EUROPEAN CARTON MAKERS ASSOCIATION

The new ECMA Good Manufacturing Practice Guide

Approach and provided guidance.

Jan Cardon
Advisor ECMA Food Safety Committee

1. Introduction
European Carton Makers Association

Membership

European structure with 14 national associations
Direct membership
Represents direct and indirect 500 companies. (> plants, 80 % market volume)

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

50% food
Sector turnover > 10 000 mln €
Volume output > 5 000 kT
50 000 employees

ECMA Food Safety Committee

Chairman

- Smurfit Kappa:
  Jack Pieterson

TC Members

- AR Packaging
  Robert Mayr
- ECMA:
  Mike Turner, Jan Cardon
- FFI:
  Christian Schiffers
- Graphic Packaging International:
  Robert Cockshull, Mathilde Gros
- Mayr Melnhof Packaging:
  Ute Stemmer-Letnik
- Schur Pack
  Andreas Lührs
- SEDA:
  Carmine Iuvone
- Van Genechten Packaging:
  Michael Avemarg
- Westrock:
  Barbara Herbst, Elaine Murray

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

2. FCM Legislation

ECMA strongly in favour of Harmonised food safety legislation :

- Creates a level playing field.
- Avoids operational uncertainty.
- Decreases the costs and complexity for demonstrating compliance.
- Enhances the internal market and the overall level of FCM safety. Mutual recognition is essential businesswise, well-accepted harmonised legislation should be the pursued end goal.
- Avoids endless public debates.

Review legislation welcomed

ECMA involved in the different consultation rounds (Baseline, Ecorys …)

Comments Roadmap :

- In favour of a transparent inventory lists with all regulated substances (EU, national …) and their use. (+ room for including assessments by industry according to well defined rules)
- The final FCM needs to be safe, but to achieve it is essential to have accurate information from upstream in the supply chain.
- ECMA members 90% SME companies.
  Ecorys report identified the particular difficulties for SME's.
  Lower leverage, less information obtained, more difficult to perform cost effective WCC calculations …

Accurate information essential

Council of Europe Resolution CM/Res (2020)9 on the safety and quality of materials for contact with food. (Section on DOC)

"Food contact materials and articles under the scope of the resolution are to be accompanied by a declaration of compliance". A DOC needs to be issued at all stages of the supply chain and means that the manufacturer of the food contact material or article assumes responsibility for the suitability for food contact, including the safety of all released substances, unless he has informed the next business operator in the supply chain further specified compliance work needs to be performed."

"The FCM manufacturer have to make available information on the substances used, impurities and reaction and degradation products, including those known or foreseen to be generated at later production stages, for which the business operator has identified that further compliance work needs to be conducted at the next stages in the supply chain."

Converters

- Have to verify what needs to be further checked.
- Need to respect the use instructions
- Have to work according to appropriate **good manufacturing practices**.

