



**EUROPEAN
CARTON MAKERS
ASSOCIATION**

Food Safety Developments in the folding carton industry supply chain

Assessment FCM legislation

ECMA GMP and involvement in self regulation

Information sharing

Mineral oils : solutions and best practices

Jan Cardon - ECMA
Advisor Technical Committee

European Carton Makers Association



Membership

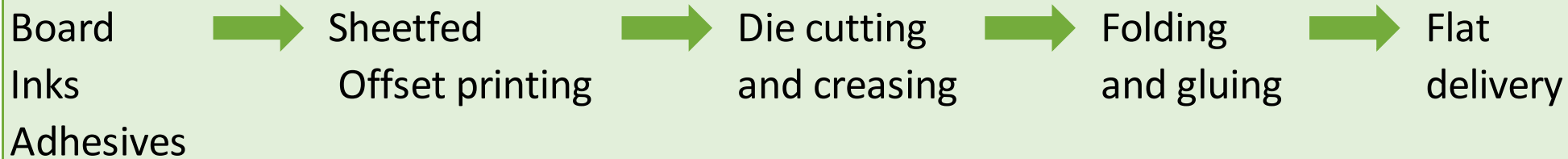
European structure with 13 national associations

Direct membership

Represents direct and indirect 500 companies. (> plants, 75 % market volume)

Activity

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



50% food

Sector turnover > 10 000 mln €

Volume output > 5 000 kT

> 75 000 employees



ECMA Technical Committee



Chairman

- Smurfit Kappa:
Jack Pieterse

TC Members

- A&R Carton
Robert Mayr
- ECMA:
Jan Cardon, Hans van Schaik
- Edelmann:
Dieter Moessner
- FFI:
Christian Schiffers
- Graphic Packaging International:
Rahhal Benfaida
- Mayr Melnhof Packaging:
Heinz Traussnig
- MPS/Westrock:
Barbara Herbst, Achim Lerschen, Delphine Ménard, Elaine Murray
- SEDA:
Carmine Iuvone, Paolo Minichini
- Van Genechten Packaging:
Michael Avemarg

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



1. Assessment FCM Legislation



Paper & Board



- Nine MSs (Belgium, The Czech Republic, Greece, France, Croatia, Italy, The Netherlands, Slovakia) have measures on paper and board
- CoE also publishes two resolutions
- 565 substances risk assessed (ESCO lists)
- **More than 1700 substances regulated across MSs (including c.1100 from, CoE)**
- **147 substances (6%) common to three or more MSs (or two MSs including CoE)**
- Industry refers to BfR, CFR, CoE, NL, IT

Agreement on restrictions agreed by 3 or more MSs for paper and board

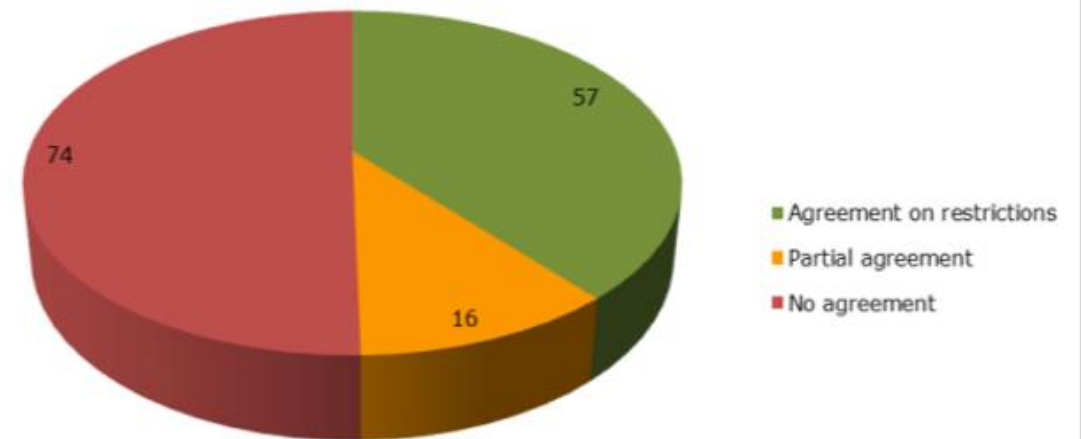


Figure 38: Pie chart on the extent of harmonisation or provisions on P&B

Adhesives



- Presence of national legislation already implemented
- Six MSs have provisions with lists of authorised substances (no negative lists)
- OML, SML and QM/residual set out in two MSs (Spain, Croatia), QM or compositional restrictions in Germany, France and The Netherlands
- **Approximately 1.323 substances are considered across MSs**
- **Only nine substance (0.7%) are common across three MSs or more**
- Professional associations indicate a convergence of national rules taken as reference, where BfR Rec. XXVII (and XIV), FDA 21 175.105, 177.1390, 177,1395 seem the most referred to



Printing inks



- Four countries (France, The Netherlands, Slovakia, Switzerland) have provisions with authorised substances
- A CoE list also exists
- Predominance of the Swiss national legislation
- **Approximately 5.124 substances are considered across MSs**
- **Only 34 substances (1%) are common across three MSs (only five with same restrictions)**
- The materials sector and a number of EU countries exhibits a convergence for predominance of the Swiss national rule



