Negative effects of Packaging on the Food
Official Control on Food Contac Materials (FCM)

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Dairy products
Cheese, butter, margarine etc....
Dry and solid goods (cereals and cereal based products)
Water, juices, beverages, alcoholic and non-alcoholic drinks
Oils and fats
Bread and cereals based products
Meat and products thereof ... i.e. ham, sausages
Food packaging – What is the purpose?

✓ Protection from the ‘outside’ environment, to prevent the transfer of substances ‘in’ and ‘out’ of the packaged food.

- air (oxygen)
- loss of gas (carbonated beverages)
- moisture loss/ incorporation
- light (and UV radiation)
- foreign aroma compounds
- microbial contamination
- temperature instability
- mechanical influences

✓ Marketing
Materials for Food Contact Material products (FCM)

- Plastic
- Glass
- Metals and alloys
- Ceramics
- Paper and board
- Rubber and elastomers
- Regenerated cellulose
Plastic Packaging

Advantages

- Light-weight
- Various shapes (flexible – rigid)
- Colors
- High level of protection – hygiene
- They do not brake compare to other materials (e.g. glass)
- Versatility (various applications)
Plastic FCM

Disadvantages

- Long life (environmental non-friendly)
- Cost of production
- Migration of substances to food content

Recycling
What is a polymer?

“..organic macromolecular compounds obtained by polymerisation, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules.” Directive 2002/72/EC

Not plastics:
regenerated cellulose film, elastomers and natural and synthetic rubber, paper and paperboard, wax surface coatings, ion-exchange resins, silicones.
Variables that influence the polymerisation process are:

- Monomers
  - chemical structure
- Catalysts
  - structure of the polymer chain
- Temperature
  - length of the polymer chain
- Pressure
  - cross links
- Additives
  - crystallinity

Properties
What is a polymer-structure

The degree of crystallinity affects the materials:
- crispness (crystalline)/toughness (amorphous)
- barrier/permeability properties
- melting point/glass transition temperature
- transparency

Tm (crystalline melting temperature): The temperature where all crystals in a crystalline material are melted.

Tg (glass transition temperature): The temperature below which all movement of the molecules is stopped.

Tm > Tg
Plastics: Technology (Extrusion)

Rigid – Flexible Plastics
Materials for… concern

- **Monomers/oligomers:** Basic unit or small polymer chains (e.g. ethylene, propylene, etc.)

- **Additives used in the production of plastic FCMs:**
  - Plasticizers (15-40% in PVC, i.e. DEHA, DEHP)
  - Anti-ageing (Antioxidants < 1%)
  - Surface properties modifiers (Anti-static, lubricants 1-4%), Colorants
  - Foaming agents (e.g. carbon dioxide)
  - Improving substances (e.g. Flame retardants, fillers, biocides, mold release agents, reinforcements etc.)

- **Adhesives**

- **Printing inks**
Migration

Migration rate: \[ \frac{dm}{dt} = -D \cdot A \cdot \frac{dC}{dt} \]

- \( m \): quantity of the substance that migrates to food
- \( C \): substance concentration in the plastic packaging
- \( D \): migration coefficient
- \( A \): surface that the migration is taking place
- \( t \): time

Factor that influence migration:
1. Concentration of substance/s that migrate
2. Contact Surface
3. Contact time
4. Temperature
5. Molecular weight
6. Structure
7. Nature of the substance/s
Most common types of polymers

- Polyolefins (PE, PP)
- Substitute olefins (PS, PVC, PVdC)
- Polyesters (PET)
- Polycarbonates (PC)
- Polyamides (PA, nylon)
Polyethylene Terephthalate (PET or PETE):

High Density Polyethylene (HDPE):

Vinyl (Polyvinyl Chloride or PVC)

Low Density Polyethylene (LDPE)

Polypropylene (PP)

Polystyrene (PS)

Other
Plastic – Starting Materials

Polyethylene (PE): LDPE – HDPE

**Properties**: It has very good technical characteristics e.g. stiffness, $T_g$, good barrier properties, low permeability in $H_2O$ & $O_2$.

**Additives**: Colouring substances, carbon black, antioxidants, antistatic and lubricants etc.

**Applications**: Bags for bread, vegetables, chicken, ham or meat for fridge and freezer, containers (squeezable) for salt and sauces, bowls for food storage. Milk, water and juice containers, trash and retail bags, liquid detergent bottles, yogurt and margarine tubs, cereal box liners.
Polypropylene (PP)

**Properties:** Has higher Tg than PE and withstands higher temperatures also has lower permeability in O₂ & H₂O.

Polypropylene has excellent chemical resistance, is strong, and has the lowest density of the plastics used in packaging. It has a high melting point, making it ideal for hot fill liquids. **PP is found in everything from flexible and rigid packaging** to fibers and large molded parts for automotive and consumer products. It is a safe, toxin-free alternative for food and beverage containers.

