

European legislation on food contact materials



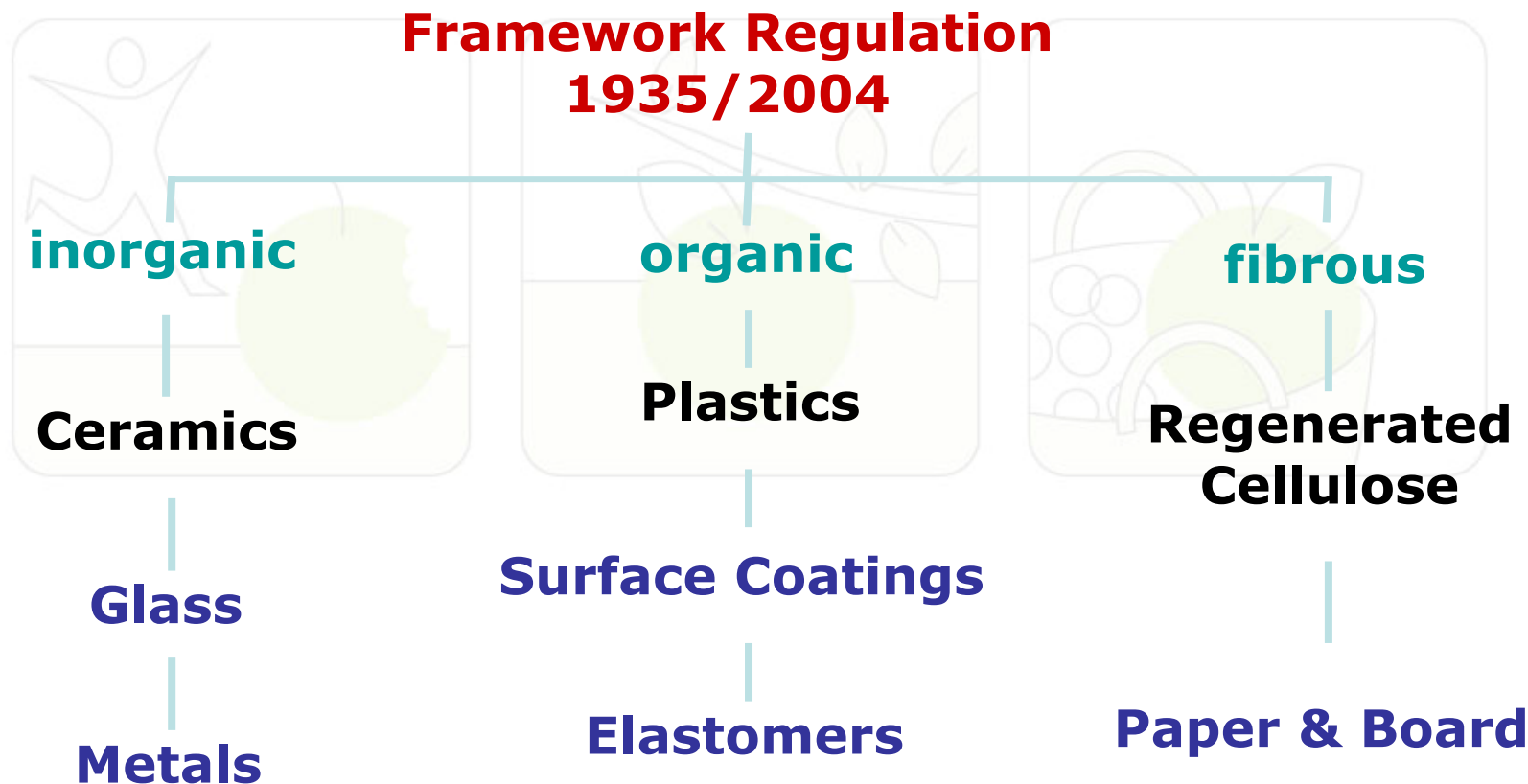
Annette Schäfer



SUMMARY

- **The harmonisation process in EU**
- **Framework Regulation (EC) No 1935/2004**
- **Plastics 2002/72/EC and migration testing**
- **Ceramic 84/500/EEC**
- **Regenerated Cellulose 93/10/EEC**
- **Other materials/substances**

Harmonisation plan



Framework Regulation (EC) No 1935/2004

To what materials and articles does it apply?

All materials which can reasonably expected to come into contact with foodstuffs i.e.