Harmonized legislation required



- Creates clarity and reduces operational uncertainty
- Brings a level playing field
- Avoids patchwork of national legislations
- Reduces the compliance costs
- Avoids endless public debates

Proposal (January 2017)

- Development one general union list of substances for FCM
- Material specific testing and compliance assessment
- Hosting database ? EFSA / JRC
- Brings transparency
- All modern assessment tools should be taken in account
(In silico screening ...)
- List exist at JRC. (and Belgian CoE database)

<https://www.ecma.org/news/ecma-statement-regarding-the-announced-harmonised-measure-on-printed-food-contact-materials.html>



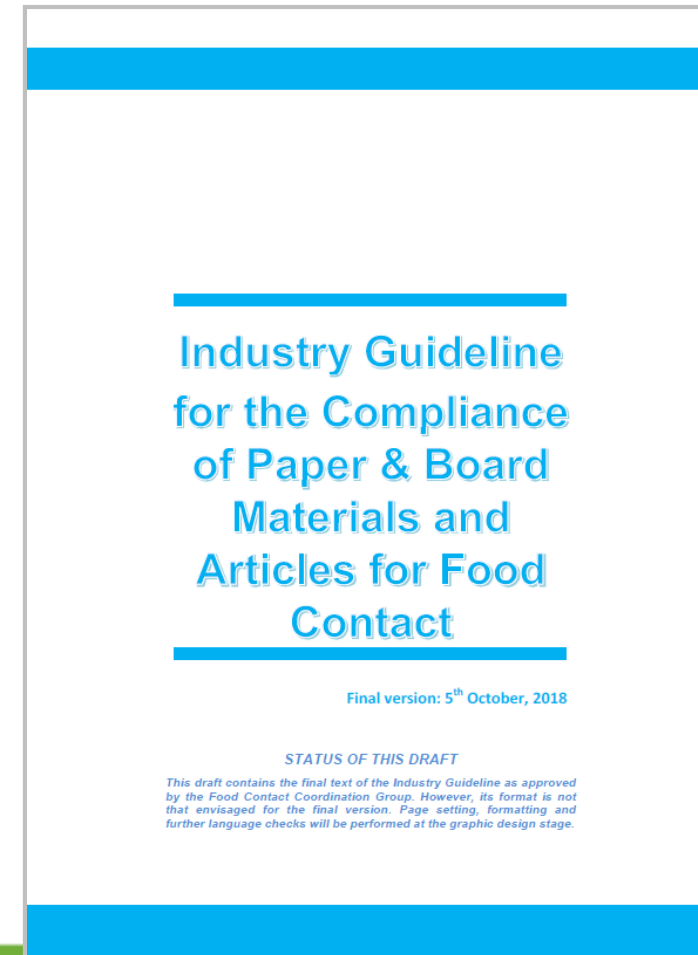
2. ECMA GMP and involvement in self-regulation



CEPI/CITPA Food Contact Coordination Group

General guideline

- Scope
- Core requirements
- Testing for compliance
- Traceability guidelines
- Labelling guidelines
- Supply chain communication
- Guidance on preparing a Declaration of Compliance
- Definitions and references



Packaging Ink Joint Industry Taskforce



- Allows industry to perform risk assessments of substances
- Well defined processes
- Auditing by control authorities or third parties
- Transparency

Attempt to define a responsible
feasible way forward

Common ground with proposals expressed
by Commission (2017)



Position of the Packaging Ink Joint Industry Task Force (PIJITF) on the planned EU Measure on Printed Food Contact Materials ("pFCM measure")

The EU Commission has announced its intention to adopt new Union legislation regulating the printing ink layer as part of printed food contact materials (FCMs) in 2018.

The PIJITF represents the value chain from the manufacturers of ink raw materials to food business operators.

The PIJITF proposes a harmonized approach which ensures high levels of consumer protection and which can be delivered within a relatively short time frame.

ECMA GMP: Specific guidance for cartons



- Available in 6 languages on www.ecma.org



English



German



Italian



Spanish



French



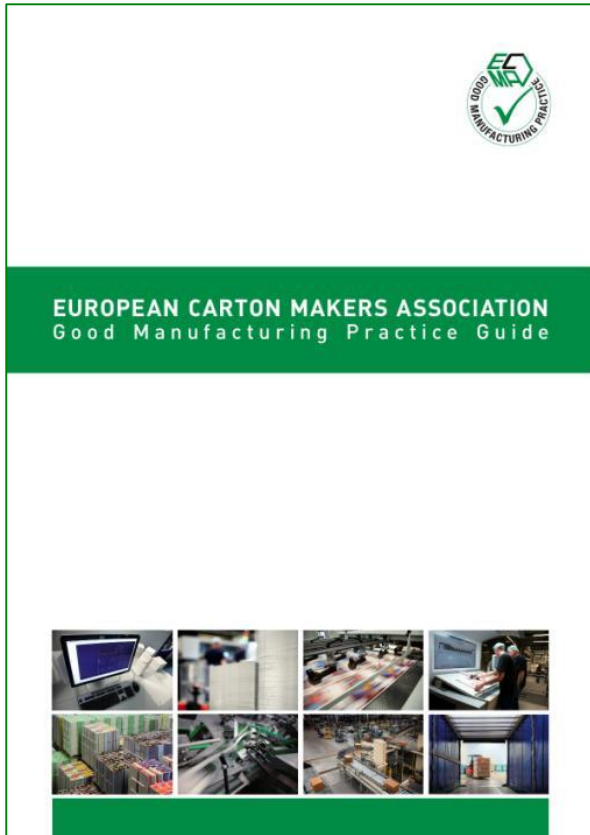
Swedish

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



ECMA GMP:

