



Preventing contamination from food packaging and other food contact materials

*Teagasc Food Packaging seminar for SMEs
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Overview

- Contamination
 - How packaging can contaminate food
- Legislation to prevent contamination
- Complying with the legislation



The jargon

FCM: food contact materials

M&A: materials and articles, term used in food legislation for all FCMs

Migration: unintended transfer of substances (e.g., residues of processing chemicals, impurities) from an FCM into foodstuff



Food contact materials include:

- Packaging materials
- Cutlery
- Dishes
- Food processing machines
- Containers
- Chopping boards
- ...



Plastics

- Polyethylene (HDPE, LDPE, LLDPE)
- Polypropylene (PP)
- Polyvinylchloride (PVC)
- Polystyrene
- Polycarbonate
- Polyethylene terephthalate (PET)
- ABS
- PVdC
- etc., etc.



Plastics additives

Anti-oxidants

Plasticisers

Lubricants

Emulsifiers

Fillers

Flame retardants

Impact modifiers

Stabilisers

UV absorbers

Preservatives

Optical brighteners

Foaming agents

Release agents

etc.



Potential impurities

- Residual monomers
- Polymerisation by-products
- Production chemicals (e.g. lubricants)



Examples of migration

- Tin migrating from **steel cans**
- Mineral oils from **jute bags**
- BADGE migration from **coatings**
- DIPN from packaging made from **recycled paper**
- Heavy metals from **ceramics**
- Aromatic amines from laminated **plastics**
- ITX from inks on **cardboard/plastic**
- Plasticised jar **gaskets**: ESBO, phthalates, SEM



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◦ **Withdrawal of Black Nylon Kitchen Utensils due to migration of Primary Aromatic Amines**
Alert Notification: 2008.07

11 September 2008

Category II: For Information

Country of Origin: China

Product: Nylon Kitchen Utensils

Batch Code: N/A



Message

Following routine sampling and testing by the HSE, the FSAI was notified of non-conforming food contact materials (Black Nylon Kitchen Utensils) on the market. These non-compliant products exhibited excess migration of Total Primary Aromatic Amines in contravention of Commission Directive 2002/72/EC and European Communities (Plastics and Other Materials) (Contact with Food) Regulations 2007; S.I. No. 587 of 2007.

Nature of danger

The products of concern (ladle, mashers, spaghetti server, turner, straining spoon, pasta scoop and slotted spoon) were found to exhibit excessive migration of substances known as Primary Aromatic Amines. Some of these substances are considered to be potentially harmful to human health, however any risk from the use of these utensils, is likely to be extremely small.

The implicated products were on sale in Tesco, Atlantic Homecare, Woodies DIY and other small independent retail outlets. These products have been removed from sale as they are not in compliance with food safety legislation.

Further checks on similar products are being conducted by the HSE.

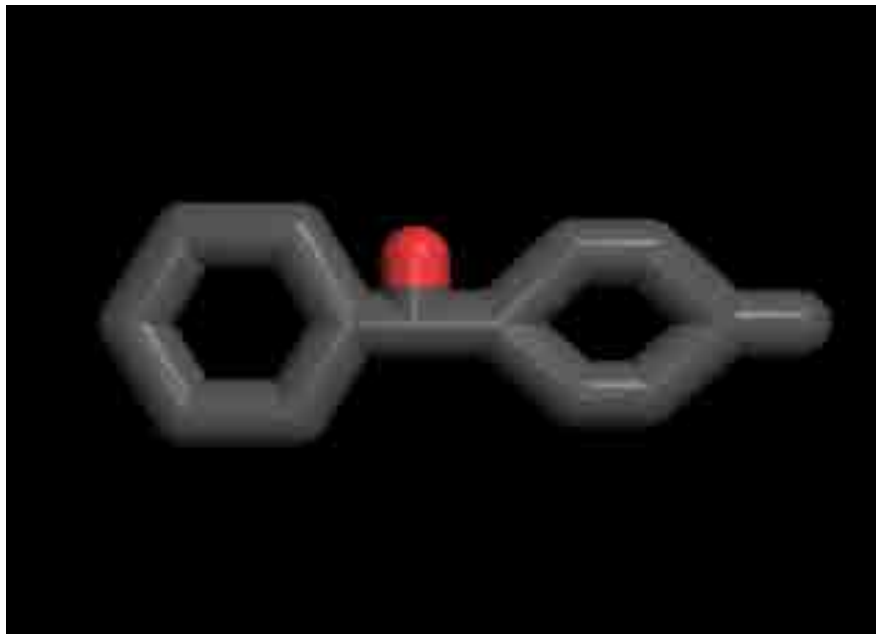
The FSAI has informed the European Commission of the issue.

