EUROPEAN CARTON MAKERS ASSOCIATION

ECMA's viewpoint on the inception impact assessment of the roadmap for revising the EU FCM Regulations

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1. Introduction
European Carton Makers Association

Membership

European structure with 14 national associations
Direct membership
Represents direct and indirect 500 companies (90 % SMEs).

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

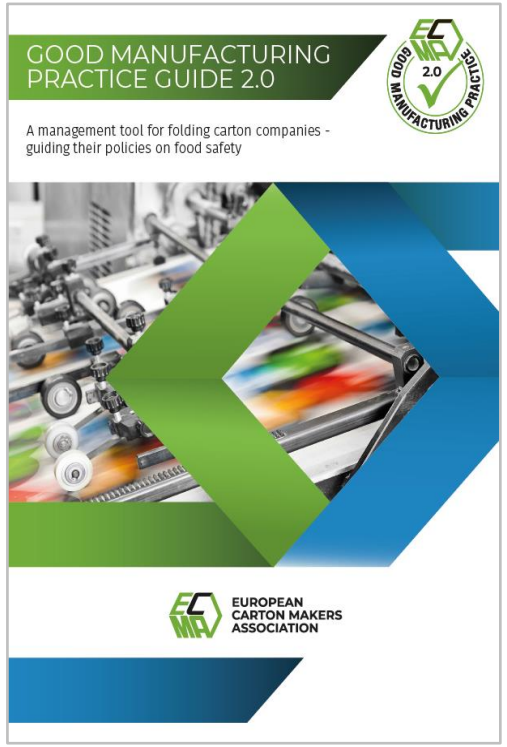
ECMA Food Safety Committee

ECMA is grateful to the committed food safety experts from member companies and associations, deeply involved in the development of guidance for the membership and in defining the external FCM positions.

Currently represented : AR Packaging, FFI Fachverband Faltschachtel Industrie, Graphic Packaging International, Mayr Melnhof Packaging, Schur Pack, SEDA International Packaging Group, Van Genechten Packaging, WestRock.

2. Review ECMA GMP

Benchmarking Existing GMP versus GFSI schemes



Geers FCM Consultancy

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
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

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3. Inception Impact Assessment (IIA) Identified fundamental issues

IIA " Lack of functioning internal market and possible safety issues non-plastic FCMs."

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.
- Facilitates public argumentation.

Identified fundamental issues.

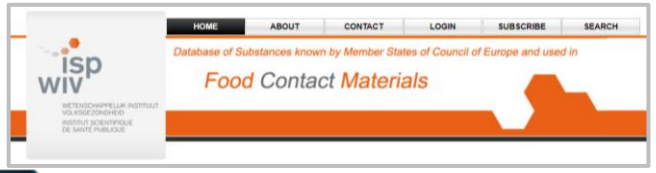
IIA "The positive authorised list approach and lack of focus on final article"

In favour of one transparent inventory list with all regulated and used substances (EU, national …).

Essential to allow industry to perform risk assessments for not evaluated substances "in accordance with internationally recognised scientific principles."

- Stimulates innovation.
- Avoids just 10 ppb for not evaluated substances.
- Information sharing in the supply chain needed.
- Part 2 in inventory.

Belgian Authorities CoE Database
JRC Baseline Study : IT Tool announced
Food Contact Chemicals Database



Identified fundamental issues.

Focus on the final product.
Single focus on starting substances not sufficient, but remains a cornerstone for safe products.

IIA : "Lack of prioritisation of the most hazardous substances and up-to-date assessments"

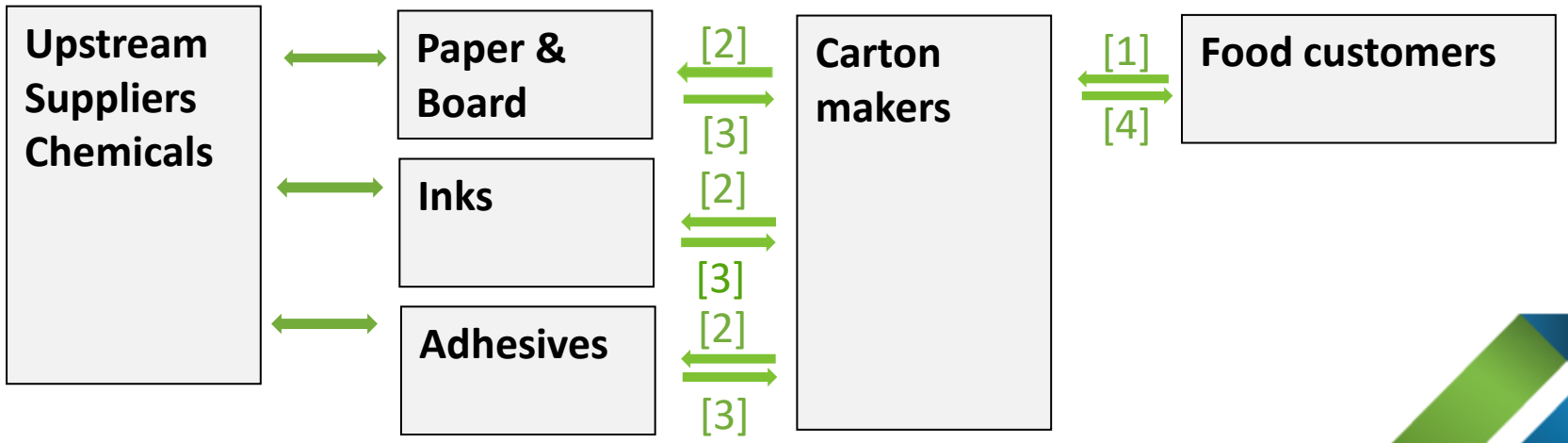
Structured harmonised clear information on <u>most</u> hazardous chemicals required.
Hazard / Exposure / Risk : **Keep the dialogue open** between authorities and industry.
Pragmatic plans forwards.