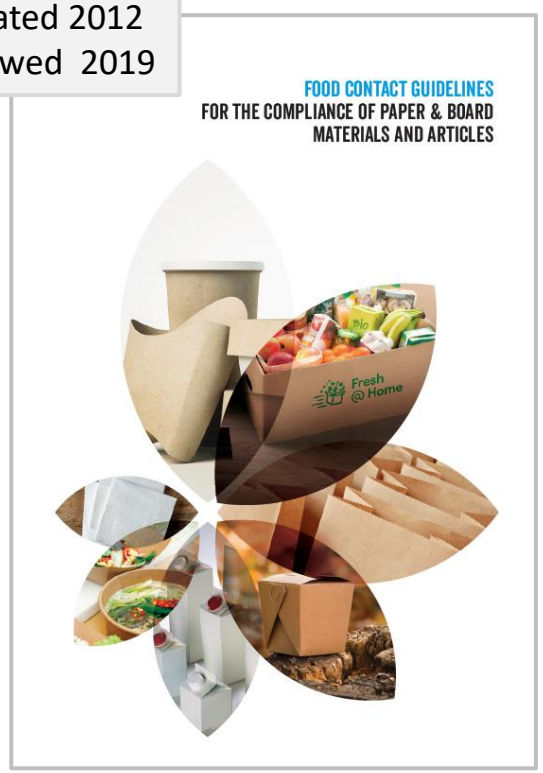
3. ECMA GMP and CEPI/CITPA guideline

CEPI/CITPA Food Contact Coordination Group

General guideline

- Scope
- Core requirements
- Testing for compliance
- Paper for recycling - Requirements for use in FCM & FCA
- Traceability guidelines
- Labelling guidelines
- Supply chain communication
- Guidance on preparing a Declaration of Compliance
- Definitions and references

2010
Updated 2012
Reviewed 2019



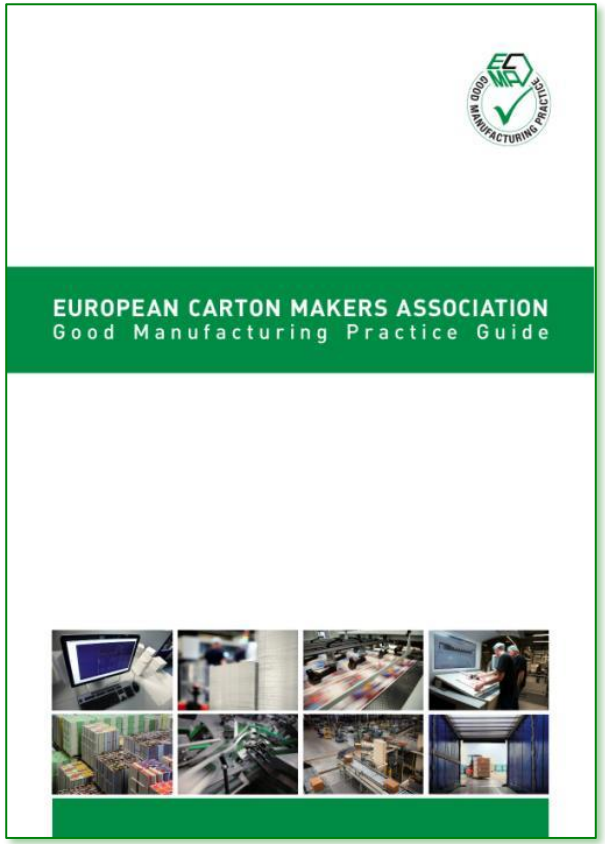
ECMA GMP Version 1
Specific guidance for cartons

- Available in 6 languages on www.ecma.org

1. Introduction
2. Regulation and guidance
3. Migration
4. **Recommendations for compliance**
5. **Guidance on inks and varnish**
6. Process flow
7. References
8. Glossary
9. Q & A
10. Self-compliance declaration

Benchmark

- Prerequisite to have Quality and Hygiene certified management systems
- Performed benchmarking