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



VS



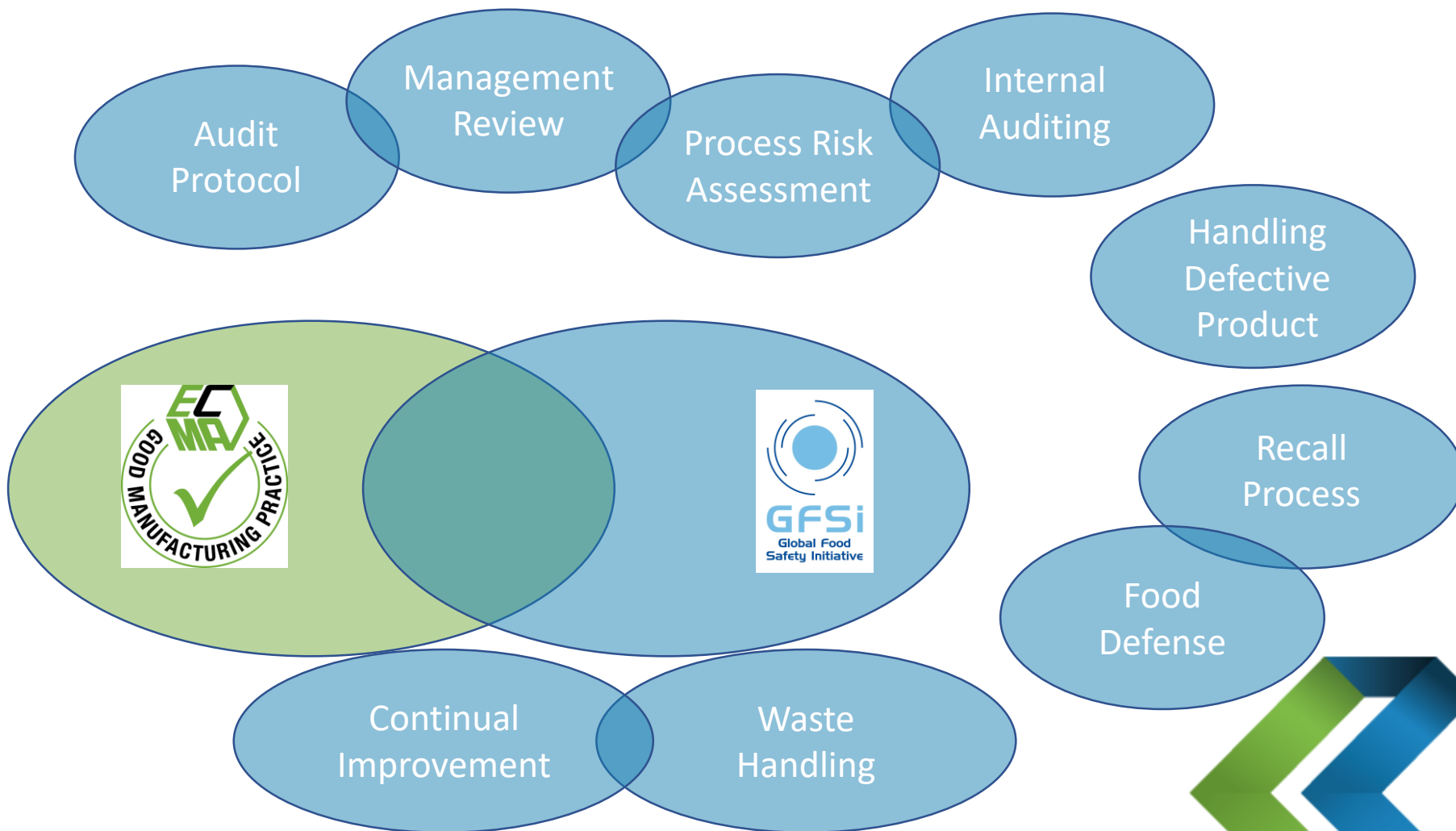
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Similarities