- ↘ **Food packaging**
- ↘ **Kitchen articles**
- ↘ **Machines and other articles for food manufacture**

Framework Regulation

General requirements



↪ **Safety**

↪ **no change in characteristics of food**

↪ **Taste**

↪ **odour**

↪ **composition**

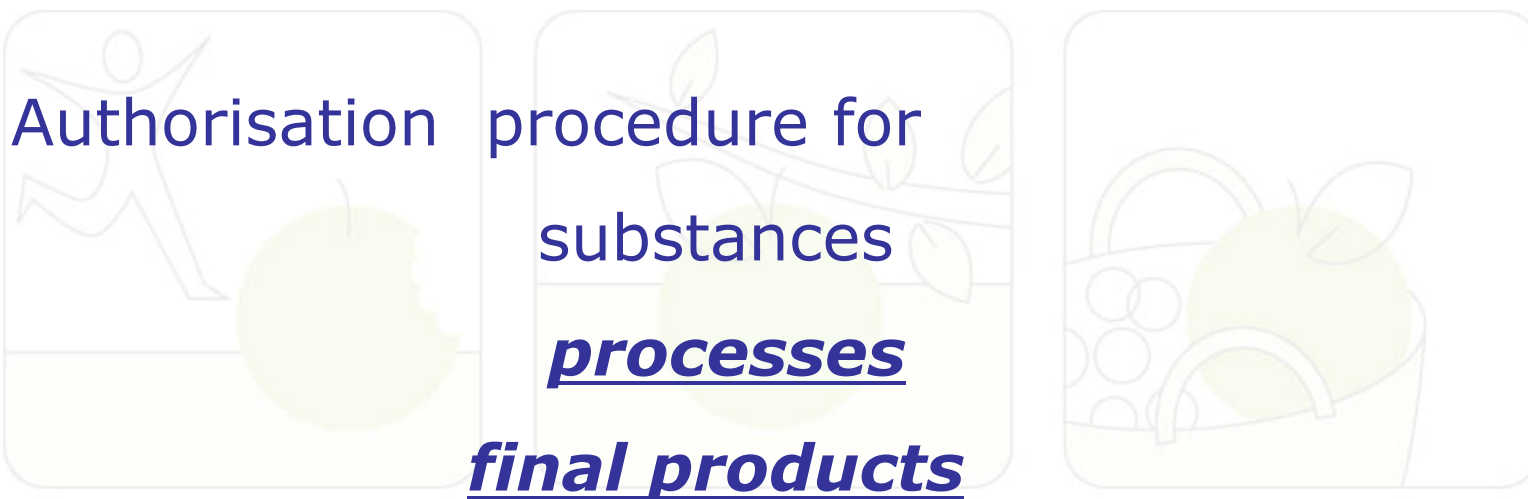
Framework Regulation

Implementing Provisions

↪ **Specific measures**

↪ **Regulation**
↪ **Decision**
↪ **Directive**

Framework Regulation



in a positive list

Authorisation procedure



Framework Regulation

Labelling and Declaration of Compliance

- **Positive labelling for all empty food contact materials not clearly intended to come into contact with foodstuffs + symbol**
- **Declaration of compliance shall be supported by appropriate documentation to be available to competent authorities on demand (“record keeping”)**

Framework Regulation

Traceability

- at all stages of manufacture, processing and distribution
- responsibility one step 'above' and 'below' in supply chain
- make information available to competent authorities
- traceable through labelling or documentation

- **Obligation for Traceability but choice of means**
- **Applies from 26. October 2006**
- **For imported products up to the importer**

Framework Regulation

➤ **Confidentiality**

- Applicant indicates confidential information
- Give verifiable justification for harming competitive position
- Commission determines confidentiality; informs applicant

➤ **Not confidential:**

- (a) name of applicant & substance;
- (b) info on the safety assessment;
- (c) analytical methods

Confidential info may be made public if there is evidence of a problem for human health

Framework Regulation

➤ Active packaging

- extend the shelf-life or
- maintain or improve the condition of packaged food
- deliberately incorporate components that
- release or absorb substances into food

➤ Intelligent packaging:

They monitor the condition of

- packaged food or
- the environment surrounding the food

Framework Regulation

Active and intelligent packaging

➤ General Requirements

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

Framework Regulation

Active and intelligent packaging

➤ Labeling

- Identification of non edible parts
- Identification of the material or article as “active” or “intelligent”
- Identification of the released active components
- Information on the permitted uses of active systems to allow compliance with food legislation

➤ Specific rules in specific measure

Plastic Food contact materials

Which rules apply in Europe?

- For plastics fully harmonised (monomers)
EU rules apply
- For plastics not fully harmonised (additives)
EU rules apply and
national laws apply for the part not harmonised (e.g.
colorants, solvents, adhesives)
- Application of “mutual recognition principle”

Plastic Food contact materials

Directive 2002/72/EC and amendments

- General rules and lists of authorized substances with migration limits

Directive 82/711/EEC and amendments

- Basic rules for migration testing

Directive 85/572/EEC and amendments

- List of simulants

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

- Vinyl chloride

Directive 2002/72/EC

Field of application

- homogenous plastics or
- plastic mono-layers or
- plastic multi-layers made only of plastic (flexible packaging)

Often Member States apply the EU rules to

- plastic layers in a multi-material structure

Directive 2002/72/EC

Safety requirements

Restrictions for individual substances expressed as:

SML = specific migration limit of the substance

QMA = maximal quantity of the substance in material per surface area

based on toxicological evaluation by
European Food Safety Authority

Directive 2002/72/EC

Restrictions based on following assumption

- Person of 60 kg consumes
- everyday
- during lifetime
- 1 kg of foodstuffs
- always in contact with plastic
- always containing substance
- at maximum permitted quantity

System is conventional and considered very restrictive

Directive 2004/19/EC

List of authorised additives

- Before 31 December 2006 all the petitions related to the other substances included in the national lists should be supplied and accepted by EFSA
- A further Directive set out before 31 December 2007 will establish the date where **the list of additives will become a positive list**
- Not yet listed: catalysts, colorants, solvents and adhesives

Compliance for additives not covered by EU legislation

- National legislations
e.g. BE/DE/FR/IT/NL/SP List of authorised substances
- or, in their absence,
The general “safety requirement”: Application of international procedure for risk assessment i.e. comparing the estimated exposure data obtained by experimental data or scientific evidence against toxicological data

Compliance for impurities, degradation products, reaction products

Safety requirement of Framework Regulation

Application of international procedure for risk assessment i.e. comparing the estimated exposure data obtained by experimental data or scientific evidence against toxicological data

Directive 2002/72/EC

Inertness of the plastic

Overall migration limit applicable to all plastics :

→ **60 mg of substance/kg of food or**

→ **10 mg of substance/dm² of surface area**

Compliance with migration limits

Rules for migration testing (time, T and simulants):

Directives 82/711 and 85/572

General rules on Official control

Regulation (EC) No 882/2004 (OJ L 191 of 28 May 2004)

Guidance: Practical Guide (SANCO)
Note for Guidance (EFSA)
JRC
CEN

Compliance with migration limits

General Food Simulants

- **Distilled water**
- **3% (w/v) acetic in aqueous solution**
- **10% (v/v) ethanol in aqueous solution**
- **rectified olive oil**
 - **HB 307**
 - **Sunflower oil**
 - **Other fatty food simulants**

Specific Food Simulants

FOOD	FOOD SIMULANT			
	Water	Acetic acid 3%	Ethanol	Olive oil
Non alcoholic beverages	X	X	-	-
Chocolate, choc.-coated products, etc.	-	-	-	X/5
Fish : fresh, chilled, salted, smoked	X	-	-	X/3

Migration testing conditions

CONDITIONS OF CONTACT IN ACTUAL USE

TEST CONDITIONS

Contact Time

$t \leq 0.5 \text{ hours}$
 $0.5 \text{ h} < t \leq 1 \text{ hour}$
.....
 $t > 24 \text{ hours}$

Test Time

0.5 hours
1 hour
.....
10 days

Contact Temperature

$T \leq 5^\circ \text{ C}$
 $5^\circ \text{ C} < T \leq 20^\circ \text{ C}$
 $20^\circ \text{ C} < T \leq 40^\circ \text{ C}$
.....
 $121^\circ \text{ C} < T \leq 130^\circ \text{ C}$

Test Temperature

5° C
 20° C
 40° C
.....
 130° C

Compliance with migration limits

Migration testing can be avoided when

- **100% assumed migration is $<$ SML**
- **Results obtained with more severe testing conditions show compliance with OML or SML**
- **Generally Recognized Mathematical Modeling is applied**

Ceramics

Directive 84/500/EEC + amendment 2005/31/EC

- 
- **Migration limits for lead and cadmium**
 - **Migration testing in 4 % acetic acid**
 - **Declaration of compliance and supporting documentation (including test results)**

Regenerated Cellulose Film (RCF)

Directive 93/10/EEC + amendment 2004/14/EC

- **Applicable to all cellophane except synthetic casings**
- **List of authorised substances and content in the final article**
- **Declaration of compliance**
- **RCF with a plastic coating: plastic coating compliant with Directive 2002/72/EC, whole article respect SML and OML**

BADGE/BFDGE/NOGE in coatings

Regulation (EC) No 1895/2005

- **Applicable to plastics, surface coatings, adhesives**
- **BADGE authorised migration limit 9mg/kg**
BADGE-HCl adducts migration limit 1mg/kg
- **BFDGE and NOGE prohibited**
- **Declaration of compliance and supporting documentation**

Nitrosamines in rubber teats and soothers

Directive 93/11/EEC

- **Applicable to elastomer or rubber teats and soothers**
- **N-nitrosamines release not detectable above 0.01 mg/kg article**
- **N-nitrosatable substances release not detectable above 0.1 mg/kg article**
- **Analytical method**

WEBSITES ON FOOD CONTACT MATERIALS

JRC website

<http://cpf.jrc.it/webpack/>

EFSA website

<http://www.efsa.eu.int>

SANCO website

http://europa.eu.int/comm/food/food/chemical_safety/foodcontact/index_en.html

Guidance documents on website

Practical Guide (SANCO website)

- Practical guide for users of European directives (last updated 04/2003)

Note for Guidance (EFSA website)

- Guidance document on preparation of petitions for authorisation of substances

Questions and answers (SANCO website)

- On food contact materials legislation (last updated 11/2004)