VS

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Similarities

Factory standards

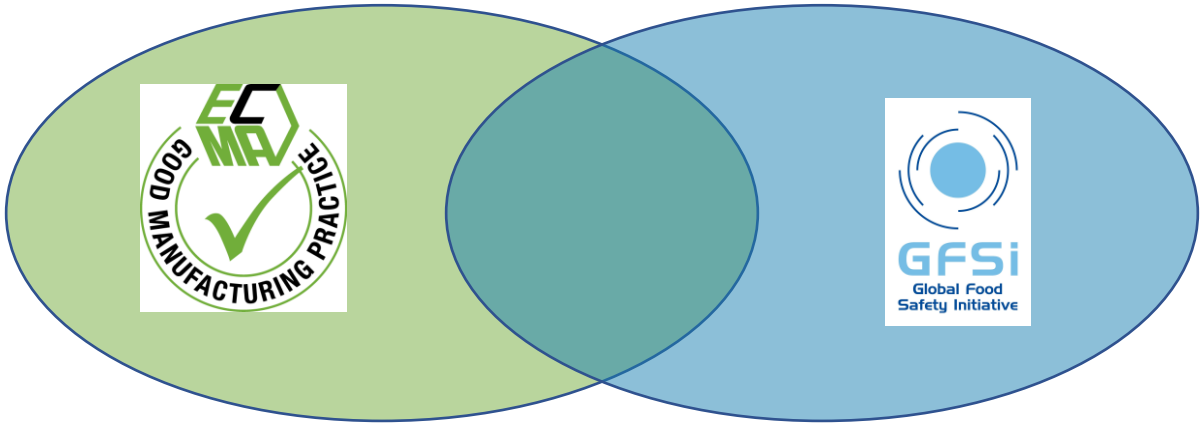
Cleaning

Process flow

Logistics

Personnel competence

Traceability



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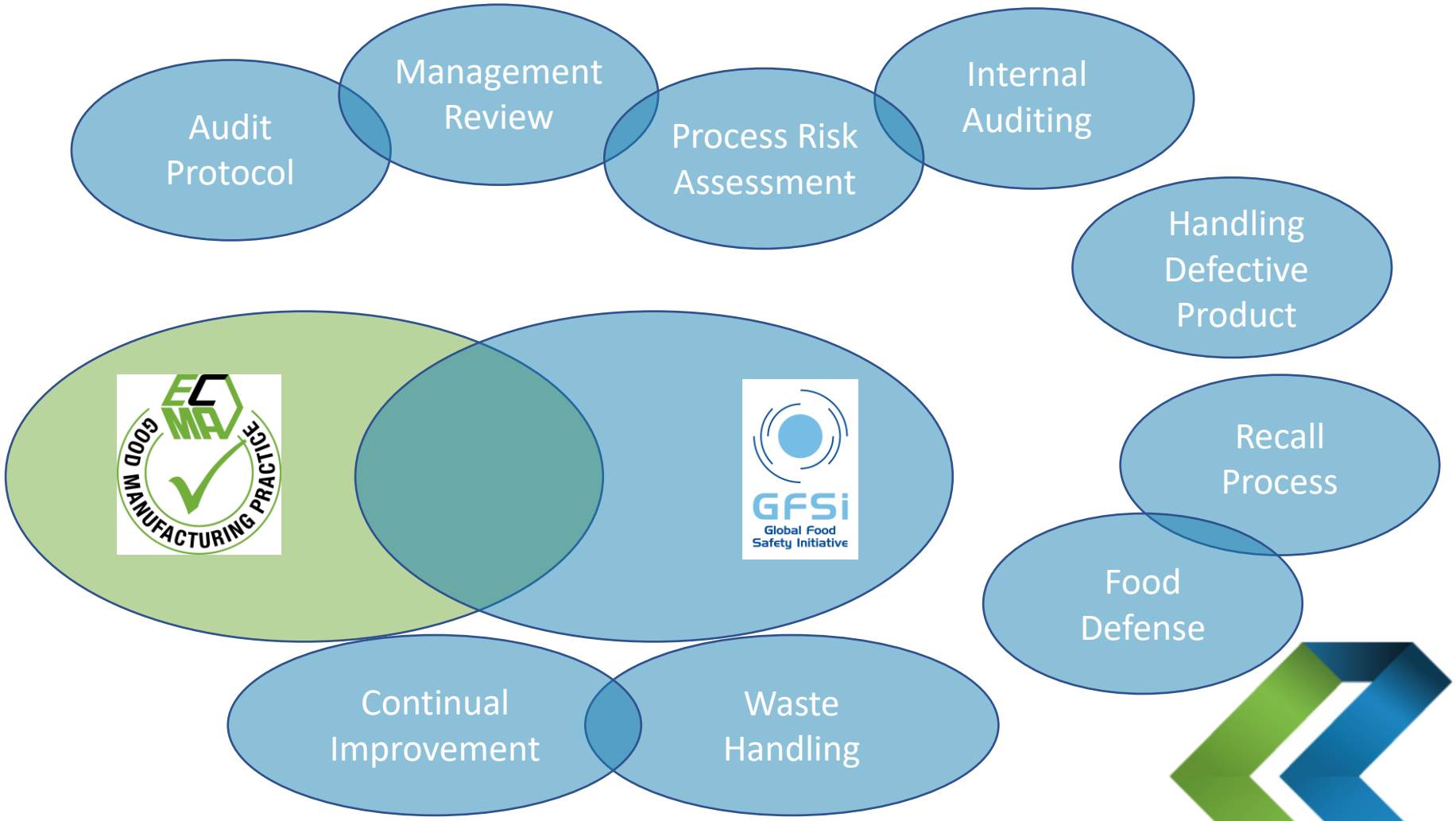
What value is added by having a public standard as a pre-requisite?