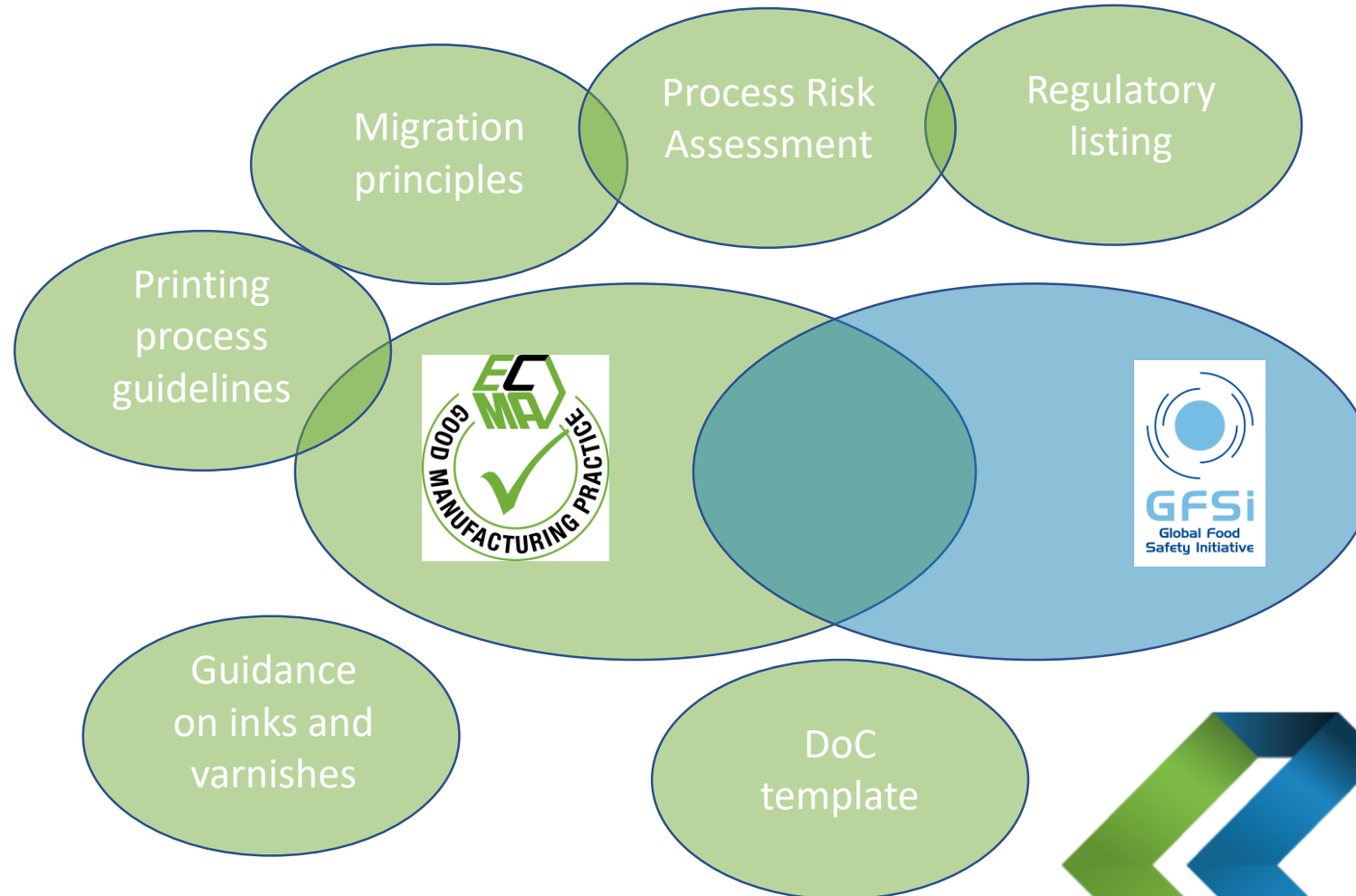
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What value is added by having a public standard as a pre-requisite?



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



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Review GMP will focus on what is specific for carton makers and on even more practical guidance



standard	ECMA GMP	BRC Packaging	ISO 22000	FSSC 22000	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	SQFInstitute Arlington USA
structure	1. Introduction and objectives 2. Regulations, recommendations and guidance documents 3. Migration 4. Recommendations for GMP compliance 4.1 key actions for the converter		4.1 General requirements	1. scope		Section A certification protocol 2.4.1 food legislation
4.2 management responsibility		1. management commitment 1.2 management review		5.1 management involvement 5.2 food safety culture		
4.3 Supplier control				4. Generic PRP's		

standard	ECMA GMP	BRC Packaging	ISO 22000	FSSC 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 development 5.2	7.3 preparation for risk assessment 7.4 risk assessment		4.14 food packaging information and customer communication	2.2 hazard analysis and risk assessment 4.1 contract agreement 4.2 specifications	2.3 specification and product development
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 2.4.3 Food safety plan	2.5.4 product sampling and testing. 13.2.9 calibration
4.12 product risk assessment (also in 4.4)		2. hazard and risk management system (proces oriented)					2.5.4 product sampling and testing. 13.2.9 calibration
4.13 (migration) testing		5.5 calibration 5.6 product inspection & testing 5.7 control of non conform product	7.10 control of non conformities 8.3 calibration	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 calibration	
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 management of recalls	5.6.1 external communication 5.7 prepared for emergencies 7.10 handling 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	2.6 product identification , traceability and recall 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
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	

