

สัมมนา การพัฒนาอุตสาหกรรมพลาสติกและผลิตภัณฑ์ยางไทย
จัดโดย สถาบันพลาสติก
วันที่ 4-5 กันยายน 2556 ห้อง Magic 2 โรงแรมนิรลิต แกรนด์

พลาสติกสัมผัสอาหาร

ความปลอดภัยและกฎระเบียบเพื่อการส่งออก

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มหาวิทยาลัยเกษตรศาสตร์



Packaging is a socio-scientific discipline which operates in society to ensure delivery of products to ultimate consumers in the proper conditions intended for its uses.

Packaging roles

Packaging responsibilities



Packaging roles

- Containment
- Protection & Preservation
- Utility & Convenience
- Information & Communication

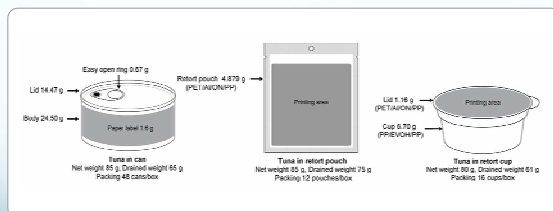


Packaging responsibilities

- Environment



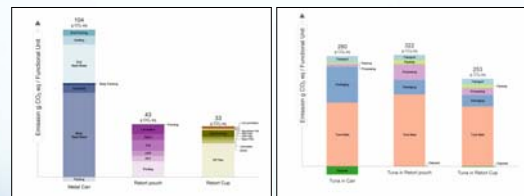
Carbon footprint of food packaging Case study: Canned tuna



Poovarodom, N., C. Ponnak and N. Manatphrom, 2012. Comparative carbon footprint of packaging systems for tuna products. **Packag Technol Sci.** 25(5):249-257



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Packaging responsibilities

- Safety
 - Packaging is a critical component to ensure safety of food products on delivery



Packaging responsibilities



Paracelsus (1493-1541)

All substances are poisons; there is none that is not a poison; the dose differentiates a poison and a remedy .

US-FDA

Safe does not mean that every substance is determined to be absolutely harmless. There is a "reasonable certainty in minds of competent scientists that a substance is not harmful under the intended conditions of use."



How dose packaging make food unsafe?



- Hazardous substances used in packaging production
 - Monomer and starting substance
 - Small molecule (<1000 dalton)
 - Additives
 - Printing ink
 - Nanoform substances

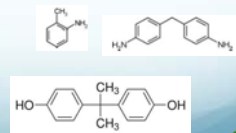


How dose packaging make food unsafe?



- Hazardous substances from decomposition or reactions

- Primary aromatic amine
- Formaldehyde
- VCM
- Bisphenol A (BPA)



How dose packaging make food unsafe?

- Interaction between food constituents and packaging materials in contact



Inexistence of completely inert food packaging materials

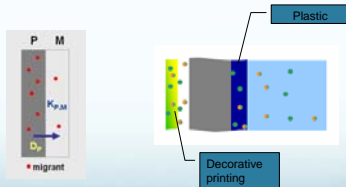


Migration



What is migration?

- The mass transfer from an external source into food by diffusion process

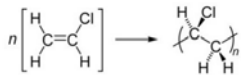


Reported incidents from April 2000 to December 2008

Category	Apr 2000	2001	2002	2003	2004	2005	2006	2007	2008	Tot.
Allergens	3	3	11	11	16	42	61	86	84	317
FCM's	4	3	2	2	4	12	15	26	35	103
On-farm	62	38	61	93	86	98	99	160	139	836
Pesticides	4	10	7	12	8	15	20	35	16	127
Labelling	3	8	4	9	19	19	93	82	126	363
Vet. meds	2	4	29	76	42	50	78	45	47	373

Source: Food Standard Agency, UK

Some incidents of migration



- 3 workers of PVC factory died from liver cancer because occupational exposure to VCM
- Restriction of VCM in working area
- Restriction of VCM in PVC and food in contact

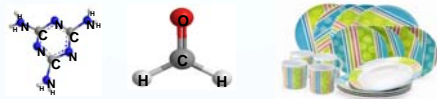
Some incidents of migration



Bisphenol A (BPA)

- Polycarbonate (PC) baby bottles, epoxy resin
- Infant development, endocrine disruptor, immune response, tumour promotion
- Ban on BPA (baby bottles): Canada (2008), Denmark (2010), France (2011), EU (2011)
- Consumer awareness strongly affects the market in USA even no banning

