



# Food Contact Materials

European legislation

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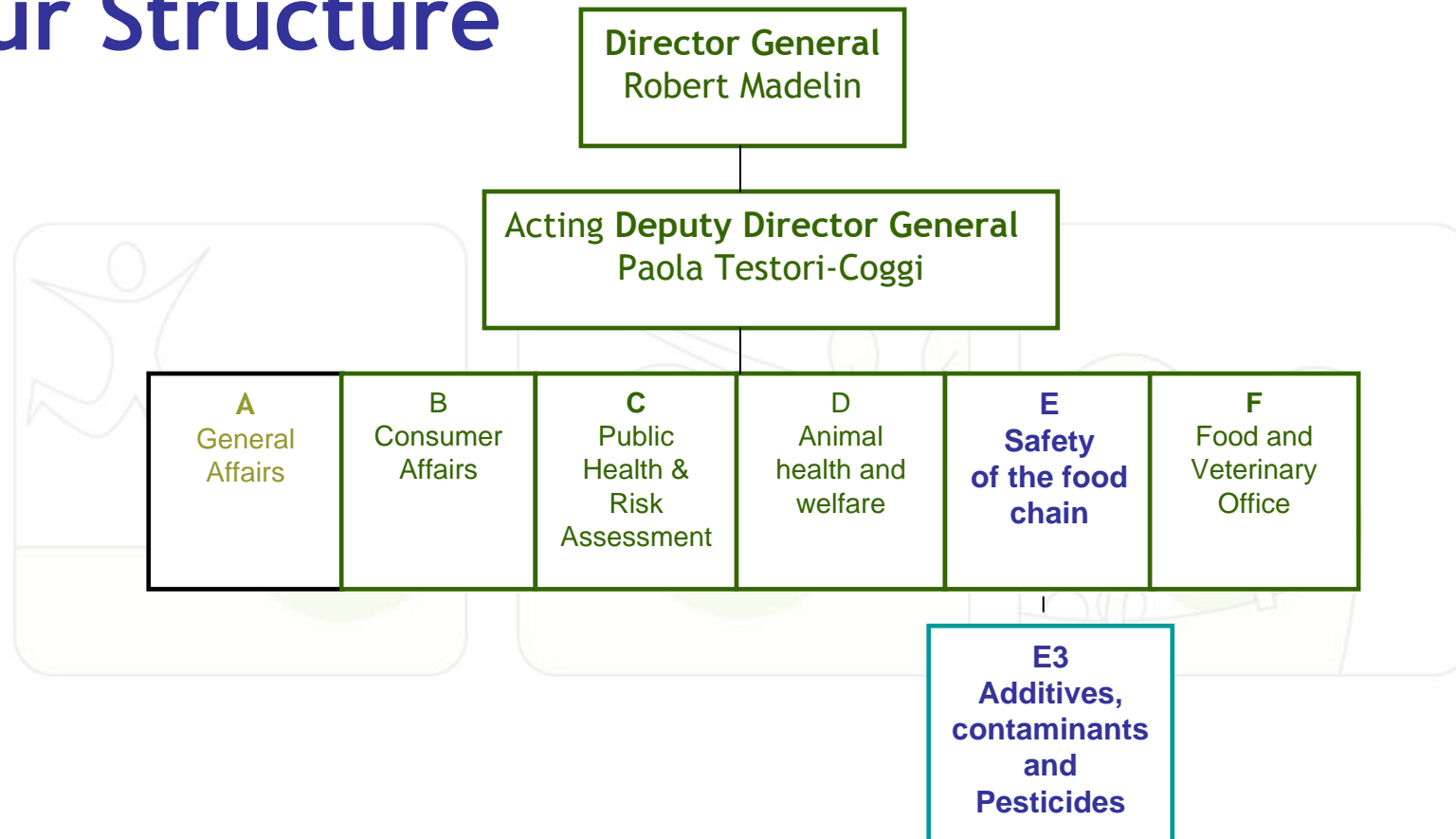
# SUMMARY

## 1. FCM legislation in EU

- **Framework Regulation**
- **Specific measures**
- **4th amendment of Plastics Directive**

## 2. Future Measures

# Our Structure



Full organigram available at:  
[http://ec.europa.eu/dgs/health\\_consumer/chart.pdf](http://ec.europa.eu/dgs/health_consumer/chart.pdf)