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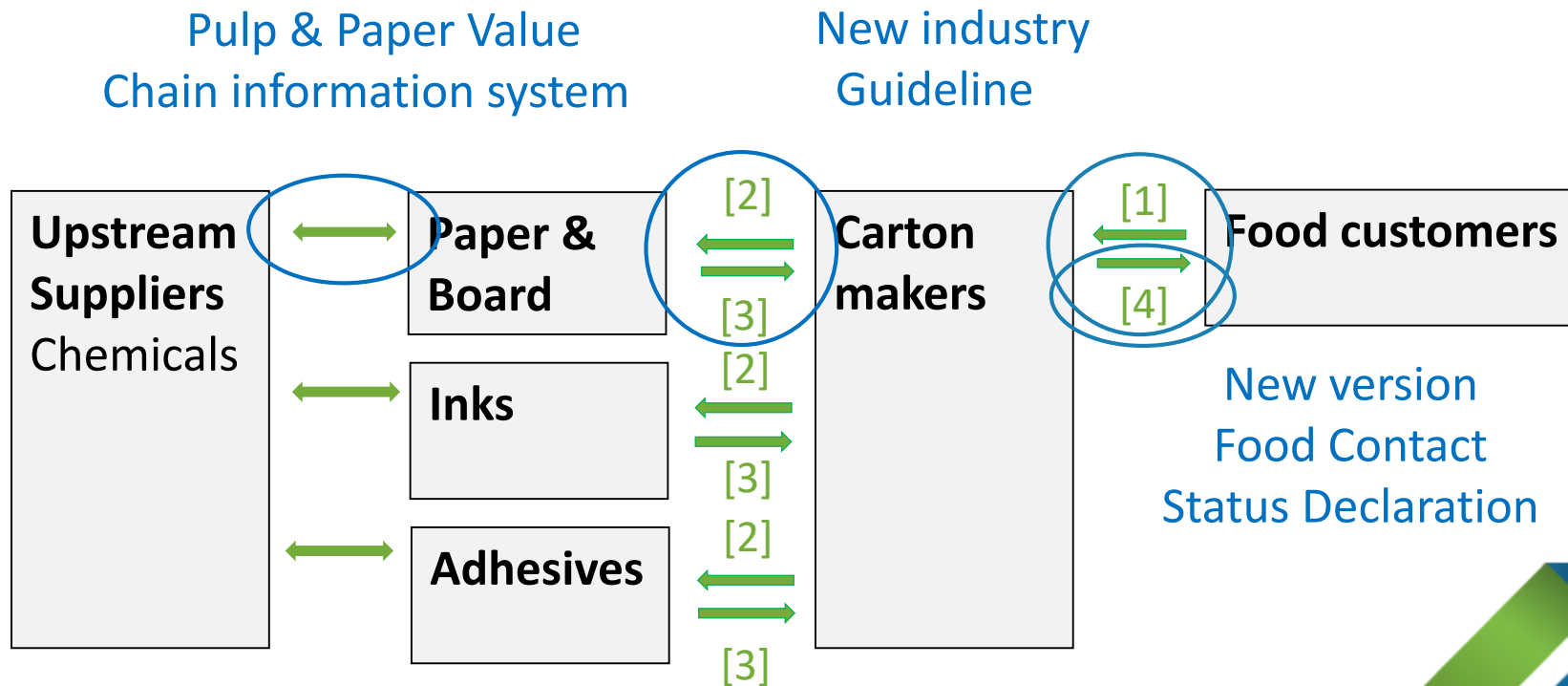


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3. Information sharing for Risk Assessment



To assess compliance essential to have a flow of adequate information between all actors in the supply chain

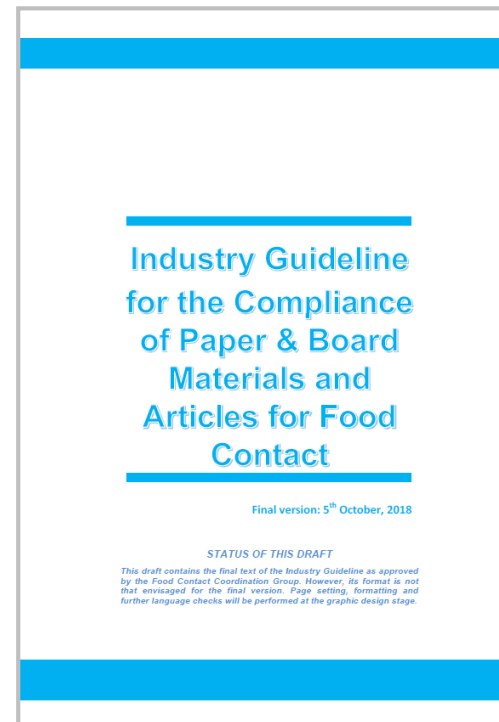


- [1] ECMA Checklist to use with customers
- [2] Relevant information on type of application
- [3] Suitability, compliance with reference legislations and Information required on migratable substances
- [4] ECMA Template Food Contact Status Declaration