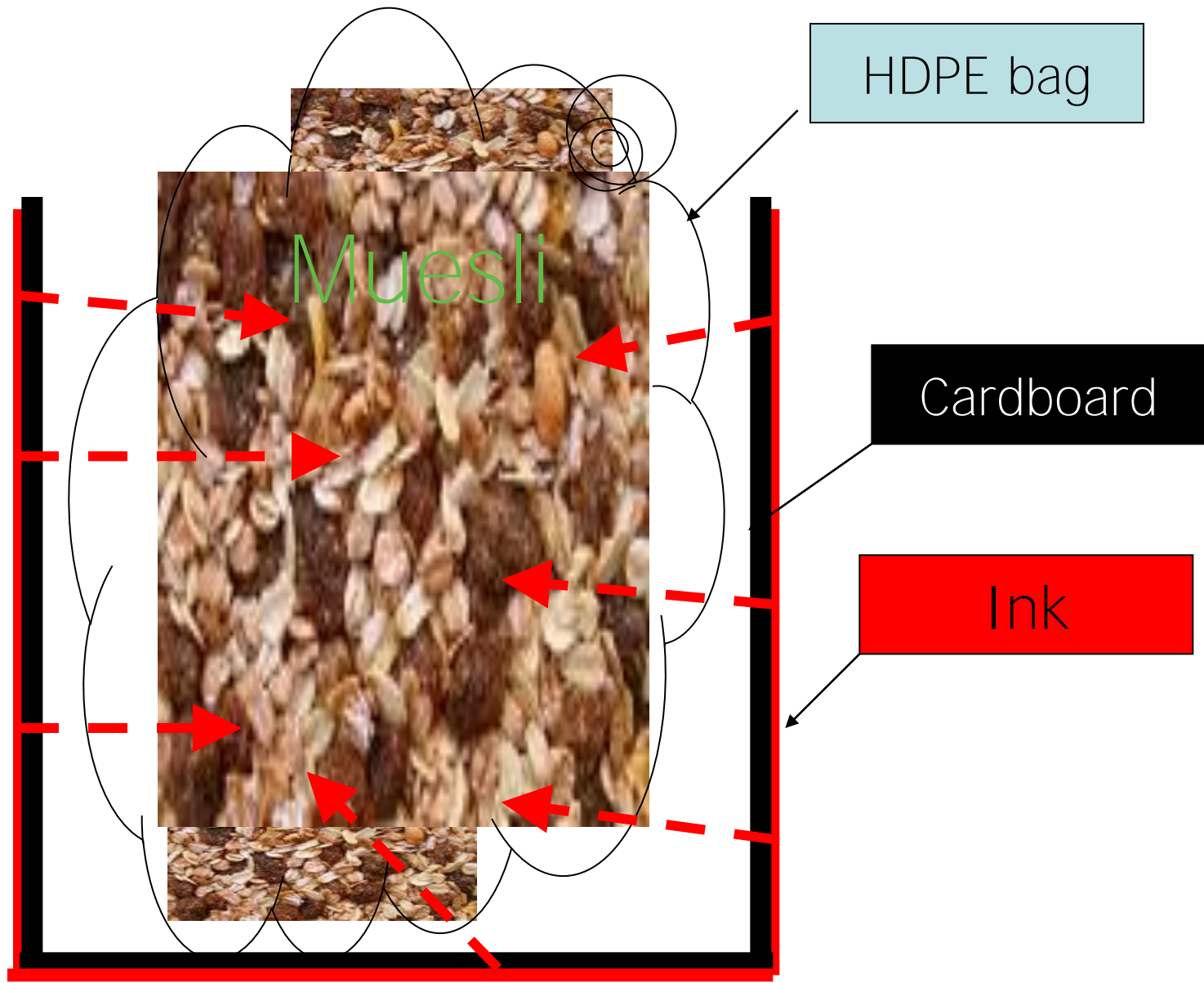
No action required; this alert is for information only

Brian Redahan

Packaging ink: 4-Methylbenzophenone

- UV photo-initiator for UV-cured printing inks
- Initially detected in breakfast cereals in Germany in February 2009 at 0.8 mg/kg
- Found in these and other foods at up to 5 mg/kg
- Source: the printing ink on the outside of the carton