## **WARNING**

**The content of this lecture does not represent necessarily the position of the European Commission.**

# Food Contact Materials in EU

- ❖ **1960** CoE
- ❖ **1970** EU starts working first framework Directive and establishing evaluation of substances at European level
- ❖ **1980** Evaluation of substances, rules for migration testing and specific measures RCF and Ceramic
- ❖ **1990** Comitology and authorisation of substances in plastics
- ❖ **2000** CRL, GMP, Update of framework Regulation



# Current EU Legislation on FCM

# REGULATION (EC) No 1935/2004

## SCOPE

- ✓ **Food packaging**
- ✓ **Kitchen articles**
- ✓ **Machines or articles for food manufacture**

# FRAMEWORK REGULATION

## GENERAL REQUIREMENTS

### ART. 3(1)

#### Compliance with GMP

- ✓ **Food Safety**
- ✓ **No unacceptable change in food**
  - composition
  - taste
  - odor



# FRAMEWORK REGULATION

## Other requirements

- 
- ✓ **Labelling**
  - ✓ **Traceability**
  - ✓ **Declaration of compliance**

## Framework Regulation (EC) No 1935/2004

General requirements for all FCM + Mandate for specific measures



### SPECIFIC MEASURES

#### EU harmonised

- GMP
- Plastics
- Ceramics
- Regenerated cellulose film
- Individual substances

#### National

- All others



# SPECIFIC MEASURES

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

### **Article 3 of Reg. 1935/2004 - GMP ensuring safety and inertness**

- **Minimum requirements all FCM**
  - 1) Quality assurance system
    - ✓ Processes design and operation
    - ✓ Premises and equipment
    - ✓ Qualification of staff
  - 2) Quality control system
  - 3) Documentation
- **Annex with specific requirements for certain FCM**
  - ✓ Printing inks

**Applies from 1 August 2008**

# PLASTICS

## **Directive 2002/72/EC and amendments**

General rules and lists of authorised substances with migration limits

## **Directive 78/142/EEC, 80/766/EEC and amendments**

Vinyl chloride monomer

## **Directive 82/711/EEC and amendments**

Basic rules for migration testing

## **Directive 85/572/EEC and amendments**

List of simulants

# PLASTICS: Directive 2002/72/EC

## Field of application

- plastic mono-layers or
- plastic multi-layers made only of plastic

Plastics shall be manufactured with substances in:

- Directive 2002/72/EC
- National legislation (additional lists for additives)\*

\* *until EU list of additives becomes a positive list*

## PLASTICS: Directive 2002/72/EC

2 types of migration limits have been established:

- **Overall Migration Limit (OML)**  
60 mg (of substances)/kg (of foods or food simulants) or  
10 mg/dm<sup>2</sup> of surface area of material or article  
Inertness of plastic - applies to all substances
- **Specific Migration Limit (SML)**  
applies to individual authorised substances

# PLASTICS: Directive 2002/72/EC

## Specific Migration Limit (SML)

- Fixed on the basis of the toxicological evaluation
- The SML is generally established according to the tox data available or TDI set by the EFSA (SCF)
- To set the limit, it is assumed that,  
Person of 60 kg consumes everyday during lifetime:
  - 1 kg of foodstuffs
  - always in contact with plastic
  - always containing that substance
  - at maximum permitted quantity