**Products:** Containers and lids for hot food & drinks. Packaging of snacks, biscuits, crisps etc. Ketchup bottles, yogurt containers and margarine tubs, medicine bottles, straws, caps.
Polyvinylchloride (PVC)

**Properties:** It’s very hard and strong, stable physical properties, PVC has excellent chemical resistance, in oils and fats and alcohols.

**Additives:** Plasticizers phthalic compounds e.g. DEHP. It contains chlorine, so its manufacture can release highly dangerous dioxins. Number 3 has been nicknamed the "toxic plastic" due to the softeners (DEHA) that with long-term exposure may cause cancer and other health issues.

**Uses:** Packaging of alcoholic drinks e.g. beer, wine and also fatty foods. Trays for products such as chocolate bars and cookies. Films for wrapping meat, vegetables and fruits. Jars for coffee and chocolate drinks.
Polystyrene (PS)

**Properties:** Rigid or foamed, is stable in acidic and alkaline environment, but not in oil. Good barrier in gases except water vapor.

**Uses:** Cups in vending coffee machines, trays for meats, vegetables and fruits in supermarkets. Also, containers for dairy products such as yoghurt and cheese, ice-cream, syrups and honey. Packaging/trays for meat, fish and vegetables. Trays for cake and margarine tubes when is used as copolymer with acrylonitrile, butadiene.
Polyamide (PA) – Nylon

**Properties:** Low permeability in gases

**Uses:** Packaging for fats and oils, under vacuum packaging of cheese and ham, boil-in-the-bag packs.

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**Polyethylene Terephthalate (PET or PETE)**

**Properties:** PET is clear, tough and has good gas and moisture barrier properties. This plastic is commonly used in PET soft drink bottles and many other injection moulded consumer product containers. **PET bottles are intended for single use, as PET breaks down with use and cannot be properly cleaned.**

**Uses:** Plastic soft drink and water bottles, beer bottles, mouthwash bottles, peanut butter and salad dressing containers, food trays and boil-in-the-bag packs.
Polycarbonate esters
(plasticizers e.g. Bisphenol-A)

**Properties:** Rigid, tough, transparent plastic articles with high heat and electrical resistance.

**Uses:** Infant feeding bottles, plates, mugs, jugs, beakers, microwave oven ware and storage containers.
Potential hazards linked with the most common polymer materials

**Polyethylene Terephthalate (PET or PETE):** PET bottles are intended for single use, as PET breaks down easily and cannot be properly cleaned. **Concerns over the built-up of bacteria due to insufficient and infrequent cleaning.** Scratches and imperfections in the plastic may host germs.

**High Density Polyethylene (HDPE):** Low risk of migration

**Vinyl (Polyvinyl Chloride or PVC):** Due to the chlorine presence, concerns over the migration of highly dangerous toxins (DEHA), which, after long-term exposure, may cause cancer or other health issues.

**Low Density Polyethylene (LDPE):** It does not transmit any know chemical into food.

**Polypropylene (PP):** It is a safe, toxin-free material for food contact articles/products.

**Polystyrene (PS):** It could leach potential toxins into foods.

**Other:** Either is made of more than one of the above materials (or sum of them) or other materials (i.e. PLA-polylactide or PC-polycarbonate). Polycarbonate is a material of concerns because is linked with BPA (potential hormone disruptor that mimics estrogen).
Plasticizers

- **Phthalates** (DEHP, DiPN etc.) - EU legislated migration limits (PVC plasticizers to increase their flexibility, transparency, durability, and longevity. Application as lubricants, stabilizers, in glues, food containers and wrapping etc.) Highly toxic, volatile, carcinogenic, endocrine disruptors, indications responsible for children’s asthma & allergies, etc.