"Of course there will always be a need to further work with RA, where some particular substances may still need to be present or where there may still be exposure but this would be foreseen to go hand in hand with an appropriate RA."

Identified fundamental issues.

IIA : "Exchange of safety and compliance information in the supply chain is poor and the ability to ensure compliance is compromised."

Templates developed for carton manufacturers :



[1] **ECMA Checklist** to use with customers

[2] Relevant information on type of application

[3] **ECMA Supplier questionnaire** : Suitability, use instructions, required further compliance work.

[4] ECMA Template **Food Contact Status Declaration**

Identified fundamental issues.

"The key issue is that you know what is migrating, without making the difference between NIAS and the substances which were intentionally added … at the beginning of the process.
However this very much would require that you know which substances are there. So it is impossible to do this approach for a business operator like a converter or even further down the supply chain without having knowledge of the kind of substances which are in his materials. So therefore at the same time you would need a very comprehensive clear transparent system to pass compositional information down in the supply chain. …"

ECMA questionnaire for obtaining information from suppliers (2 levels on present substances)

- Advanced : **composition of FCM**
- If not information requirements **similar to CoE Resolution**

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."

Identified fundamental issues.

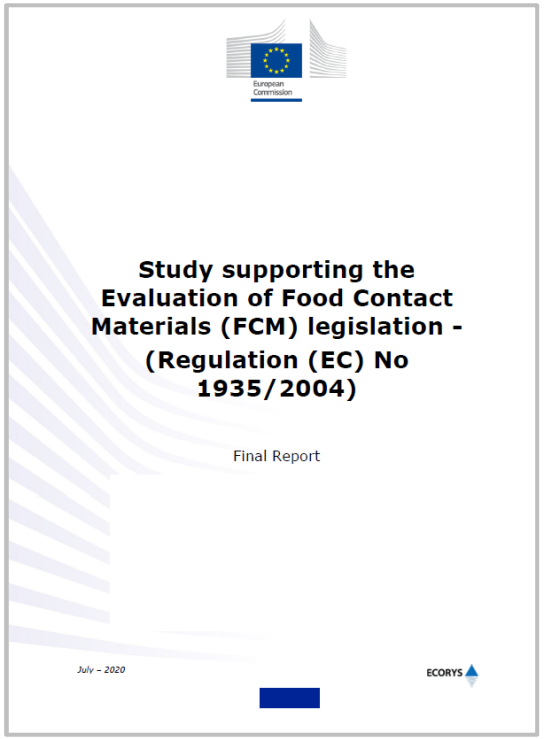
IIA : "Rules do not sufficiently take in account the specificity of SMEs."

Many SME carton makers specialized in food packaging deeply committed to food safety !

Ecorys report

The results of the SME panel … Overall, for SMEs it is ***more difficult*** *to demonstrate compliance as they do not have the leverage to require complete DoCs from suppliers.*

Without adequate information not possible to perform cost-effective worst-case calculations or to use less expensive safe alternatives.



Identified fundamental issues.

Outcome certain court cases with SME carton makers involved has been unfair.
The full chemical knowledge is with the suppliers.
For SMEs not feasible to follow all scientific publications related to the safety of substances.

Especially for SMEs, CoE DOC wording would represent a …

… significant step forward.

4. Inception Impact Assessment Objectives and policy options

IIA "Ensure the safety and sustainability of the final FCM."
"Shifting the focus onto final materials."

Safety of final FCM needs to be assured, taking in account migration which may come from different materials used.

In case accurate information is available, worst case calculations are cost effective.