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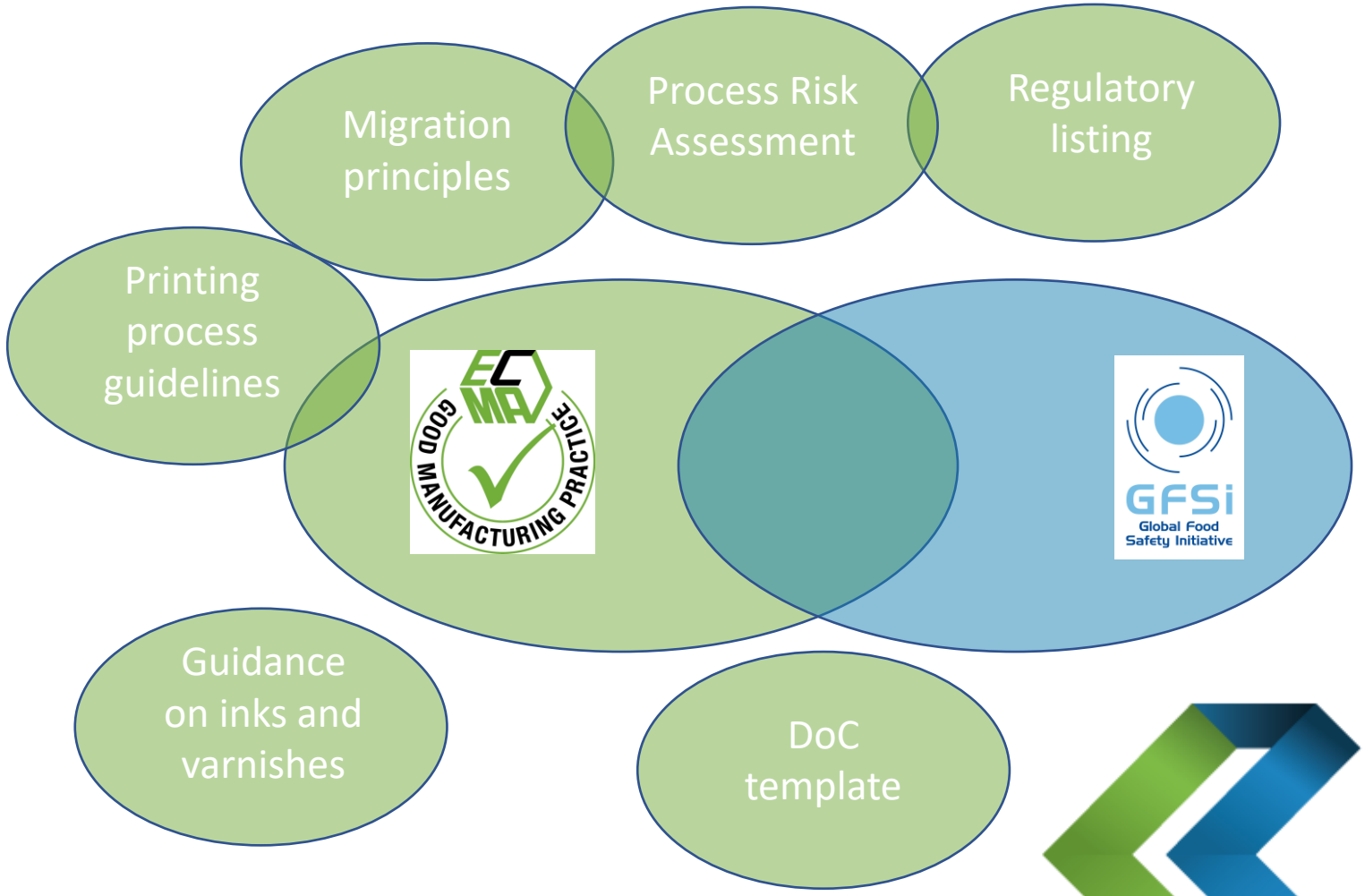
What added value does ECMA GMP provide over existing public Food Safety Standards?



