


# UPDATE ON CROSS SECTOR GROUP ACTIVITIES

---

DG and Member State Meeting

10<sup>th</sup> November 2020

 on behalf of the Cross Sector Group (CSG)

1

## Why a Cross Sector Group (CSG)?

- In November 2016, European Parliament stressed the need to harmonise FCM legislation and the applicability of 1935/2004 in today's environment.
- Industry was asked for input into the way forward for harmonised and non-harmonised FCM&As (Food Contact Materials & Articles).
- Cross-sector group formed with both harmonised and non-harmonised FCM&As.
- The goal is to develop output that could assist the way forward for legislation.
- Increased complexity due to different needs and requirements for materials, articles and equipment.

2

## Composition of the CSG

Over 30 association representatives of which 24 currently active, from:

- Food Industry
- Converters and article producers
- Formulators and material producers
- Suppliers of Raw Materials
- Different sectors, some very complex<sup>1</sup>
- Suppliers of raw materials are across all sectors
- Convertors and formulators are part of one or more sectors
- Food industry affected by all sectors

<sup>1</sup> endorsement of the position statements and letters is optional. Logo signifies agreement

3

## Overview of how Cross Sector Group functions

**Plenary – representatives** agree on **overarching principles** to demonstrate safety of their products

**Individual Sectors** decide on how to implement the overarching principles to their sector

**Individual Associations** decide on how to implement the overarching principles to their products

**Individual companies** decide on how to implement the overarching principles to their products

4

## Areas tackled by CSG

### Proposals for the way forward to ensure compliance with Framework Regulation 1935/2004 and any potential changes

#### Communication

- Trust and Transparency
- An article supplier needs a different approach and information than a substance supplier

#### Risk Assessment and Risk Management

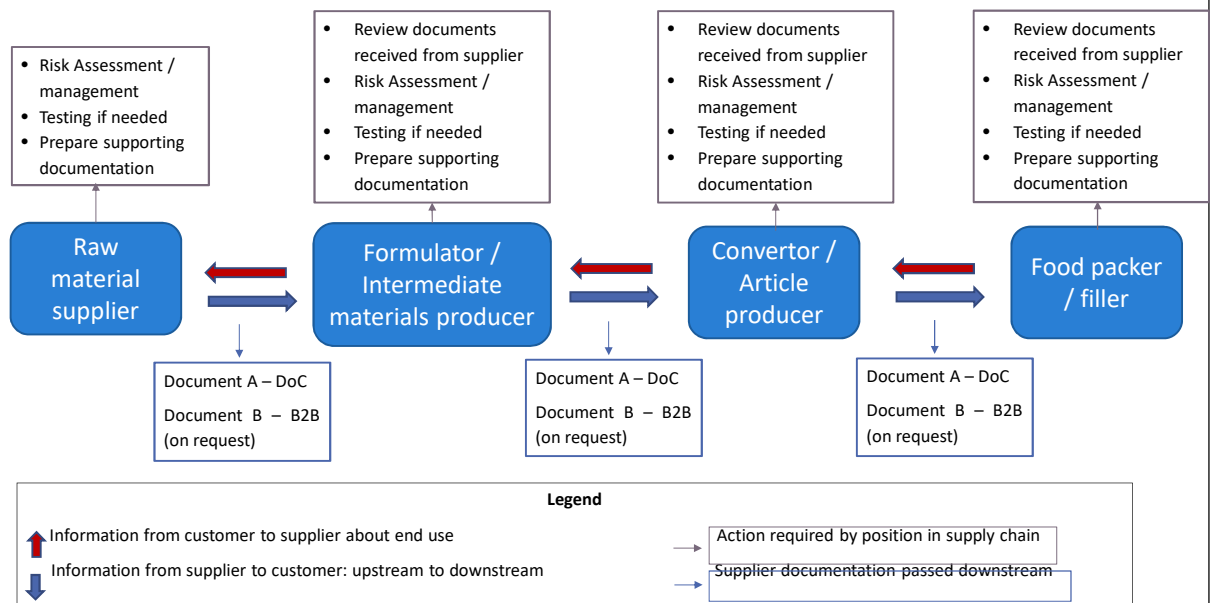
- We ask consideration by DG SANTE, Member States and EFSA that our proposals for self-risk assessment and management would be acceptable