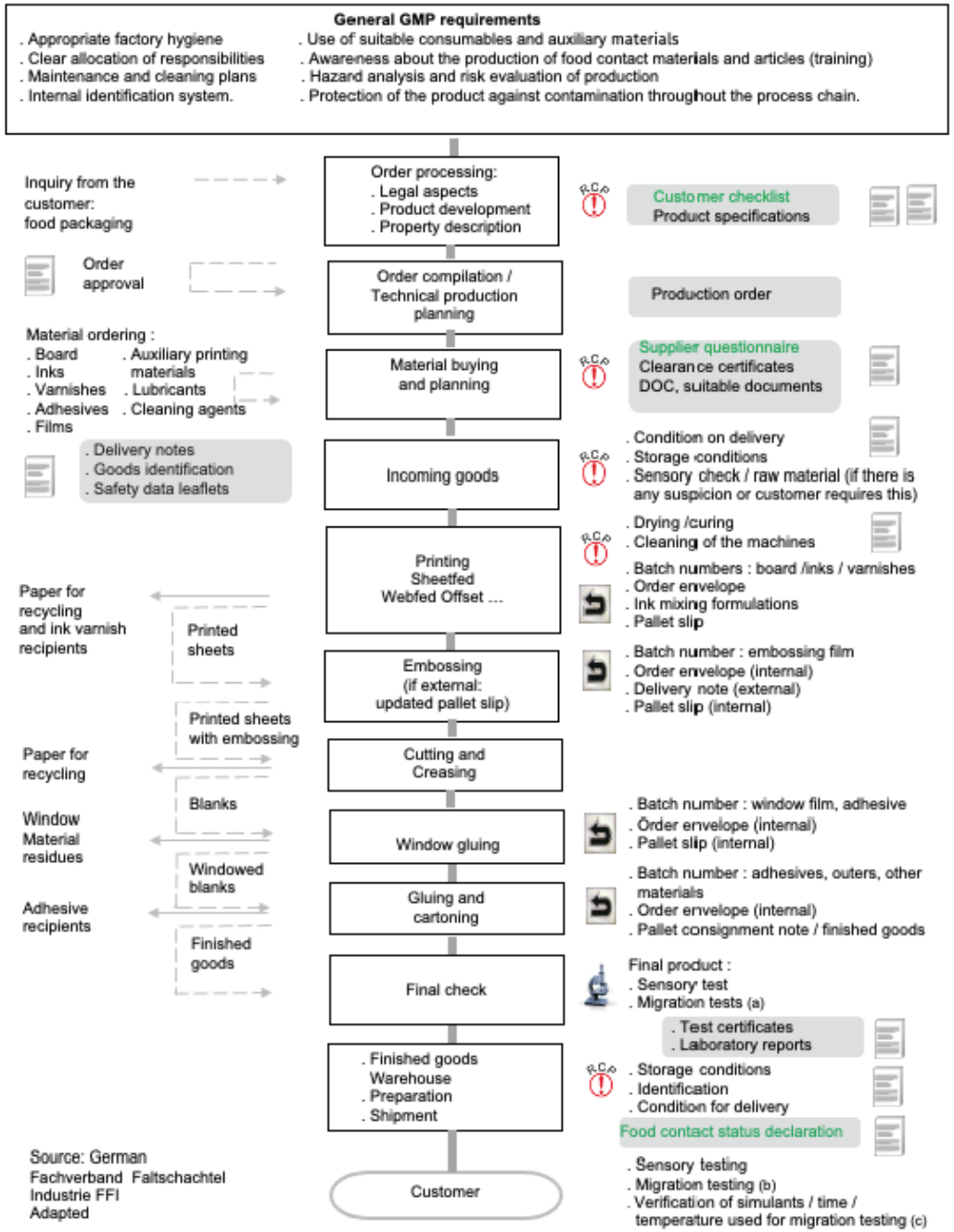
Increased focus on compliance of final article should not lower the responsibility of the upstream suppliers.

Objectives and policy options

Downstream users

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

Annex 1: Process flow – General GMP Requirements



Source: German Fachverband Faltschachtel Industrie FFI Adapted

Objectives and policy options

IIA "Prioritizing the assessment and management of substances."

Tackling the unassessed substances in a pragmatic way.
EFSA and ECHA in a well-coordinated steering role.
Business operators allowed to perform RA

IIA "Ensure exchange information in the supply chain, support SME's and enforcement of the rules. Improving quality and accessibility of supply chain information for compliance an enforcement."

Accurate communication and a **clear determination of responsibilities** is essential.
Just an indication on compliance with a reference legislation is not sufficient.
Safety assessments are about the substances present.

5. Core messages

- New ECMA GMP publication.
- In favour of 1 transparent substance list for all FCM.
- Open dialogue and pragmatic plans forwards.
- Declaration of compliance at all stages of the supply chain and **actor introducing a substance assumes responsibility** for safety including NIAS which may be generated in the downstream production processes …
- **Downstream user : checks** what needs to be, **respects** use instructions and **operates** in accordance with GMP.

Food safety is a journey

The direction 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.

EUROPEAN
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Thank you