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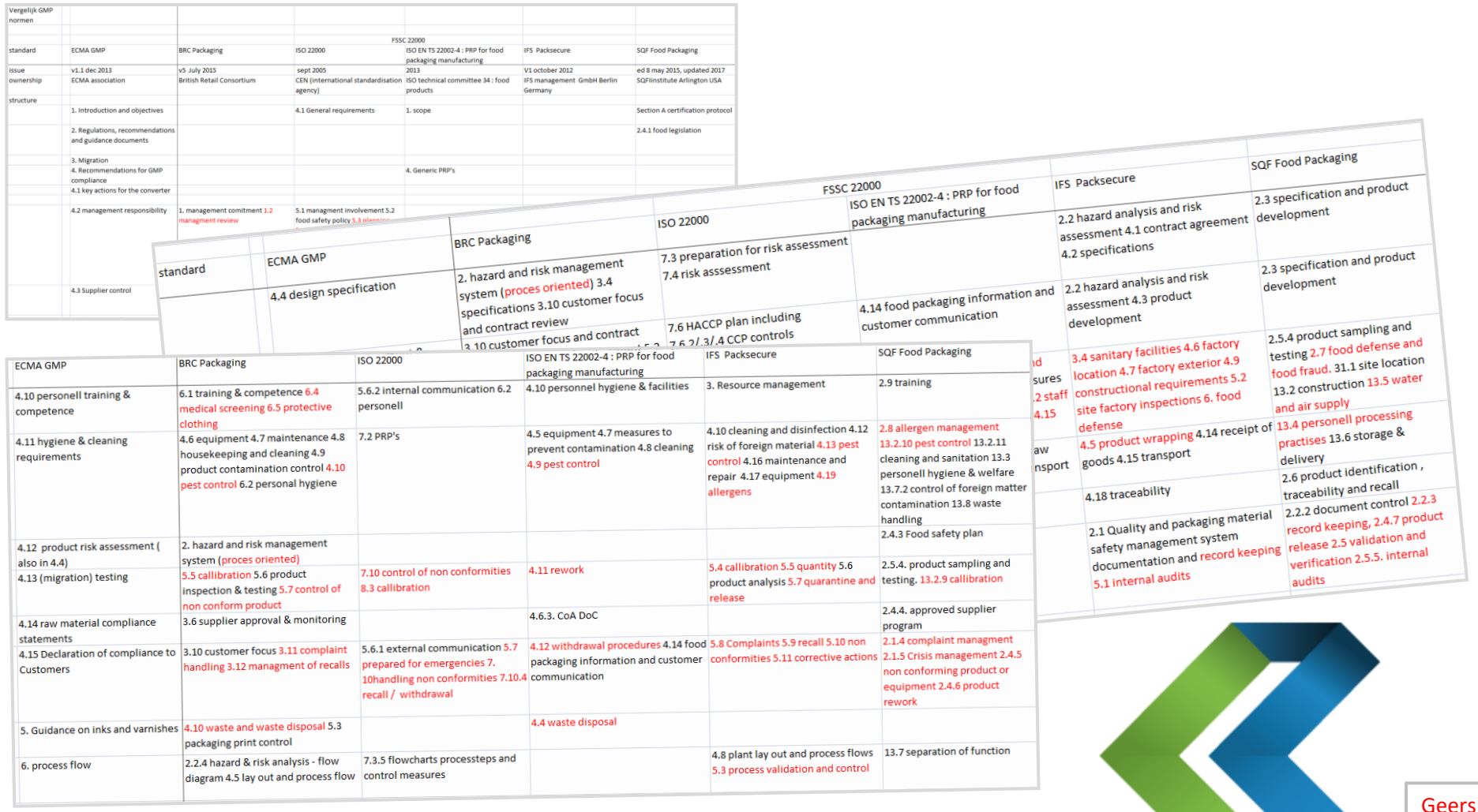
Detailed comparison