#### Seeking support from non-industry sectors

#### Feedback to Ecorys / DG SANTE report

5

## Communication Flow Chart



## Trust & Transparency – Agreed Sept 2018

Transparent processes are key, need of openness / readiness for external scrutiny. All FCM&As must have supporting documentation<sup>1</sup> in place for sharing with enforcement authorities.

### Requirements

- All actors to have in place auditable systems and procedures to demonstrate safety/compliance.
- A verification process shall be in place to review that all information for suitability, relevance and completeness is available.
- All independent verifiers shall follow EU harmonised criteria established with and supported by enforcement authorities.
- Independent verifiers shall confirm that risk management measures are clearly defined and incorporated into the system.

<sup>1</sup>GMP regulation where applicable, plus available industry guidelines

7

## Risk Assessment / Risk Management (RA/RM)

- **The CSG fully supports a Risk rather than a Hazard approach to assessing the safety of FCM&As.**
- RA/RM may vary within the complexity of the supply chain.
- RA/RM are dependent on the sector, the position within the value chain and the type of business.
- It is incumbent on each sector/supply chain to develop their own detailed guidelines on how to risk assess and risk manage their materials.


8

## Hazard

vs.

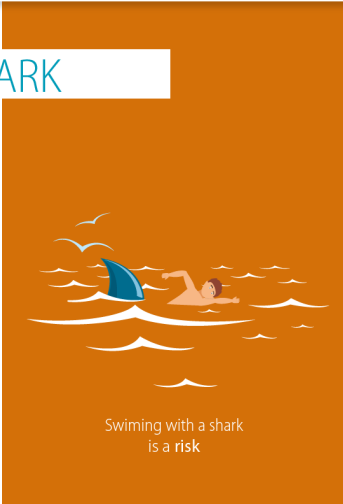
## Risk

A Hazard is something that has the potential to harm you



A shark in the sea is a hazard

Risk is the likelihood of a hazard causing harm



Swimming with a shark is a risk

SHARK

Source: EFSA 9

## RA/RM Over-arching principles (1)

- All known substances potentially migrating from FCM&As, including NIAS, must be risk assessed and risk managed.
- Knowledge of hazard and exposure is required to perform a risk assessment.

$$\text{RISK} = \text{EXPOSURE} \times \text{HAZARD}$$

- Hazard evaluation of substances should be undertaken by the first operator in the supply chain introducing those substances.
- All should use internationally recognised scientific principles in their risk assessment.

## **RA/RM Over-arching principles (2)**

- Higher up the supply chain = the greater knowledge of hazard.
- Lower down the supply chain = the greater knowledge of exposure.
- Communication of information must be transmitted both up and down the supply chain.
- Individual Sectors will detail the information to be transferred and:
  - Make clear to the next business operator in the supply chain that a risk assessment has been undertaken.
  - Provide sufficient details to the next business operator to be able to perform their own risk assessment, if needed.

11

## **RA/RM Over-arching principles - 3**

- The risk assessment and risk management processes used must be documented and form part of the supporting documentation (SD)
- Supporting documentation must be auditable and available to Competent Authorities on request.
- Supporting documentation should state which approaches have been used and why.

NOTE: The Cross-Sector Group is working on a more detailed approach to RA.

12

## Seeking Support from Non-Industry Sectors

### OUR PROPOSAL:

- Sharing the trust and transparency document to relevant bodies and following the guidance.
- Relevant bodies will have the opportunity to provide feedback and comments to the CSG.
- The CSG proposals for RA/RM will be shared with DG SANTE
- Any proposals arising will be assessed by CSG to be incorporated.

