EU Regulations on Food Contact Materials

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Europe – 27 Member States
One Market

that trades internationally.....
Regulatory Process in Europe

Council Member States

European Commission

European Parliament

Co-decision

Comitology

EFSA
European Legal Acts overview

- **Directive**: needs to be transposed by MS
- **Regulation**: immediately applicable
- **Decision**: addressed to (a) specific recipient(s)

All can be Co-decision or Comitology acts

General requirements for all FCM + Mandate for specific measures


Also

SPECIFIC MEASURES

Materials

- Ceramics
- Regenerated cellulose film
- Plastics
- Recycled plastics
- Active and intelligent Materials

Substances

- Vinyl chloride monomer
- Nitrosamines
- BADGE, BFDGE & NOGE

of 27 October 2004
on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
FRAMEWORK REGULATION (1935/2004)

General requirements and definitions

- Empowers the Commission to adopt specific measures for groups of materials
- Sets out the role of EFSA
- Establishes an authorisation procedure
- Sets out labelling requirements
- Requires traceability systems
- Declaration of compliance needed when specific measures taken
- Procedure for safeguard measures
- Inspections and control measures
FRAMEWORK REGULATION (1935/2004)

What does it apply to?

*Materials and articles:*

- Already in contact with food
- Intended to be brought in contact with food
- Expected to come into contact with food or transfer their components to foods (normal and foreseeable use)

Doesn’t only mean packaging.....also utensils, pipes in food machinery, conveyer belts etc....
What it doesn’t apply to?

- Antiques
- Covering or coatings of food consumed with the food (e.g. cheese rinds)
- Fixed water supplies
FRAMEWORK REGULATION (1935/2004)

General requirements

Food Safety

- No unacceptable change in food composition or organoleptic characteristics

- Must not mislead the Consumer (labelling, advertisement)
FRAMEWORK REGULATION (1935/2004)

EU-wide specific measures

- (potentially) for materials and articles listed in Annex I
- combinations of those materials and articles
- recycled materials and articles

Specific measures can take the form of a Regulation, Directive or Decision
FRAMEWORK REGULATION (1935/2004)

National specific measures

- In the absence of specific measures Member States may adopt National provisions
- These measures have to be notified to the Commission before their adoption
FRAMEWORK REGULATION (1935/2004)

**Authorisation procedure**

- Application submitted to Member States
- Assessed by EFSA within specific timescale
- If acceptable, authorisation via comitology
- Authorisations are generic
- Authorisations can be modified or suspended
- Business operators using a substance have to inform the Commission on new scientific data/information
Labelling

What?
- words ‘for food contact’ or specific indication or symbol
- special instructions
- name & address of manufacturer, processor or seller

How?
- language easily understood by purchasers
TRACEABILITY

Where? At all stages of production and distribution

Who? Business operators

What? From who and to who materials or articles are supplied (where appropriate also applies to substances or products)

To? Available to competent authorities on demand

How? Appropriate system to allow their traceability
FRAMEWORK REGULATION (1935/2004)

Declaration of compliance

When a specific measure is adopted

- Materials and articles must be accompanied by a written declaration stating that they comply with the rules applicable to them.
- Appropriate documentation shall be available to demonstrate such compliance.
- The documentation shall be made available to the competent authorities on demand.
- In the absence of specific measures, MS can adopt national provisions to require declarations of compliance.
FRAMEWORK REGULATION (1935/2004)

Declaration of compliance

Detailed DoC requirements exist for:

- Plastics
- Recycled plastics
- Ceramics
- Active and Intelligent materials
**FRAMEWORK REGULATION (1935/2004)**

*Safeguard measures*

- Information that the use of a material or article in compliance with specific EU legislation endangers human health.
- MS can temporarily suspend or restrict that material or article within its territory.
- Commission has to take a decision to either adapt specific EU legislation or to ask MS to withdraw the suspension/restriction.