More likely effects

- Long-term effects on human health arising from consumption of trace quantities of chemicals
- Effects on taste/odour of food
- Prosecution!
- Consumer concern and negative publicity



The solution:

- ❖ Legislation on safe manufacture and use of food contact materials (FCM);
- ❖ Safety evaluations of ingredients;
- ❖ Industry controls & testing;
- ❖ Official controls & testing



EU legislation on food contact materials (FCM)



EU Harmonised laws

Framework Regulation (EC) No 1935/2004

General requirements for all FCM + Mandate for specific measures

GMP Regulation (EC) No 2023/2006



SPECIFIC MEASURES



Materials

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



Substances

- Nitrosamines
- Epoxy substances



Hygiene of packaging

- **Hygiene** is not covered by food contact materials legislation
- Covered by Regulation (EC) No 852/2004
 - Annex II, Chapter X



British Retail Consortium & Institute of Packaging developed a Global Standard (issue 3 in 2008) **for 'Food packaging and other packaging materials'**

- Document focuses on hygienic production of food packaging;
- Compliance with this industry document does **not** equal compliance with FCM legislation.



Framework Regulation (EC) No 1935/2004

- General requirements for preventing food contamination, including labelling and traceability, declaration of compliance
- Allows for specific measures on individual FCM (17 groups listed in Annex I)
- Authorisation of substances or processes by EC, after evaluation by European Food Safety Authority
- Modification, suspension and revocation of authorisation
- Permits national laws to continue
- Safeguard measures



FCM Legislation covers...

- **Manufacturers** of food contact materials
- **Importers** of food contact materials
- **Retailers** of food contact materials
- **Food establishments** using food contact materials
- **Food establishments** selling packaged food



Underlying Principle

Any material or article intended to come into contact with food directly or indirectly **must be sufficiently inert so that substances are not transferred to food** in quantities large enough:

- to endanger human health or
- to bring about an unacceptable change in the composition of the food or
- a deterioration in its organoleptic properties (*taint*)

Article 3, Reg 1935/2004



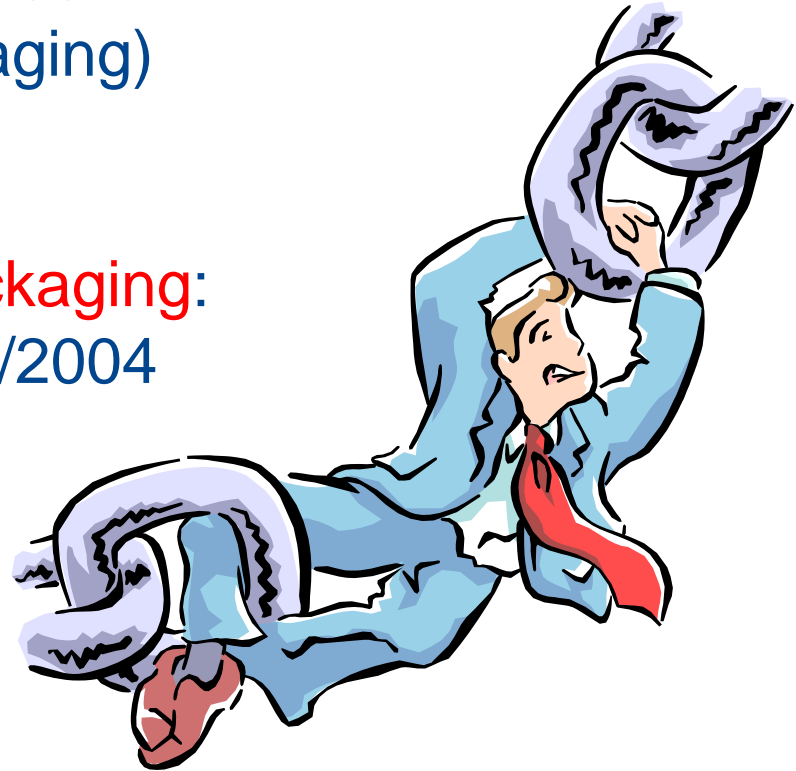
Traceability requirements

For food:

Article 18 of Regulation 178/2002
(does not include food packaging)


For food packaging:

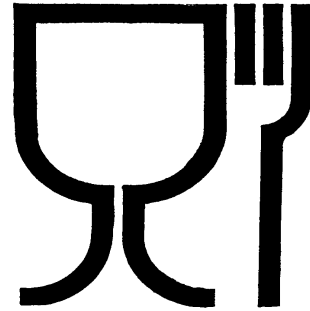
Article 17 of Regulation 1935/2004



Labelling – Article 15 of Reg. 1935/2004

Materials and articles (not already in contact with foodstuffs) must be accompanied by:

- The words “for food contact”, or
 - a specific indication as to their use (e.g. soup spoon), or
 - a notice showing the symbol. 
 - and, if necessary, any special instructions for safe use.
 - And (trade) name & address or reg. office of supplier in EU
 - And adequate labelling/identification for traceability
-
- Detailed rules laid down for implementation



Declaration of compliance

- **Written declaration required for materials & articles subject to specific legislation stating that they comply with the applicable rules**
- Legally required only for materials & articles subject to EU harmonised rules, e.g. plastics
- Appropriate documentation to demonstrate compliance must be available to the competent authorities on demand
- Specific requirements laid down for plastics, recycled plastics, ceramics, epoxy coatings, active FCMs, ...



Good Manufacturing Practice

- **Commission Regulation (EC) No 2023/2006**

- **Applies to manufacturing, processing & distributing Food Contact Material**



Specific measures



Plastics Regulation (EC) No 10/2011 (replaced Directive 2002/72/EC)

Specific laws for making plastics, more detailed than other FCMs

Requirements include restrictions on uses & migration of substances

Positive list of:

- Monomers & starting substances
- Additives

Declaration of compliance



Specific requirements for plastics

Plastics are subject to an Overall Migration Limit (OML), as a general measure of what's migrating

Substances used in the manufacture of plastics can be subject to a Specific Migration Limit (SML)

Annex specifies how testing should be carried out

Other restrictions and specifications may also apply



Declaration for plastics: Reg. 10/2011

1. Name & address of the business issuing declaration
2. Name and address of EU manufacturer or importer of food contact material, or FCM substances
3. Identity of the plastic material or substances
4. Date of declaration
5. Confirm that FCM complies with Reg 10/2011 & Reg 1935/2004
6. Information on any substances used for which there are restrictions under Reg 10/2011 to allow users to comply
7. Information on any substances used for which there are restrictions under food law, to allow users to comply
8. Specifications for safe use (foods, time/temp, S/V)
9. For plastic multi-layer materials using 'functional barrier' layers, confirmation that finished FCM complies with relevant parts of Reg 10/2011

Regulation (EC) No 282/2008 on recycled plastics



- The problem: how to prevent contamination of food from a packaging made from 'rubbish'?
- Regulation requires the individual **authorisation of recycling process** by Commission, after a toxicological evaluation by EFSA.
- Critical points in the recycling process:
 - the sourcing of the raw material;
 - the capacity of process to reduce contamination.

Register not yet in place

Other specific laws on:

Ceramics Directive 84/500/EEC

- Limits on heavy metal migration
- Declaration of compliance
- Test methods

Regenerated Cellulose Film

Dir. 2007/42/EC

- Includes RCF uncoated, coated with RCF & coated with plastics
- RCF composition restricted
- Plastic coatings to comply with law on plastics



Other specific laws on:

Certain epoxy chemicals

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



Active & intelligent materials



Active packaging

Packaging that alters the food, improves or maintains its condition

Can add extra substances to the food or absorb oxygen, moisture, etc.



Intelligent packaging

Provides useful information for the consumer of the packaged food;

E.g. freshness indicators, time-temperature indicators, atmosphere monitors, etc.



Legislation on active & intelligent FCMs

Regulation 1935/2004 has extra rules:

- Intelligent packaging must not give misleading information
- Non-edible parts (e.g. sachets) must be labelled
- Must be labelled as active/intelligent
- Extra information for active packaging that releases substances

Specific **Commission Regulation 450/2009**,
requires **authorisation** for active/intelligent components,
after evaluation by EFSA



Other food contact materials

Must comply with Framework Regulation, 1935/2004, and GMP Regulation 2036/2006

These requirements include responsibility to ensure **products are safe**

Risk assessments, compliance with other national regulations/guidelines (EU Member States or other countries, Council of Europe resolutions)

Most MS have some additional **national legislation; only 9 don't (BG, CY, EE, IE, LT, LI, LX, MT, UK)**





Legislation on Food Contact Materials

• **European Communities (Plastics and Other Materials) (Contact with Food) Regulations 2007 [S.I. No. 587 of 2007]**

- Give effect to all the EU legislation on food contact materials
- 'Signposts' the relevant requirements
- Defines offences and penalties
- Defines powers of authorised officers in official agencies
- **NO ADDITIONAL REQUIREMENTS**