Table 3. DECLARATION OF COMPLIANCE – LIST OF CONTENTS

Main Element	Details	Comment
Date	1. Date of Declaration of Compliance	
Business operator issuing the Declaration of Compliance	2. Identity and address of the organisation which manufactures the materials or articles.	
	3. The address of the manufacturing site. The address of the manufacturer.	Only if different from the first address
Identity of the materials and articles	4. Generic product description.	
	5. Trade name or grade description, including other relevant identifying information. Description of the product and its structure.	
Confirmation of compliance with legislation and Industry Guidelines	6. Statement that the product complies with the relevant requirements of the <i>Framework Regulation</i> and relevant Industry Guidelines .	
	7. Statement that the different non-harmonised materials (paper & board, inks, adhesives, coatings) as well as polymer layers in MMMLs comply with existing reference legislation and industry guidelines, when these exist.	
	8. Known migrants with SML restrictions for paper and board in BfR XXXVI or other relevant lists of authorised substances, and intentionally added substances that, based on risk assessment can potentially migrate to food, should be communicated to downstream operators.	Compulsory
	9. Dual use substances (deliberately added only) with quantitative restriction in food legislation	When risk assessment indicates that there is a risk of transfer to food
	11. Statement on end uses or the restrictions of use, if any (e.g. food type, temperature).	



General DoC guidance.
 [2-3] P&B - Converters
 [1-4] Converters - Food customers



Specific ECMA guidance on Food Contact Declarations [4]



1. General product information
2. Material description
3. Confirmation intended food contact
4. Declaration from the raw materials suppliers
Board
Printing inks
Varnishes
Adhesives
Window film
5. Performed overall risk assessment and required further compliance work

Food Contact Status Declaration

Article 16 of Regulation (EC) No 1935/2004 requires a written declaration stating that the materials and articles covered by a specific measure comply with the applicable rules to them. Paper and board packaging does not fall under this requirement.

Committed to food safety and an optimal food safety communication in the supply chain, our company shares herewith adequate information on the food safety status of the delivered cartons in accordance with the template adopted by the ECMA Technical Committee (Version 3 - July 2017). This template has been developed for all cartons delivered for food applications, irrespective the presence of barriers between the food and the carton.

1. General Product Information

Customer :	
Carton supplier :	
Address supplier :	

Material description

Article number	Article description

2. Material description (from the outer to the inner layer)

Varnish :	
Ink :	
Adhesive :	
Board :	
Polymeric layer :	

3. Confirmation of the Intended Food Contact

Our company confirms that the product on this statement complies - knowledge - with the applicable requirements of the EU "Framework" Regulation (EC) no. 1935/2004 on materials and articles intended to come in contact with food and with regulation (EC) no. 2023/2006 on good manufacturing practice for materials and articles in common agreement further compliance checks may however be required for the substances specifically mentioned in section 5 of this declaration.

The converting process is in accordance with the ECMA GMP.

This declaration is based on the following shared information covered in the customer food safety checklist :

Properties of the food (consistency, fat content, chemical properties, surface/volume ratio)	
Processing of the packed food (temperature ...)	
Layers and type of barrier in place between the carton and the food (presence of a functional barrier...)	
Use by the consumer (heating, overall maximum storage period ...)	

Promotional items, inserts and stickers provided by the customer for integration in the carton require a food safety declaration from the customer. Promotional items, inserts and stickers integrated at a later stage, as well as the adhesives used by the packer/filler are out of the scope of this declaration and must be evaluated by the end user.

[In case the packer/filler confirmed the presence of a functional barrier between the carton and the food, there is no need to fill in section 4.]

4. Declarations from the raw material suppliers

4.1 Board (no specific harmonized EU legislation)

4. Mineral Oils: Solutions and Best Practices



How to achieve positive compliance with Article 3?

Germany

Draft 4 Mineral oil regulation (March 2017)

Migration from a P&B Food Contact Material made of paper for recycling

- No MOSH limit
- MOAH C16-C35 below limit of 0.5mg/kg food

Limits in place

MOSH C10 - C16 12 mg

MOSH C16 - C20 4 mg/kg

[BfR (2012) Protokoll der 10 Sitzung der BfR
Kommission für Bedarfsgegenstände von 29
November 2012]

Latest development

Broad scale testing of food samples by 4 German laboratories.
Objective to define per food category “normal” ranges of
MOSH contaminations and thresholds.



Belgium

MOSH not mutagenic nor carcinogenic
MOSH (C16-C35) : 5-150 mg/kg of food

Proposed action thresholds for MOSH (C₁₆-C₃₅) in different food products (mg/kg) ^(*):

Milk and dairy products	5
Fruit and fruit products	10
Composite food (including frozen products)	15
Grains and grain-based products	15
Vegetables and vegetable products	20
Starchy roots and tubers	20
Snacks, desserts, and other foods	20
Meat and meat products	30
Sugar and confectionary	30
Fish and fish products	60
Herbs, spices and condiments	70
Animal and vegetable fats and oils	100
Legumes, nuts and oilseeds	150
Eggs and egg products	150

^(*) edible parts

MOAH (C16-C35) :
Gaps regarding toxicity.
Carcinogenic potential of
certain components.
Analytical detection limit
0,5 mg/kg food.

