



# Introduction to Product Safety Compliance of Food Contact Materials

FCM workshop



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# DPSIR Analysis FCM Safety



## Driver

FCM are essential for the distribution of food. Free movement of goods ensures their availability at best price in EU

## Pressure

FCM are not inert and could therefore transfer their components to food

## State

Exposure to dangerous constituents

## Response

Legal frame on FCM and industry responsibility

## Impact

Potential danger to human health

# DPSIR Analysis FCM Safety



## **Driver**

FCM are essential for the distribution of food. A considerable expertise on their behaviour exists

## **Pressure**

Lab equipment ever more performant

## **State**

Substances are detected in food

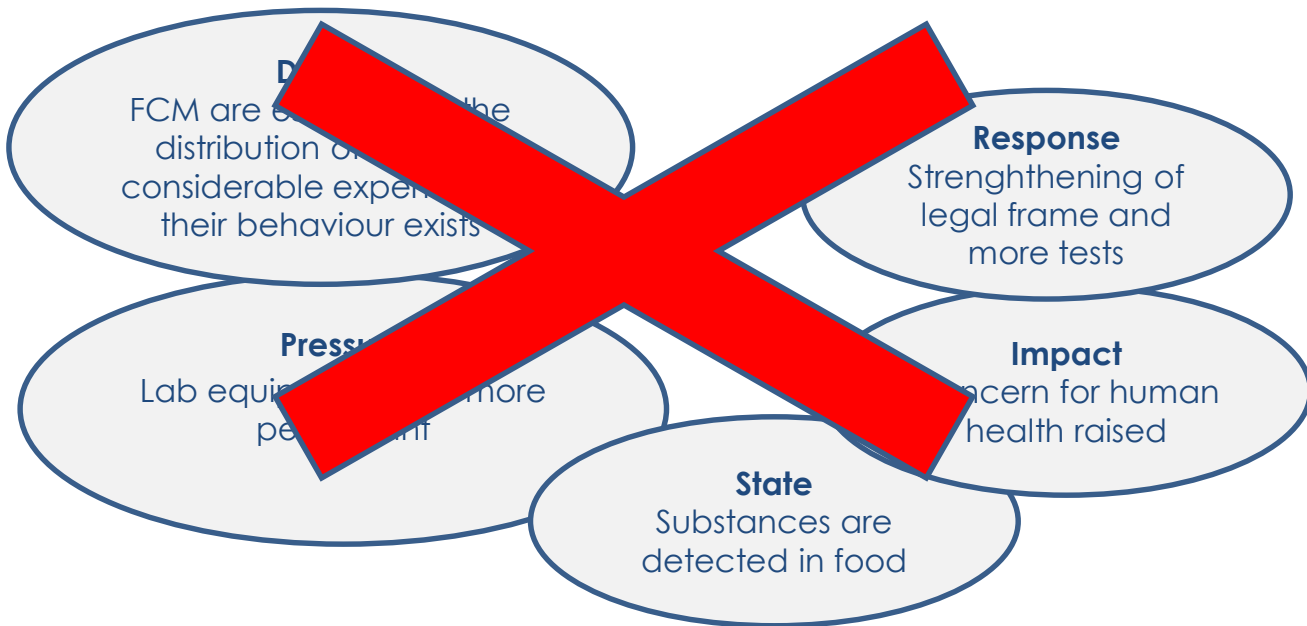
## **Response**

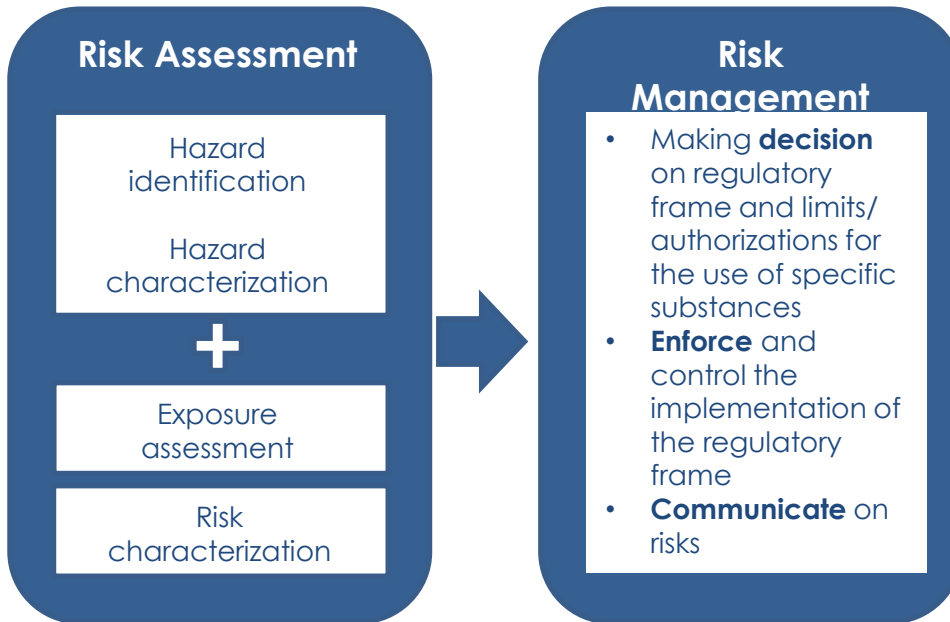
Strengthening of legal frame and more tests

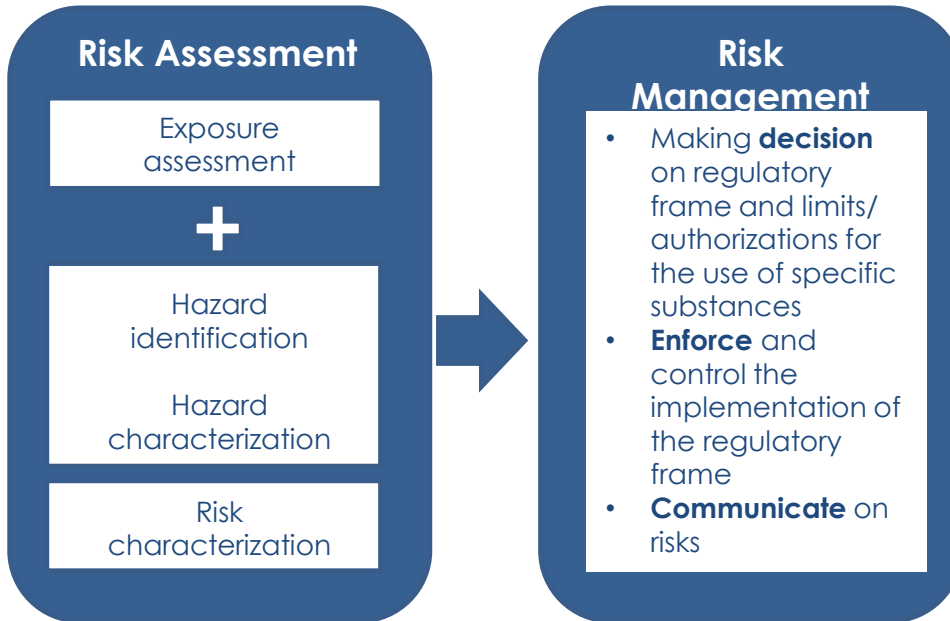
## **Impact**

Concern for human health raised

# DPSIR Analysis FCM Safety







# Food Safety Management Objectives



## Balance between

- Delivering solutions meeting consumers needs at affordable price
- A high level of human health
- The need to focus compliance resources to minimize risks
- Responsibility
- Exchange of information (within industry)
- Clear information (towards consumer)
- The necessary control (internal and external) to ensure the same high level of safety accross actors in the supply chain and accross EU