- **Di(2-ethylhexyl) phthalate** DEHP, SML=1.5 mg/Kg food
- **Diisononyl phthalate** DINP, SML=9 mg/Kg food
- **Butyl benzyl phthalate** BBP, SML=30 mg/Kg food
- **Diisodecyl phthalate** DIDP, SML=9 mg/Kg food

**Bis(2-ethylhexyl) adipate (DEHA)** - SML=3mg/dm² (plasticizer in PVC films - carcinogenic).

- **BPA (Bisphenol A) and its derivatives** – (SML=0.6mg/Kg food) (Indications for hormone disruptor – Some countries have banned products for children that contain BPA- Canada, Denmark, France)- EFSA opinion soon.
Additives

**Substances with dual use** (adequate information relative to the substances which are subject to a restriction in food)

- BHT SML 3 mg/kg
- Phosphoric acid (no SML value (it means 60 mg/kg)
- Boric acid, SML(T) = 6 mg/kg
- Sodium tetraborate SML(T) = 6 mg/kg
- EDTA (Ethylenediaminetetraacetic acid no SML value (it means 60 mg/kg)

**Primary Aromatic Amines (PAA) - intermediate to azo dyes:**
Carcinogenic– not detectable in nylon kitchenware
(detected limit: 001mg/Kg)
Epoxy derivatives
(Regulation 1895/2005/EC)

Applicable to: plastics, adhesives, surface coatings of cans
(Not applied to: containers > 10,000 lt)

BADGE (bisphenol-A diglycidyl ether): SML: 9mg/Kg
BADGE-HCl SML: 1mg/Kg

NOGE & BFDGE are prohibited
Adhesives/Laminates

Some of them are covered by EU legislation & national legislation

- Hot melted (melted thermoplastics that glue when are heated)
- Pressure sensitive
- Chemical reacted (viscous paste hardening by a chemical reaction)
- Polymer in a solution (evaporation of solution)

i.e. Formaldehyde with melamine resin form a **thermoset plastic** (melamine resin) used in kitchenware - (EU legislated migration limits)

- Melamine **SML=30mg/Kg**
- Formaldehyde **SML=15mg/Kg**
Laminated multi-layer materials

Plastic bags PE laminated (PET/AL/PE)

PET → Printing → Lamination → PET/Al → Lamination → PET/Al/PE → Slitting

AI

Extrusion

PE

Outer layer

PET

Ink

Adhesive

Al

Adhesive

PE

Inner layer/surface
Printing inks

- No EU Limits!
- Regulation 2023/2006/EC (GMP)
- Choice of starting materials, not: toxic, mutagenic, carcinogenic
- Photo-initiators of UV applications found in inks, adhesives, coatings (i.e. benzophenone, 4-methylbenzophenone, ITX-2-isopropyl thioxanthone).
New Trends in the Food Packaging Technology

• Active & Intelligent Food Contact Materials
  - Recycled plastics
  - Printing inks
  - Materials other than plastics
    - biodegradable materials (i.e. cellulose – Polylactic acid, etc.)
    - recycled fibers for paper & board,
    - adhesives,
    - silicones
    - metals & alloys
    - nano-materials
Official Control on Food Contact Materials
(MANCPs: Priorities – Findings)
The aim of official control on food and food contact materials is:

- Safe food and FCM produced or sold in each EU Member State
- Protection of consumers interests from health risks and fraud
Reg. 882/2004/EC
(on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules)

Requirements for **national control plans (MANCPs)** & **annual reports**

Each MS must have an integrated MANCP (multi-annual nation control plan) which should:

- Implement
- Update
- Revise
- Report to EU Commission annually

MANCPs ensure effective implementation of official controls.

Also with the reports are the basis of assessment from FVO of official control implementation by each nation.
MANCP

- Strategic objectives of MANCPs

- Role and responsibilities of competent authorities (CA) and other local authorities (LA) that undertake the official control. (CA responsible for priorities on control – LA responsible for implementing the official control (i.e. sampling, etc.)

- Description of how CA and LA meet the requirements of Reg.882/2004/EC

- Description of how the CA and LA collaborate in order to achieve effective control and protect consumers and public health
Annual Reports of MANCPs

- Progress towards implementing the national control plan.
- Results of official controls.
- Details of the type & number of non-compliances identified.
- Details of actions taken to ensure effective operation of the national control plan, including enforcement action.
- Details of amendments made to the national control plan.
Priorities of MANCPs for the official control on Food Contact Materials (FCM) based on:

- Existing EU and national legislation - Regulatory limits
- Previous results of non-compliance – previous problems
- RASFFs notifications
- Emerging Risks (i.e. 4-methylbenzophenone)
- Exposure and use of materials
- EFSA risk assessments
- FVO comments
- EC and EFSA request for info
- Singularity of each MS – special reasons (i.e. domestic industry)
- Information from other countries (EU colleagues) – consumers

**Framework Regulation**


**GMP Regulation**

- Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

**Legislation on specific materials**

- **82/711/EEC** Council Directive of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs.
Overview of Community legislation (last update 20/10/2009)