FOOD ADDITIVES & CONTAMINANTS: PART A
<https://doi.org/10.1080/19440049.2018.1512758>

Analysis of mineral oil in food: results of a Belgian market survey

Annelies Van Heyst ^a, Mathias Vanlancker ^b, Joeri Vercammen ^b, Kathy Van den Houwe ^a, Birgit Mertens ^c, Marc Elskens ^d and Els Van Hoeck ^a

^aService Organic Contaminants and additives, Sciensano, Brussels, Belgium; ^bInterscience, Louvain-la-neuve, Belgium; ^cService Risk and health impact assessment, Sciensano, Brussels, Belgium; ^dDepartment of analytical and geochemistry Vrije Universiteit Brussel, Brussels, Belgium



SciCom

Scientific Committee of the Federal Agency for the Safety of the Food Chain

Advice 19-2017 of the Scientific Committee of the FASFC on action thresholds for mineral oil hydrocarbons in food

http://www.afsca.be/scientificcommittee/opinions/2017/_documents/Advice19-2017.pdf

Mineral Oil Monitoring



Belgian Test Results

Source : presentation

Annelies Van Heyst

Sciensano 15/05/18

MOSH	SciCom		
	Action threshold	<	>
	mg/kg		
Animal and vegetal fats and oils	100	9	0
Grains and grain-based products	15	99	0
Vegetables and vegetable products	20	13	0
Legumes, nuts and oilseeds	150	29	0
Snacks, desserts and others	20	10	0
Sugar and confectionary	30	24	1
Fish and fish products	60	7	0
Meat and meat products	30	6	0
Total			

LC-GC-FID

Clean up of samples

MOSH

MOAH

MOAH	Analytical		
	Detection limit	<	>
	mg/kg		
Animal and vegetal fats and oils	0,5	5	8
Grains and grain-based products	0,5	95	7
Vegetables and vegetable products	0,5	11	1
Legumes, nuts and oilseeds	0,5	31	0
Snacks, desserts and others	0,5	3	2
Sugar and confectionary	0,5	17	5
Fish and fish products	0,5	7	0
Meat and meat products	0,5	6	0
Total		175	23

The Netherlands

Mineral oils in food; a review of toxicological data and an assessment of the dietary exposure in the Netherlands.

- Total MOAH not an indication on toxicity
- Determination of the sources for MOAH contamination and take measures against the harmful sources

Paperboard packaging made of recycled materials is often used for dry foods such as rice, pasta, breakfast cereals and chocolate sprinkles.

Intake calculations made clear the intake via these foods makes **only a small contribution** to the total exposure to mineral oils via food.

Measures on paperboard packaging would have **limited effect**.



<https://www.rivm.nl/dsresource?objectid=5742723e-b026-453d-b528-f8619b5fe3b4&type=pdf&disposition=inline>

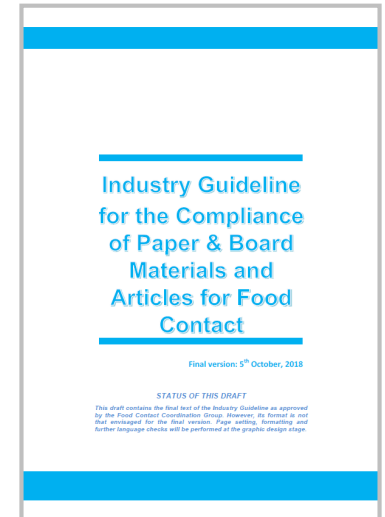
Ways to reduce/ avoid the MOSH /MOAH migration and especially the PAH



Substrate

- Virgin cardboard
- Optimized recycled board
- Recycled board with a barrier layer on the reverse side or an adsorbent
- Recycled board with an inner bag providing a functional barrier

Testing for non intentionally added substances (NIAS)



NIAS REQUIREMENTS ONLY RELVANT FOR PAPER/BOARD GRADES USING RECYCLED FIBRE PULP					
Substance	Requirement	Source	Source	Method	Food type
	<i>QMA</i>	<i>SML</i>			
Polyaromatic Hydrocarbons (PAHs)		0,01 mg/kg food ^a	EFSA, BFR	prEN	All
Mineral Hydrocarbons ^b					



Use of EuPIA GMP compliant inks (Low migration inks)



page 1 of 3

EuPIA Customer Information Note

regarding the use of
sheetfed offset printing inks/varnishes
(setting and/or oxidative drying, or UV/EB curing)
and water-based coatings

for the manufacture of food packaging made from paper and board

Executive Summary:

- Special food packaging sheetfed printing inks and varnishes are recommended for the manufacture of food packaging
- All other sheetfed printing inks and varnishes are **not suitable** for the manufacture of food packaging
- Standard sheetfed inks can only be used for the manufacture of food packaging where an absolute barrier is present and where any transfer of ink ingredients, e.g. by invisible set-off, can be ruled out by appropriate packaging design and manufacturing process