Vergelijk GMP normen						
				FSSC 22000		
standard	ECMA GMP	BRC Packaging	ISO 22000	ISO EN TS 22002-4 : PRP for food packaging manufacturing	IFS Packsecure	SQF Food Packaging
issue	v1.1 dec 2013	v5 July 2015	sept 2005	2013	V1 october 2012	ed 8 may 2015, updated 2017
ownership	ECMA association	British Retail Consortium	CEN (international standardisation agency)	ISO technical committee 34 : food products	IFS management GmbH Berlin Germany	SQFIinstitute Arlington USA
structure						
	1. Introduction and objectives		4.1 General requirements	1. scope		Section A certification protocol
	2. Regulations, recommendations and guidance documents					2.4.1 food legislation
	3. Migration					
	4. Recommendations for GMP compliance			4. Generic PRP's		
	4.1 key actions for the converter					
	4.2 management responsibility	1. management comitment 1.2 managment review	5.1 managment involvement 5.2 food safety policy 5.3 planning			
	4.3 Supplier control					
standard	ECMA GMP	BRC Packaging	ISO 22000	ISO EN TS 22002-4 : PRP for food packaging manufacturing	IFS Packsecure	SQF Food Packaging
	4.4 design specification	2. hazard and risk management system (proces oriented) 3.4 specifications 3.10 customer focus and contract review 3.10 customer focus and contract	7.3 preparation for risk assessment 7.4 risk asssessment 7.6 HACCP plan including 7.6.2/.3/.4 CCP controls	4.14 food packaging information and customer communication	2.2 hazard analysis and risk assessment 4.1 contract agreement 4.2 specifications 2.2 hazard analysis and risk assessment 4.3 product development	2.3 specification and product development 2.3 specification and product development
ECMA GMP	BRC Packaging	ISO 22000	ISO EN TS 22002-4 : PRP for food packaging manufacturing	IFS Packsecure	SQF Food Packaging	
4.10 personell training & competence	6.1 training & competence 6.4 medical screening 6.5 protective clothing	5.6.2 internal communication 6.2 personell	4.10 personnel hygiene & facilities	3. Resource management	2.9 training	
4.11 hygiene & cleaning requirements	4.6 equipment 4.7 maintenance 4.8 housekeeping and cleaning 4.9 product contamination control 4.10 pest control 6.2 personal hygiene	7.2 PRP's	4.5 equipment 4.7 measures to prevent contamination 4.8 cleaning 4.9 pest control	4.10 cleaning and disinfection 4.12 risk of foreign material 4.13 pest control 4.16 maintenance and repair 4.17 equipment 4.19 allergens	2.8 allergen management 13.2.10 pest control 13.2.11 cleaning and sanitation 13.3 personell hygiene & welfare 13.7.2 control of foreign matter contamination 13.8 waste handling	
4.12 product risk assessment (also in 4.4)	2. hazard and risk management system (proces oriented)				2.4.3 Food safety plan	
4.13 (migration) testing	5.5 callibration 5.6 product inspection & testing 5.7 control of non conform product	7.10 control of non conformities 8.3 callibration	4.11 rework	5.4 callibration 5.5 quantity 5.6 product analysis 5.7 quarantine and release	2.5.4. product sampling and testing. 13.2.9 callibration	
4.14 raw material compliance statements	3.6 supplier approval & monitoring		4.6.3. CoA DoC		2.4.4. approved supplier program	
4.15 Declaration of compliance to Customers	3.10 customer focus 3.11 complaint handling 3.12 managment of recalls	5.6.1 external communication 5.7 prepared for emergencies 7. 10handling non conformities 7.10.4 recall / withdrawal	4.12 withdrawal procedures 4.14 food packaging information and customer communication	5.8 Complaints 5.9 recall 5.10 non conformities 5.11 corrective actions	2.1.4 complaint managment 2.1.5 Crisis management 2.4.5 non conforming product or equipment 2.4.6 product rework	
5. Guidance on inks and varnishes	4.10 waste and waste disposal 5.3 packaging print control		4.4 waste disposal			
6. process flow	2.2.4 hazard & risk analysis - flow diagram 4.5 lay out and process flow	7.3.5 flowcharts processteps and control measures		4.8 plant lay out and process flows 5.3 process validation and control	13.7 separation of function	
					4.18 traceability	2.6 product identification , traceability and recall
					2.1 Quality and packaging material safety management system documentation and record keeping 5.1 internal audits	2.2.2 document control 2.2.3 record keeping, 2.4.7 product release 2.5 validation and verification 2.5.5. internal audits
						2.5.4 product sampling and testing 2.7 food defense and food fraud. 31.1 site location 13.2 construction 13.5 water and air supply
					4.5 product wrapping 4.14 receipt of goods 4.15 transport	13.4 personell processing practises 13.6 storage & delivery
					3.4 sanitary facilities 4.6 factory location 4.7 factory exterior 4.9 constructional requirements 5.2 site factory inspections 6. food defense	