Complying with the legislation



Prevention of packaging contamination

Ensure **HACCP system** includes hazards derived from packaging materials

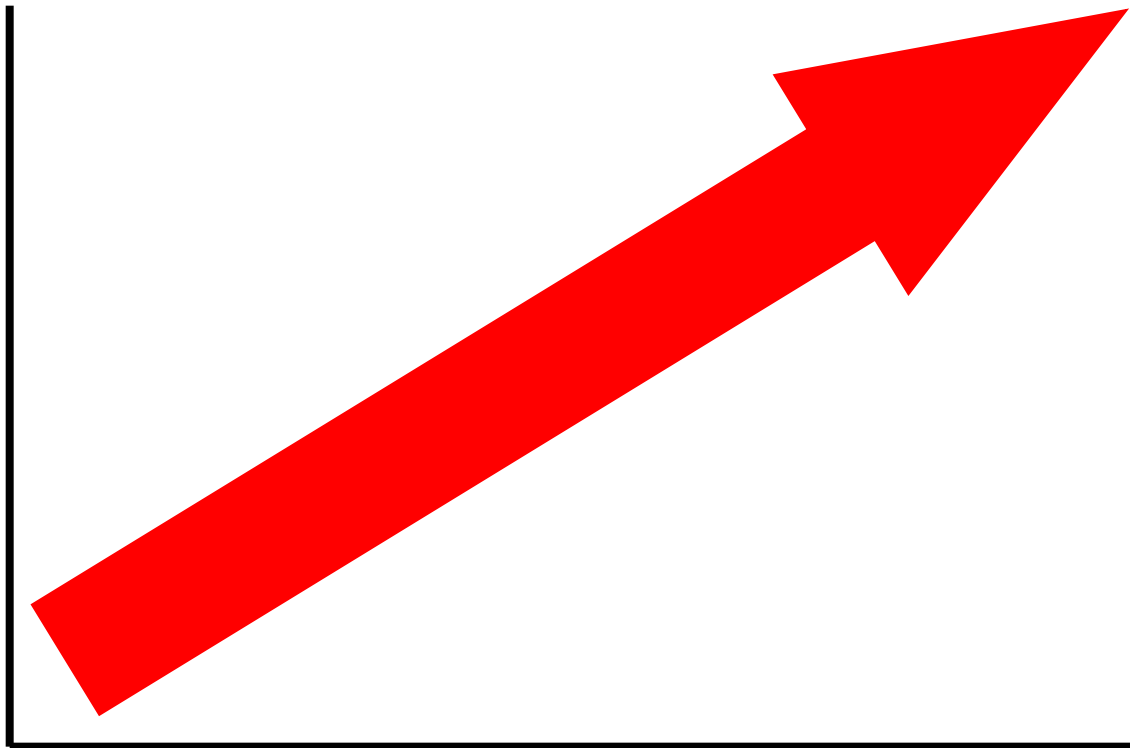
Possible control measures:

- **Documentation**, defined in the legislation
 - specification for use of the packaging material
 - ensure it is being used as specified
- **Approved supplier** audit / listing
- **Validation**
 - Spot checks on packaging materials using an accredited laboratory



Effects on migration

Increasing migration →



- Increased temperature →
- Increased contact time →
- Increased contact area →
- Increased % fat in food →



Migration tests are done, using model 'foods' for 5 food types

<u>Food type</u>	<u>Food simulant</u>
Aqueous foods:	10% ethanol/water
Acidic foods:	3% acetic acid/water
Alcoholic foods:	20% ethanol/water
Fatty foods:	Vegetable oil or 50% ethanol
Dry foods:	Tenax [®] polymer

Temperature, surface area & contact time also affect migration

So packaging may be suitable for some applications and not others:

*Does **actual** use match the **intended** use?*



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Further information

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

European Commission (all FCM legislation, information):
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/index_en.htm

European Food Safety Authority (opinions, guidelines):
<http://www.efsa.europa.eu/en/panels/fip.htm>

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

Joint Research Centre (test methods):
http://ihcp.jrc.ec.europa.eu/our_labs/eurl_food_c_m

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



Summary

- Contamination of food can arise from multiple sources, including food contact materials
- Producing safe food remains an industry responsibility
- Packaging and food industries need to co-operate to ensure safe food, compliant with regulations
- Food contact materials must be properly labelled and traceable
- Good manufacturing practice required
- Specific and individual substances rules in addition to Regulation (EC) No 1935/2004 general requirements
- Good Declarations of Compliance help you!





Food Safety

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