2007/42/EC Re-arranged Cellulose Film
2005/31/EC 1st amendment
84/500/EEC Ceramics

Plastic Materials

78/142/EEC Monomers
2004/1/EC Additives
2004/19/EC 1st amendment
2004/19/EC 2nd amendment
2005/79/EC 3rd amendment
2007/19/EC 4th amendment
2008/39/EC 5th amendment
(EEC) No 975/2009 6th amendment
2002/72/EC Monomers
78/142/EEC Additives
80/766/EEC VC in PVC analysis
2004/19/EC VC in food analysis
81/432/EEC Migration Testing
85/372/EC List of simulants

2007/2004 Framework

2006/EC Good Manufacturing practice
(applicable to all Food Contact Materials)

(EEC) No 282/2008 Recycled Plastics
1895/2005/EC BADGE/BFGE/NOGE
93/11/EEC Nitrosamines

Elastomers and Rubbers
Active and intelligent materials

82/711/EEC Nitrosamines

93/8/EEC 1st amendment
97/46/EC 2nd amendment

Paper and Board
Glass
Wood
Cork
Metals and alloys
Textiles
Adhesives
Ion-exchange resins
Printing inks
Silicones
Varnishes and coatings
Waxes
General requirements for all FCM – Mandate for specific measures

Field of Application (Article 1) - 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)

Not only packaging – also equipment such as kitchen utensils, machinery for food production etc.
Articles and materials should be manufactured in compliance with GMP so that under normal of foreseeable conditions of use, they do not transfer their constituents to food in quantities that could:

- endanger human health (food safety)
- bring unacceptable changes to:
  - food composition
  - organoleptic characteristics of food

Also:
Labelling, advertisement and presentation should not mislead the consumers
Framework Regulation 1935/2004/EC

- Gives the general requirements and definitions
- Empowers the Commission to adopt specific measures for groups of materials
- Defines EFSA’s role
- Authorization procedure for new substances
  - Labelling (Article 15)
- Declaration of compliance when specific measures taken (Article 16)
- Traceability (Article 17)
- Safeguard measures
- Inspections and control measures
Quality Assurance System (Not HACCP or Hygiene) (Article 5)

- Selection of starting materials (chemicals) to ensure the compliance of the final article with Article 3 of 1935/2004
- Operations design to ensure the compliance of the final articles as regards contamination, reaction and degradation products

Quality Control System (Article 6)

Establish testing frequency of the final product in view of compliance

Documentation (Article 7)

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

Printing inks

1. Application to the non-food contact side of a material or article that substances from the printed surface are not transferred to the food-contact side:
   (a) through the substrate
   or
   (b) by set-off in the stack or the reel,
   in concentrations that lead to levels of the substance in the food which are not in line with the requirements of Article 3 of Regulation (EC) No 1935/2004.

2. Same applies to **handling and storage** of finished and semi-finished products.

3. The printed surfaces shall not come into direct contact with food!
Directive 2002/72/EC and amendments

Field of application:
- plastic mono-layers or
- plastic multi-layers made only of plastic (flexible packaging)
- plastic layers forming gaskets in lids (July 2008)

There are positive lists for:
- Monomers
- Additives

**do not include** substances used in:
- coatings
- epoxy resins,
- adhesives and adhesion promoters,
- printing inks
Directive 2002/72/EC

- **Overall migration limit (plastic inertness):**
  
  60 mg of substances/kg of food
  
  or
  
  10 mg of substances/dm² of surface area

- **Restrictions for individual substances:**
  
  SML = specific migration limit of the substance
  
  or
  
  QMA = maximal quantity of the substance in material per surface area

- **Conditions/restriction of use**
Communication through RASFF & actions in case of an incident

- Official control
- Complaint
- Company’s shelf-control

Incident
Risk for Human Health

Product Recall or withdrawal

RASFF notification/alert
Notifications from EU MS official control….
Findings of official control implementation

Industry and trade problems:

• Lack or limited knowledge on legislation in some links of the production chain (importers and some food producers)

• Difficulties in the dialogue with FCM producers

• Declaration of Compliance (DoC) Reg. 1935/2004/EC (Article 16), difficult to understand – misleading information

• Lack of information on use from customers

• Difficulties in Traceability / Labelling
Strategy focus..

- Information dissemination - inspectors keep updated

- Collaboration with EU colleagues (i.e. new developments in analytical methods, experience in controls)

- Information to FCM producers up to trade and user (food production companies) regarding to legislation requirements (i.e. DoC etc.)

- More controls
Thank you very much for your attention!!!