# 1. Europe European Legislative Overview



**Framework Regulation (EC)  
No 1935/2004**

**GMP Regulation (EC)  
No 2023/2006**

## Materials specific Measures

## Substance specific Measures

**Regenerated Cellulose**  
2007/42/EC

**Ceramics**  
84/500/EEC

**A & I materials**  
(EC)450/2009

**Plastics Regulation**  
(EU) No 10/2011 (PIM)

**Reg.1895/2005**  
~~BADGE/NOGE~~  
~~Dir. 93/41/EC~~  
Nitrosamines

**Recycled Plastics**  
282/2008

European Commission

**Paper & Board**  
(DE, NL, IT, FR, CH)

**Coatings**  
(DE, NL, IT, ES, BE)

**Adhesives**  
(DE, ES, IT)

**Ion exchange Resins**  
(ES)

**Printing inks**  
(CH, upcoming DE)

**Rubbers**  
(NL, DE, ES, FR)

Member States

Glass, Wood, Cork, Textile, Metal, Silicones, Waxes



# Some Remarks



- Common principles outlined in the **Framework directive**
  - Article 3 : product safety
  - Article 9-12 : authorization for specific materials, applications, substances
  - Article 16 : declaration of compliance and supporting documentation
  - Article 17 : traceability
- And **GMP**

## Framework Regulation Art. 3: General Safety Requirements

- **Materials** and articles must be manufactured in compliance with GMP so that, under normal or foreseeable conditions of use, they **do not transfer their constituents to food in quantities which could:**
  - **endanger** human health;
  - bring about an **unacceptable change** in the composition of the food;
  - **deteriorate** the organoleptic characteristics of food
- **Labelling** or advertizing must **not mislead consumers**

## GMP (EC No. 2023/2006)

- Materials and articles must be manufactured in accordance with Good Manufacturing Practices
  - For all FCM and all stages of production
  - General requirements for establishing QA and QC and documentation
  - Provides specific rules for printing inks on non-food contact side (no transfer)
  - Specific plastics industry GMP guidelines already established years ago

# Plastics Regulation 10/2011



- **Overall migration limit** as a general measure for exposure minimization (10 mg/dm<sup>2</sup> or 60 mg/kg of food)
- **Specific ingredients can only be used following assessment of risk by EFSA and authorization** by EC. Those often will be accompanied by a Specific Migration Limit (if equal or lower than OML)
  - **Positive list of monomers and additives**
  - **Incomplete harmonized list of polymerization production aids**
- Specifies the testing conditions
- Specifies the format of the Declaration of Conformity
- Explicitly the safety requirements by highlighting the obligation to also assess the safety of **non intentionally added substances** (NIAS) **(Art. 19)**

# On the Menu



- **Context :**
  - European strategy on plastics
- **Implementation of plastics regulation**
  - **Not intentionally added substances**
    - Migratox : bioassays, a complement to advanced exposure screening?
    - JRC/EuPC Joint Project on NIAS Identification (tomorrow)
  - **Safety of recycled plastics**
  - **Repeated use articles**

# On the Menu



- **Different regulatory perspective : China?**
- **Practical experiences for product safety and compliance :**
  - rigid plastics converter
  - Food industry
- **Science :** MOSH, MOA, POSH (tomorrow)

# New Regulatory Frame?



- Which balance to achieve?
- **EU FCM state of Play and evaluation (EC)**
- **Strategy on common approach for risk assessment (EuPC)**
- **Legislative suggestion for FCM (PLEUR)**
- **Printed Food Contact Material Measure and the Approach of  
EuPIA**

# Final Introductory Thoughts



- In order to enable optimal safety but affordable regulatory compliance, compliance resources have to be focused where it matters
- Can only be achieved if stakeholders share common objectives, reference frame, adequate tools (scientific methodologies and information)
- The industry cross-sector group on FCM is a first step for this but more stakeholders including authorities should participate
- Trade associations and scientific community should develop better understanding of safety and practical tools enabling safety assessment and management
- A balance between self-control and external control (ex ante or ex post) should be achieved





*Have a good and  
enjoyable conference*