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New GMP approach required

- 2011 : need to improve awareness and provide descriptive guidance.
- Since public GFSI certification schemes more widely used.
- **Focus on what is specific for carton makers and hands on practical guidance.**
- **Avoid duplication, between text in legislation, standards and ECMA GMP.**
- BRCGS Packaging Issue 6 most used.

4. GMP Version 2.0 Provides guidance in relation to GFSI schemes.

Decision to develop first sector specific guidance in relation to BRCGS
Identification of sections requiring particular guidance :

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 2.2.3 description of product ... 2.2.4 Process flow diagram ...

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

BRCGS Section 2.2 HARA
Clause 2.2.4 Process flow required

Public access to the BRCGS standard :
www.brcgs.com - Store - Global Standard Packaging Materials Issue 6 - free PDF

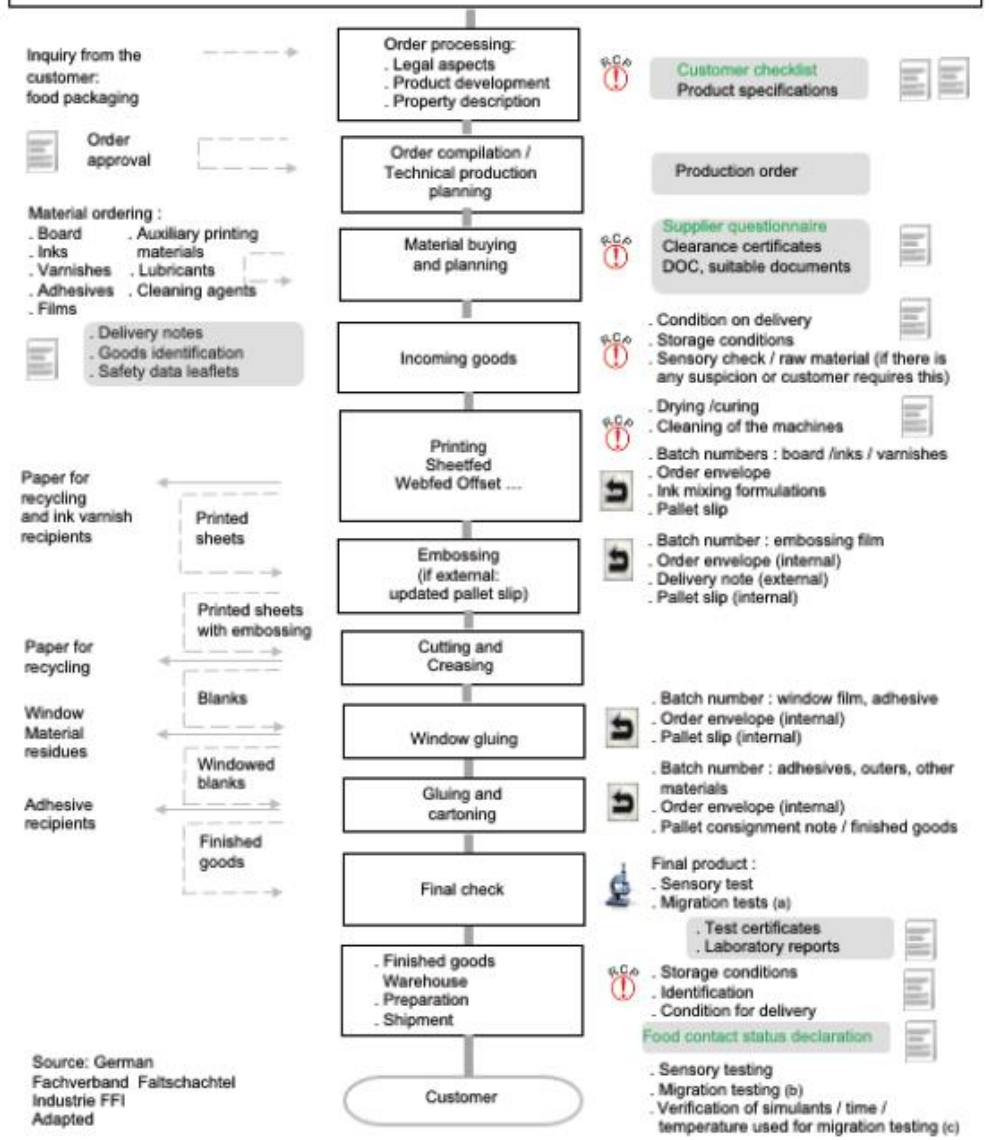
BRCGS Clause	Guidance ECMA
2.2.4	A process flow diagram as requested here is intended to be serving as a guide to perform step by step risk assessment. Therefore the process flow needs to follow the product from raw material to finished product, step by step, and include the use of additives and / or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

Annex 1: Process flow – General GMP Requirements

General GMP requirements

- Appropriate factory hygiene
- Clear allocation of responsibilities
- Maintenance and cleaning plans
- Internal identification system.
- Use of suitable consumables and auxiliary materials
- Awareness about the production of food contact materials and articles (training)
- Hazard analysis and risk evaluation of production
- Protection of the product against contamination throughout the process chain.



Source: German Fachverband Faltschachtel Industrie FFI Adapted

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.

BRCGS Clause 2.2.7 Identification of necessary control measures

BRCGS Clause	Guidance **ECMA**
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.

Guidance provided on how to identify the relevant control points and to differentiate between OPRP and CCP.

BRCGS Clause 2.2.7 Identification of necessary control measures

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 Section 3.7 Supplier approval and performance monitoring

BRCGS Clause	Guidance **ECMA**
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.

BRCGS Section 3.7 Supplier approval and performance monitoring

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)**

5. Summary and closing comments

- Review FCM legislation.
  The final article needs to be safe, but responsibility for the safety of substances is at the moment of introduction.

- New GMP Version 2 fits in current market expectations and avoids any double text.

- The public ECMA GMP is part of broader communication is the sector. Regular FC update mails are informing the members on new developments.

- The next update will also cover guidance in relation to FSSC 22 000

Food safety is a journey

The new ECMA GMP Version 2.0 adds a stone to indicate the right direction.

…

Launched soon !

EUROPEAN
CARTON MAKERS
ASSOCIATION

Thank you