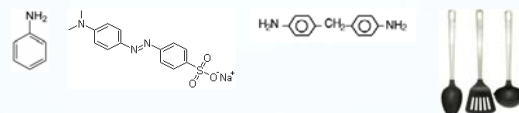
Some incidents of migration



Melamine formaldehyde

- table ware, can coating, ink, adhesive
- melamine and formaldehyde residues in food
- removed from UK market by authorities
- Regulation (EU) 284/2011 (polyamide and melamine plastic kitchenware)

Some incidents of migration



Primary aromatic amines (PAA)

- Azo dyes; yellow, red and orange colors
- polyamide kitchen utensil
- carcinogenic and mutagen
- Regulation (EU) 284/2011 (polyamide and melamine plastic kitchenware)

Safe ≠ Absolutely harmless



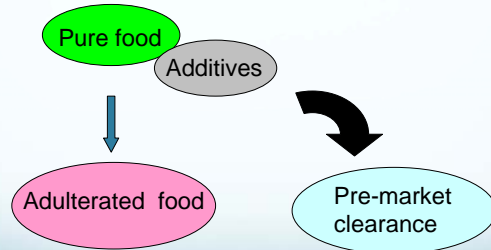
The dose makes poison

How much?

What migrates?



How food packaging is regulated in USA?



How food packaging is regulated in USA?

1997 Food and drug Administration Modernization Act (FDAMA)

Indirect food additive



Food Contact Substance

How food packaging is regulated in USA?

• Food Contact Substance

Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food

Authorized "Safe" FCS

- 21 CFR 174-179
- Food additive exemption
 - Prior sanction
 - GRAS
 - No objection
 - TOR
- Authorized FCN

Authorized FCS

Food Contact Notification (FCN)

- New FCS: new use
- Regulated or notified FCS: new use
- Notified FCS and use: new manufacturing process and impurities
- Notified FCS and use: different manufacturer or supplier

Authorized FCS

Food Contact Notification (FCN)

- The notification is **proprietary** to manufacturer that submits the FCN
 - Anyone that can demonstrate that the FCS being marketed has been manufactured or supplied by the manufacturer identified in the FCN and is being used under the conditions that are the subject of the FCN.

FDA authorizes the use of **FCS only**, not packaging materials or articles.



Code of Federal Regulations

- 21 CFR 174 Indirect food additives: General
- 21 CFR 175 Adhesives and components of coatings
- 21 CFR 176 Paper and paperboard components
- 21 CFR 177 Polymers
- 21 CFR 178 Adjuvants, production aids, and sanitizers
- 21 CFR 179 Irradiation in the production, processing and handling of food



Food additive exemptions

• Prior sanction substances

- Extract limit 1-2 ppm in water, acetic acid, or n-heptane
- No objection letter
- *De facto* regulatory exemption
- before September 6th, 1958
- FDA still has authority to regulate "Prior sanction"
 - 21 CFR 181 Prior sanctioned food ingredients



Food additive exemptions

• GRAS (Generally Recognized As Safe)

- Self-determination without approval from FDA
- Manufacturer takes responsibility on the safety
- Or, GRAS affirmation petition
- 21 CFR 186 (indirect food ingredient)
- 21 CFR 182, 184 (direct additives as FCS)



Food additive exemptions

• No migration

- Nonstatutory exemption
- "Not reasonably expected to become a component of food"
- If no migration, substance is not a food additive
- No petition or pre-market clearance required

No migration limit <50 ppb



Food additive exemptions

• Threshold of Regulation

- Dietary concentration <0.5 ppb
- Non carcinogen
- 21 CFR 174.6

• Functional barrier

- Separate food from unauthorized substances
- Prevents migration of substances from non contact surface into food

Coating / laminate



Food additive exemptions

Housewares

- Articles sold empty
- Articles intended use for consumer or food service
- Short time of contact
- Or repeated used with large volumes of food

Attention!! Nonstatutory exemption
Never formally written into law or regulations

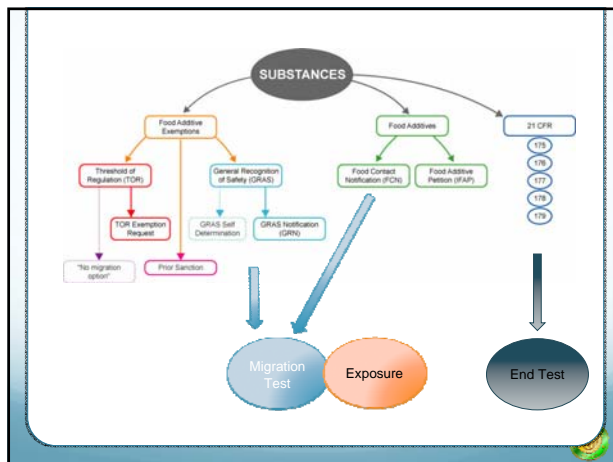
Food additive exemptions

Basic polymer/resin doctrine

- Polymer coming out of the polymerization process
- No adjuvant-type ingredient
- Polymer regulated as "generic basis" not "proprietary basis"

