviations from the recommended methods

Changes which do not occur under worst foreseeable conditions of use

The aim of the methods in this document is to provide a guideline reference for the execution of worst-case tests to assess whether a product is fit for purpose. However, whenever a method effectuates a physical or other change to the test sample, the test must be carried out under the worst foreseeable conditions of use in which these changes do not occur [13].

Situations in which the recommended methods are not suitable can be divided into (i) physical changes to the printed test substrate, and (ii) chemical changes to the migrating compounds. Known examples are given below.

Examples of physical changes to the printed test substrate

Contacts with paper experts involved in CEPI

- 10 days @ 40 °C commonly used for testing the P&B substrate.
- Migration mechanisms for paper ad board very different from plastics : much faster.

Conclusion so far :
Testing of printed and glued cartons needs often to be done at **40 °C.**

6. Items to cover in the discussion

EUROPEAN CARTON MAKERS ASSOCIATION

- Introduction ECMA and FERA.
- Presentation of the laboratory and the areas of expertise.
- Update on the main legal food safety developments in the UK. Identified differences with EU legislation ? US ?
- FERA approach to the upcoming changes in EU legislation : very low LOD for BPA and other bisphenols, very low levels of impurities (plastics regulation) … Are the migration labs prepared for those changes?
- Exchange on the typical substances in focus : PFAS, bisphenols, MO, phthalates, ED ... FERA's view on specific substances to monitor. (Prioritisation of substances)

  How is FERA presenting its test results in reports? Detail or just pass/fail?
- Barrier efficiency.
- Confidentiality in supply chains and on third party portals.

  Work for sector associations ?

Items to cover in the discussion

EUROPEAN CARTON MAKERS ASSOCIATION

- Discussion on how to assess the safety of finished cartons. (Final product needs to be safe …)

  Declarations from suppliers, analytical testing, bio assays, modelling, …

  Appropriate testing conditions. LT @ RT …
- NIAS assessment.

  General knowledge available at FERA on typical NIAS which may appear in carton board (virgin & recycled), sheet fed offset inks & varnishes, hotmelt and waterbased adhesives … (Information to challenge suppliers)

  Development of a sector **NIAS database**.

  Guidance on how to test for NIAS.

  How to exclude genotoxicity ?

  Bioassays and HPTLC.

  Accessible databases for mass spectra.
- How to handle food contamination in paper for recycling.
- Microbiological testing.
- Allergens, GMO issues.