*e.g. BPA measures in Denmark and France*
FRAMEWORK REGULATION (1935/2004)

*Inspection and control measures*

- MS have the responsibility to enforce and control EU and national legislation (Regulation 882/2004 applies to FCM)

- Commission ensures implementation of legislation by Member States

- Establishment of EURL (DPAL are NRL)

- Information through Rapid Alert System on Feed and Food RASFF

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GMP Regulation (EC) 2023/2006

Quality assurance system

• Selection of starting materials (chemicals) to ensure the compliance of the final article with Article 3 of 1935/2004 (i.e. not endanger health, not mislead etc)

• Operations design to ensure the compliance of the final articles as regards contamination, reaction and degradation products

Quality control system

• Establish testing frequency of the final product to ensure compliance
GMP Regulation (EC) 2023/2006

Documentation covering manufacturing process

- Specifications of the starting materials (toxicity, migration potential, impurities etc)
- Specifications of end product (migration limits)
- Testing results
GMP Regulation (EC) 2023/2006

These are principles, not rules

- Not the same as HACCP
- They do not concern hygiene (hygiene is responsibility of food producers)

However there are specific rules for
- printing inks (to avoid set off), both for formulation and handling
- Recycled plastics

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Plastics Directive 2002/72/EC

Specific for plastics, more detailed than other FCMs

Sets overall migration limit (OML) (60 mg/kg food)
Restricts the uses, amounts, purity & migration (SML) of substances*
  • Positive list of monomers & starting substances
  • Positive list of additives (& short ‘provisional list’)
  • Declaration of compliance (new format, May 2009)
*Excludes catalysts, colorants, by-products, inks, ...

6 amendments since 2002

4 related Directives specify how testing should be carried out: food simulants, test duration & temperature
Recast of Plastics laws

One Regulation on all plastics to combine and replace:

- Directive 2002/72/EC & its six amendments
- 4 Directives on testing plastics
- 3 Directives on vinyl chloride

However more than just a consolidation exercise....

- Changes test rules
- Merges the lists of monomers and additives

Currently with EP for scrutiny – publication early 2011

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Recycled plastics (Reg 282/2008)

- Critical control point is the **recycling process** to remove potential contaminants

- Recycling processes are authorised by Commission after evaluation by EFSA

- A condition of the authorisation is that processors must comply with the instructions specified by the process-owner

- Regulation 282/2008 specifies that MS must **audit** the recycling processors

- FVO will audit Third Country recyclers

- One application received from Ireland

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Other specific measures

**Vinyl chloride monomer** Dir 78/142/EEC

- Covers all PVC FCMs
- Content of VCM: 1 mg/kg max
- SML for VCM: 0.01 mg/kg
- Directives 80/766 & 81/432/EEC set test methods for official control
Other specific measures

**Certain epoxy derivatives**
Reg. EC 1895/2005

- Bans BFDGE, NOGE
- SMLs for BADGE & derivatives
- Covers plastics, coatings & adhesives

**Nitrosamines in teats & soothers** Dir 93/11/EC

- Limits release of N-nitrosamines
Other specific measures

**Ceramics** Directive 84/500/EEC
- Limits on Pb, Cd migration
- Declaration of compliance
- Test methods

**Regenerated Cellulose Film** Dir. 2007/42/EC
- Covers uncoated RCF, RCF coated with cellulose, or coated with plastics
- RCF composition restricted to substances in Annex II
- Plastic coatings have to comply with Dir 2002/72/EC
If that wasn’t enough......

Regulation 178/2002: “General Food Law”

- Import & Export
- Risk Analysis
- Protection of consumer interests
- Presentation
- Food safety requirements
- Transparency
- Crisis management & emergencies
- Rapid Alert
- Food Business Operator Responsibility
- Withdrawal & Notification
- Traceability
Food Business Operators (FBOs) must:

- Not place food on the market that is **unsafe**
  - Injurious to health
  - Unfit for human consumption
- Ensure that foods satisfy the **requirements** of applicable food law
- Ensure **imported** food complies with EU food law
- Ensure that **exported** food complies with EU food law unless 3rd country has own specifications
- Establish **traceability** systems
- Establish **recall** systems

Also applies to use of Food Contact Materials
Lots to take in......
Help is available.....

https://webgate.ec.europa.eu/sanco_foods/main/?event=notes.search&notes.pagination=1
Industry and other guidance

Nordic check lists
In-house documentation and traceability
Further information

Food Safety Authority of Ireland: http://www.fsai.ie


Council of Europe (Resolutions): http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/COE%27s%20policy%20statement%20food%20contact.asp#TopOfPage

Joint Research Centre (test methods): http://crl-fcm.jrc.it/

CEN (test methods): http://www.cen.eu/cenorm/homepage.htm