Mixture doctrine

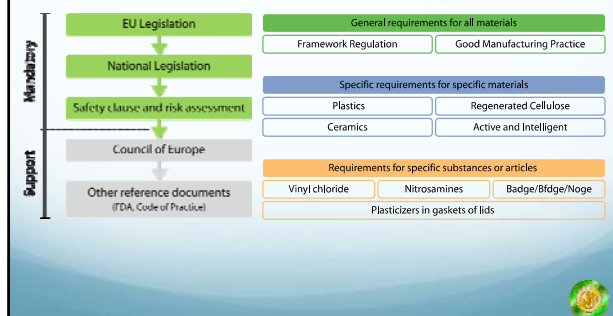
- Physical blend of different FCS for making food contact materials
- No chemical reaction or degradation
- All FCS have be authorized and complied with the relevant limitation of application
- No further FDA clearance



How food packaging is regulated in the EU?



How food packaging is regulated in the EU?



Regulation (EC) No 1935/2004

- Rules applicable to all food contact materials

Food Contact Materials and Articles or FCM

- in contact with food
- intended for food contact
- expected to come into contact with food

Food packaging

Kitchen articles

Machines/ articles



General Requirements

- Article 3
 - Materials and articles must be **manufactured in compliance with good manufacturing practice** so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could:
 - Endanger human health
 - Bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics



General Requirements

- Good Manufacturing Practice
- Safety
- Inertness (No unacceptable change in food)
 - Composition
 - Organoleptic characteristics
- No misleading to consumer (labelling; advertising)



General Requirements

- Labeling
 - When?
 - It is not already in contact with food
 - It is not evident that it is for food contact
 - What?
 - "For Food Contact" or symbol
- Traceability
 - To be able to follow a material or article through all stages of manufacture, processing and distribution
- Specific measures
 - Group of materials and articles
 - Set of requirements



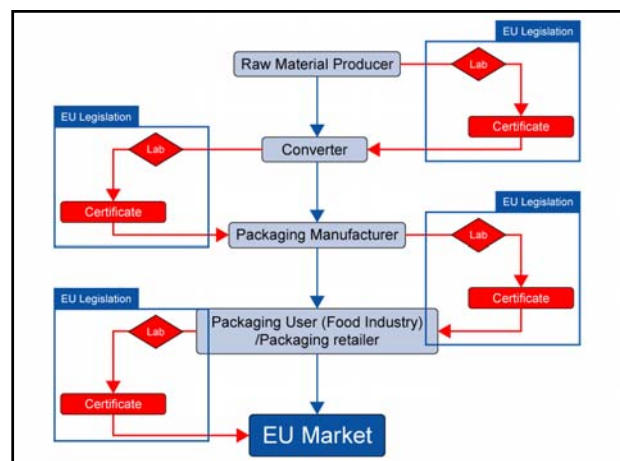
General Requirements

- National specific measures
 - In absence of specific measures
 - adoption of national provision
- Mutual of recognition
- Declaration of Compliance
 - Specific measures require
 - DoC
 - Supporting document



Specific measures

- **Active & Intelligent**
- Adhesives
- **Ceramic**
- Cork
- Rubber
- Glass
- Ion-exchange resin
- Metal & Alloys
- Paper & Board
- **Plastics**
- Printing ink
- **Regenerated cellulose**
- Silicones
- Textiles
- Varnishes & coating
- Wax
- Wood



Regulation (EC) No 10/2011

- Plastic single layer to Plastic layers in multi-material
- Union list (positive list)
- Specific requirement
 - Heavy metals
 - Primary aromatic amines (PAAs)
- Specific migration \Rightarrow safety limit
- Overall migration \Rightarrow inertness limit
- New food simulants and test conditions



How to regulate “safety” of FCM?