13

## CSG's Response to DG / Ecorys Report (1)

- CSG welcomes DG 's report
- Pleased to see the it tackles issues like:
  - The need for a harmonised risk assessment of food contact substances
  - The need to address issues related to the implementation of the legislation.
- CSG fully agrees with the conclusion: Regulation (EC) 1935/2004 provides EU added value, but its impact is reduced by incomplete implementation.
- 16 years after the entry into force, specific measures are in place for only 4 materials.
- Collected evidence suggests that harmonised legislation is more efficient than a non-harmonised approach.

14

## CSG's Response to DG / Ecorys Report (2)

- The Framework Regulation has a pivotal role in establishing the basis of safety of FCM&As.
- Traceability, labelling and the Declaration of Compliance improve transparency in the supply chain and contribute to the functioning of the internal market.
  - These tools should be extended and harmonised criteria should be introduced, to cover all FCMs.
- Positive lists (PL) approach has been effectively used in regulating plastics, but is not realistic for all non-harmonised FCMs<sup>2</sup>.
- PLs are not applicable for NIAS and would fail to be exhaustive.

<sup>2</sup>there are varying opinions about the value of PLs for all non-harmonised materials [e.g. FoodDrinkEurope].

15

## CSG's Response to DG / Ecorys Report (3)

A new approach is required:

- ⑩ Additional requirements should be technically feasible, workable for authorities for industry and proportionate to risk.
- ⑩ The impact on the implementation by SMEs must be considered
- ⑩ Changes should consider the assessments made by the competent national authorities, as well as those carried out by the industry.
- ⑩ The value and role of the Good Manufacturing Practice (GMP) to ensure product safety during manufacturing should be emphasized.

16



## CSG's Response to DG / Ecorys Report (4)

- There is a general misconception concerning lack of compliance of FCM&As not covered by harmonised legislation.
- The safety of non-harmonised materials is ensured; they fall under the Framework Regulation (EC) No 1935/2004 and are subject to risk assessment.
- For non-harmonised FCMs the need to comply with more than one national legislation is burdensome. Compliance could be eased by:
  - Mutual Recognition being better enforced.
  - Member States recognising each other's risk assessments.
  - EU harmonised approach to risk assessment, which would help innovation.

## CSG's Response to DG / Ecorys Report (5)



CSG fully supports the development of EU harmonised risk assessment guidelines for all substances.



CSG would like to participate in the development of RA guidelines with contribution of expertise in FCM&As and risk assessment.



EFSA should be involved in the development of RA guidelines.



CSG expects improvements to the current EFSA Risk Assessment/ Commission Risk Management process, with a pragmatic model that stimulates innovation.



Industry risk assessments can reduce the time to market for new substances and reduce workload for DG SANTE and EFSA.

# THANK YOU FOR YOUR ATTENTION

For further information please contact either:



19

## Active CSG members

- [APPLIA Europe – Domestic Equipment Manufacturers](#)
- [Cefic-FCA – food contact additives](#)
- [CES – Silicones Europe](#)
- [CEPE – Coatings](#)
- [CEPI –European Paper Industries \(pulp and paper\)](#)
- [CERAME-UNIE – European Ceramic Industries Association](#)
- [CONCAWE – Division of Oil Refiners Association](#)
- [CPME – PET industry](#)
- [ED/ESGA/Institut du Verre - Glass Alliance Europe](#)
- [EEA: European Enamel Association](#)
- [EuPC – European Plastics Converters](#)
- [EUPIA – Printing Inks](#)
- [EUROFER](#)
- [European Wax Federation](#)
- [FEICA – Adhesives](#)
- [FoodDrinkEurope](#)
- [FEC – The European Federation of Cutlery, Flatware, Hollowware & Cookware Industries and Brands](#)
- [FEFCO - Corrugated Packaging](#)
- [Flexible Packaging Europe](#)
- [Intergraf - European Federation for Print & Digital Communication](#)
- [Metal Packaging Europe](#)
- [Nickel Institute](#)
- [PlasticsEurope](#)
- [WBT - World Association Bottle & Teats](#)

20