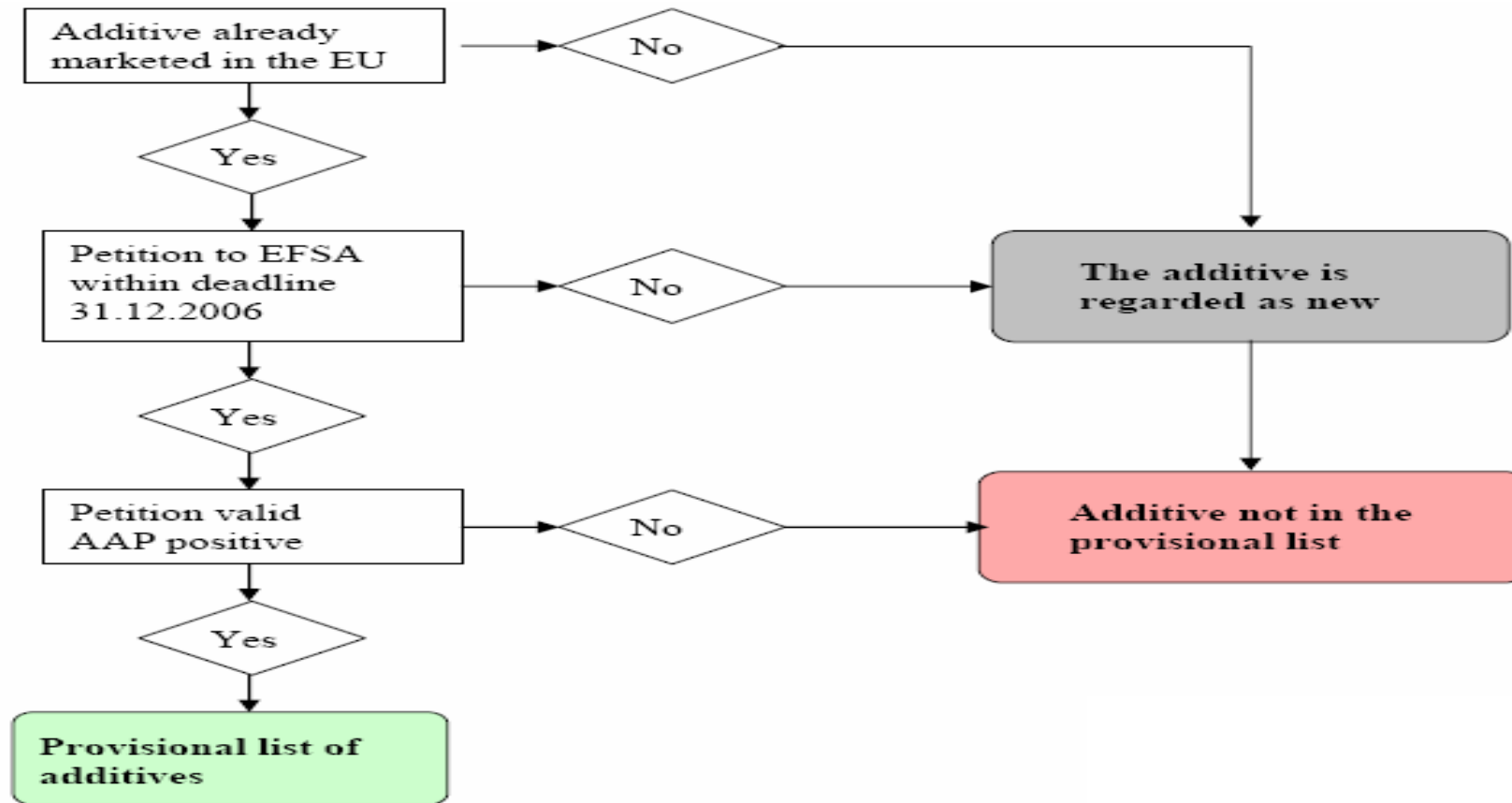


## PLASTICS: Directive 2004/19/EC

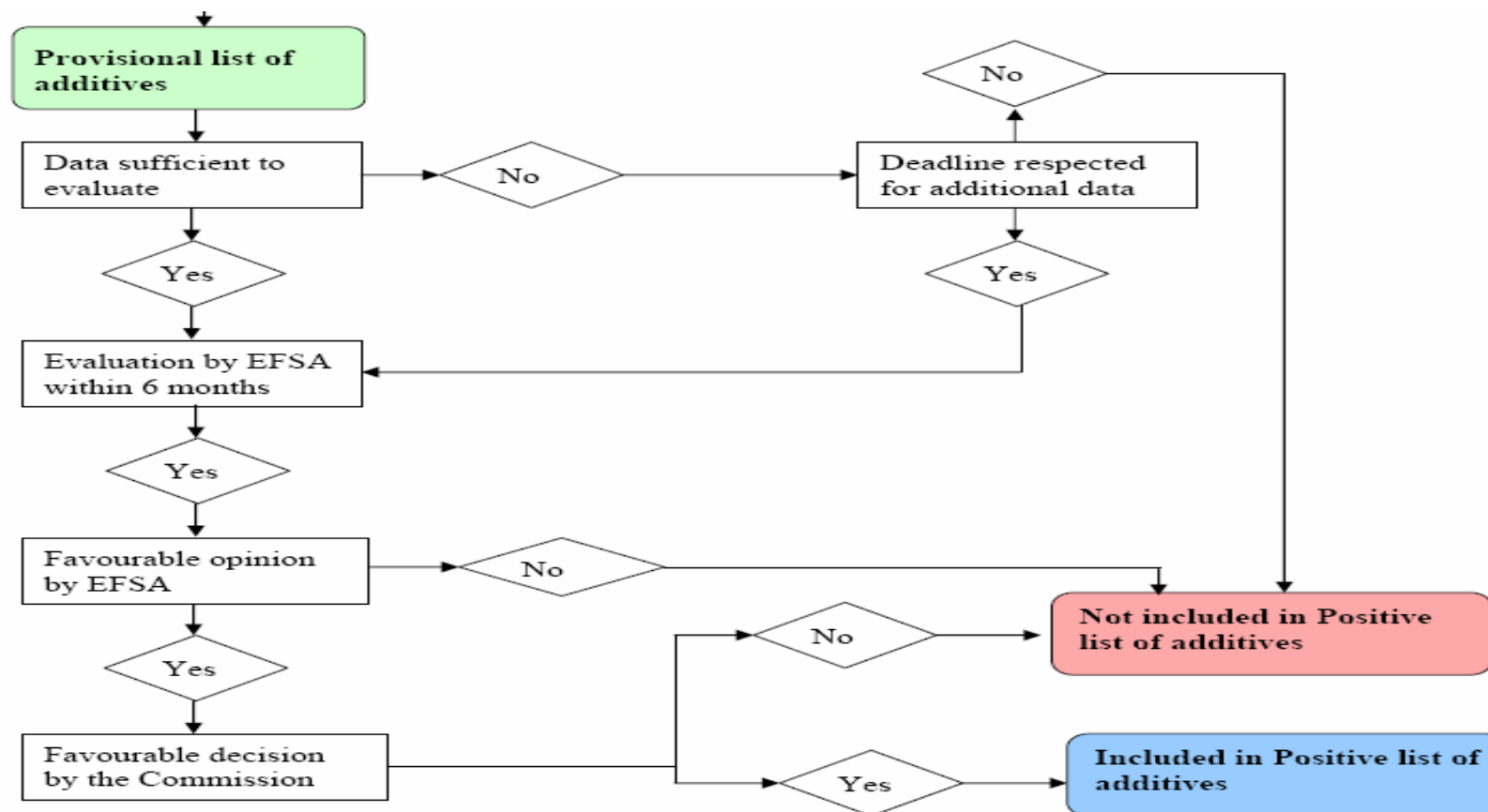
### List of authorised additives

- Until 2007: additives were authorised at Community and national level
- From 2007: additives authorised at Community level only (some exceptions)
- Website:  
[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/emerging\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/emerging_en.htm)

# Additives: establishment of provisional list



# Additives: establishment of positive list



## Directive 2007/19/EC (4th amendment)

- ✓ Plastic layers and plastic coatings forming gaskets in lids
- ✓ PPA's exemption
- ✓ Update list of authorised substances, inc. phthalates
- ✓ **F**at (consumption) **R**eduction **F**actor, FRF
- ✓ Functional barrier
- ✓ Change of simulant for milk/milk products
- ✓ Detailed Declaration of Compliance

## Regulation (EC) 372/2007

### Transitional migration limits for plasticisers in gaskets in lids

Sets migration limits for **plasticisers in lids**, until the 4th amendment of the plastics directive comes into force in the MS.

- Scope of 4th amendment of Plastics directive includes gaskets in lids
- Industry interested in plasticizers other than ESBO
- Transitional SML set at a level ensuring TDI will not be exceeded
- Lids posing a significant risk are excluded from the market
- Given time to Industry to develop compliant gaskets

# CERAMICS

Council Directive 84/500/EEC as amended by  
Commission Directive 2005/31/EC

- Restrictions for migration of lead and cadmium
- Method of analysis - determination of Pb and Cd
- Declaration of compliance

# Regenerated cellulose film

Commission Directive 93/10/EEC and 2004/14/EC

- Positive list of authorised substances
- Conditions under which the substances can be used
- Declaration of compliance
- Plastic coated regenerated celluloses film: compliance with the restrictions to substances set in the Plastic Directive

Codification approved in Standing Committee on  
20/04/2007



# ON-GOING MEASURES



## ***Recycled Plastics***

This proposal for a Regulation deals with *authorisations* of recycling processes intended for manufacturing of plastic recyclates used in recycled plastic food contact materials and articles.