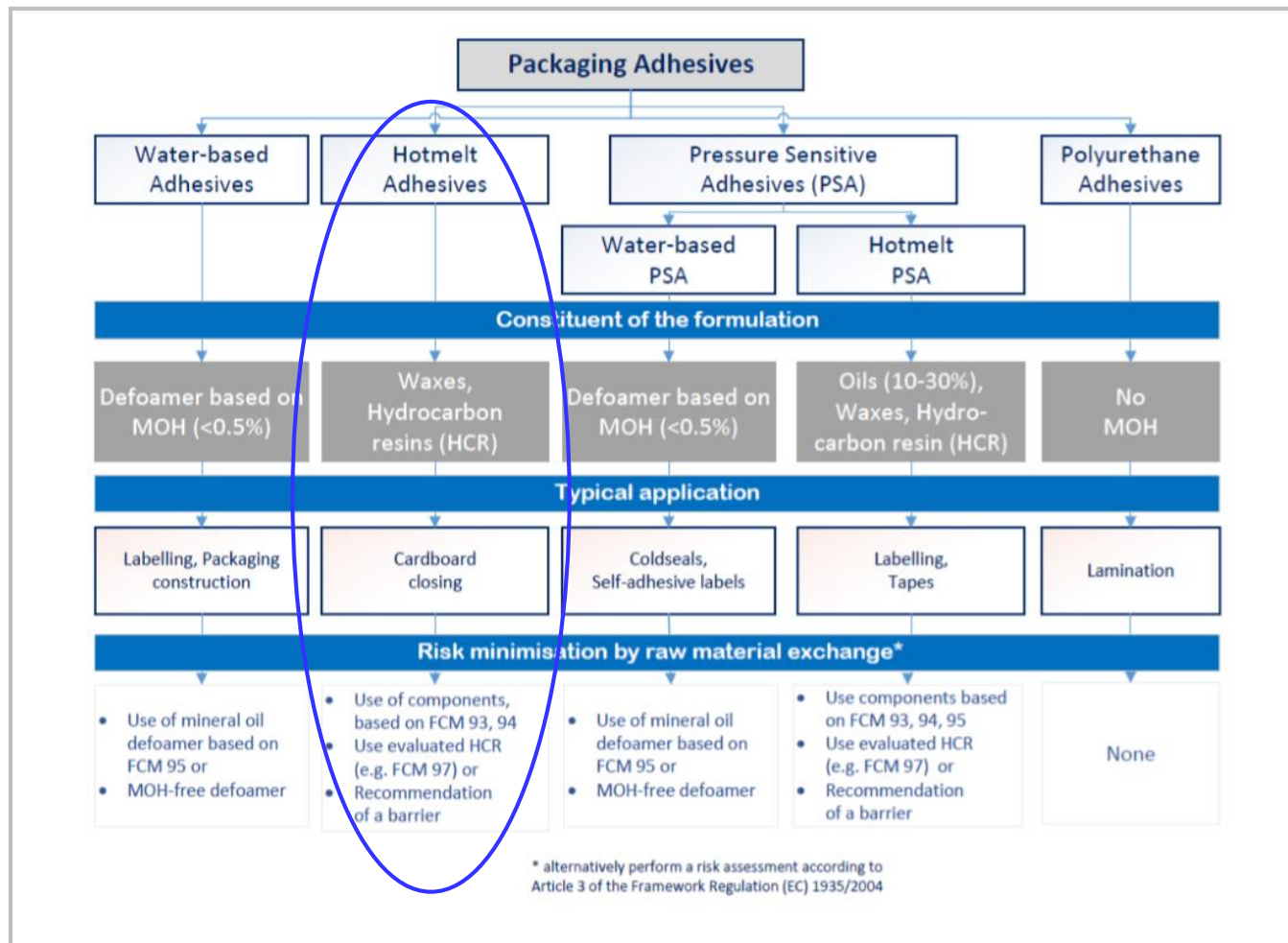
http://www.eupia.org/uploads/tx_edm/2015-10-08_EuPIA_info_sheetfed_offset_inks_for_paper_board_food_packaging.pdf



Adhesives



Substitution of MO by assessed FCM



FEICA GUIDANCE

FEICA The European voice of the adhesive and sealant industry

Brussels, 05/05/2017

FEICA guidance on evaluating the food contact status for adhesives containing mineral oil hydrocarbons

http://www.feica.eu/documents/document/20170626140900-gup-ex-g05-019_feica_guidance_fc_status_adhesives_mineral_oil.pdf



Overall Packaging Concept



Migration from transport packaging

Solutions available :

Transport packaging level

- Hybrid corrugated
- Protective inner liner
- Active carbon

Transport packaging
Responsibility customers

Separate protecting inner bag.

Coating or barrier varnish on the outside of the carton



Summary



1. **Harmonised legislation required**

General food contact & material specific assessment ?

2. **Self-regulation**

New industry Guideline and proposal PIJITF
ECMA GMP specific for carton makers

3. **Improved information sharing**

Industry guideline and new ECMA Food Contact Status
Declaration

4. **Mineral oils**

Well known need to select appropriate substrate, inks and
adhesives. (+ monitoring overall packaging concept)





The track is known. Safe cartons...

a shared responsibility
for authorities, suppliers, carton makers and customers,
for the technical departments,
the carton makers sales staff and the food customer procurement.