# ***Active and Intelligent Packaging***

## ➤ **Definitions**

## ➤ **General Requirements**

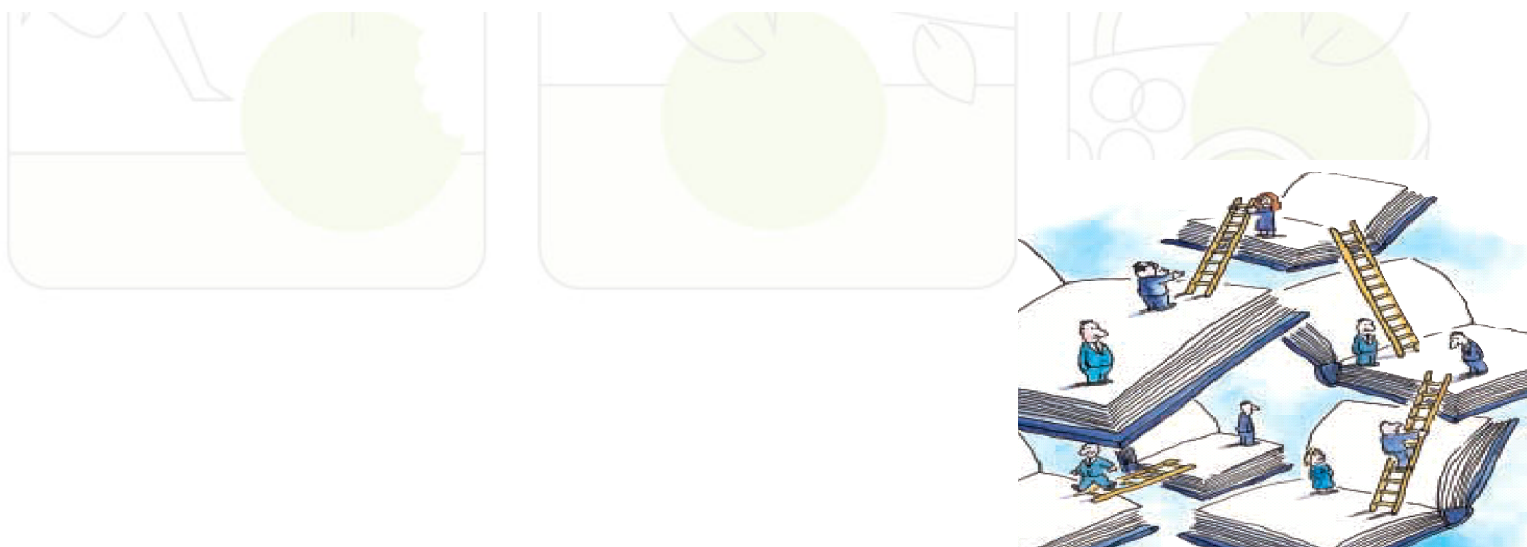
- Safe
- Released substance in compliance with food legislation
- Must not mislead the consumer

## ➤ **Labeling**

## ➤ ***Specific rules in specific measure***

## ***Plastic Implementing Measure***

- Codify 10 Directives into 1 Regulation
- Improve clarity and consistency





## Visit our website

**Food Safety - From the Farm to the Fork**

EUROPA > European Commission > DG Health and Consumer Protection > Overview > Food and Feed Safety Site Map | Who

**General Food Law** **Animal Nutrition** **Labelling & Nutrition** **Biotechnology** **Novel Food** **Chemical Safety** **Biological Safety** **Controls**

**Food Contact Materials - Introduction**

Food contact materials are all materials and articles intended to come into contact with food, not only packaging materials but also cutlery, dishes, processing machines, containers etc. This includes also materials and articles which are in contact with water intended for human consumption, such as fixed public or private water supply equipment.

- Additives
- Flavouring
- Contaminants
- Residues
- Pesticide Residues
- Food Contact Materials**
- Hormones in meat
- Fraudulent Practices

**Topics**

- Introduction
- Legislation
- Legislative List
- Scientific Advice
- Emerging Issues
- Documents

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index\\_en.htm](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm)

**CRL: <http://crl-fcm.jrc.it>**