- Compositional requirement
 - Positive list
 - Technical quality, restriction/limitation
- Specific requirements
- Specific migration
- Overall migration
- DoC (if applicable)



Compositional requirements

- Substances of good technical quality
- **Union list of authorized substances**
 - Only 1 list in Annex I with new structure
 - Monomers and other starting materials
 - Additives excluding colorant
 - Polymer production aids (PPA) excluding solvent
 - Macromolecules obtained by microbial fermentation
 - Restriction and specification



Annex I: Table 1 Union list

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
Substance No.	Ref. No.	CAS No.	Substance name	additive (yes/no)	monomer (yes/no)	FRF (yes/no)	SML (mg/kg)	SML(T) (mg/kg)	Restriction and specification	Notes compliance
1	12310	026039-43-7	adipic acid	no	yes	no	60 mg/kg	See table 2		
14	13801	0042617-29-2	n-butyl 2-(3-chloro-2-hydroxypropyl)acrylate	yes	no	no	0.01 mg/kg	See table 3		
98	17280	0000010-00-0	benzothiazole	yes	yes	no				
99	14880	0000010-21-5	lactic acid	yes	no	no				
100	14880	0000010-21-5	lactic acid	yes	no	no				
107	21980	0000075-13-6	urea	no	yes	no	ND			
127	28010	0000075-01-4	vinyl chloride	no	yes	no	ND		1 mg/kg in final product	
130	28010	0000075-11-4	vinylidene chloride	no	yes	no	ND			(1)
147	13880	0000076-10-7	acrylic acid	no	yes	no		(22)		
167	21240	0000091-08-7	2,6-naphthoquinone	no	yes	no		(17)	1 mg/kg in final product expressed as 2,6-D	(16)
180	17380	0000097-13-0	engraft	no	yes	no	ND			
117	14880	0000084-74-2	phthalic acid, dibutyl ester	yes	no	no	6.3		Only to be used as: (a) plasticizer in expanded polystyrene and articles containing more than 0.1% by weight of phthalic acid, dibutyl ester; (b) technical support agent in polyethylene in concentrations up to 0.01 % in the final product	(7)



Substances not included in the Union list

- Present in the product and cover by the self-responsibility of manufacturer
 - NIAS
 - Impurity
 - Reaction intermediate
 - Decomposition or reaction product
 - Aids to polymerization
- Risk assessment by the manufacturer based on internationally recognized methods
- National law



Specific requirements

- SML, OML, restrictions and specification
- SML for heavy metals
 - Barium 1 mg/kg food simulant
 - Cobalt 0.05 mg/kg food simulant
 - Copper 5 mg/kg food simulant
 - Iron 48 mg/kg food simulant
 - Lithium 0.6 mg/kg food simulant
 - Manganese 0.6 mg/kg food simulant
 - Zinc 25 mg/kg food simulant



Specific requirements

- Restriction for primary aromatic amines (PAA)
 - Not detected (<0.01 mg/kg food)
- Status of substances in nanoform
 - Can only be used when they have been subject to risk assessment and authorization in this form
 - SiO₂
 - carbon black,
 - TiN



Food simulanta

Ethanol 10% (v/v)	Simulant A
Acetic acid 3%	Simulant B
Ethanol 20% (v/v)	Simulant C
Ethanol 50% (v/v)	Simulant D1
Vegetable oil	Simulant D2
Poly(2,6-diphenyl-p-phenylene oxide)	Simulant E
Particle size 60-80 mesh, pore size 200nm	

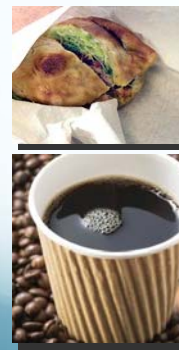


Rules of assessing compliance with migration limit

- Already in contact with food
 - Specific migration in real food
 - Real use conditions
- Not yet in contact with food
 - Specific migration in real food or food simulants
 - Screening test for specific migration is applicable
 - Overall migration in simulant A, B, C, D1 and D2
 - Screening test for overall migration is applicable



FCMs with no specific measure



Paper and board

- National law/recommendation
 - DGCCRF Notice (France)
 - BfR Recommendation (Germany)
 - Resolution and Technical documents: Council of Europe (CoE)
 - Industry Guideline: Confederation of European Paper Industries (CEPI)
- Recycled pulp – main source of contaminant



Challenging issues

- Environmental benefits and consumer protection
- Different testing/ requirement among MS

Test	Tests Required in Member States			
	Germany	France	Holland	Italy
OB/fo EN 648	Yes	Yes	-	Yes
Colour migration EN 646	Yes	Yes	-	-
Formaldehyde EN 1541	Yes	Yes	-	-
Glyoxal BIR Method	Yes	Yes	-	-
PCP CEN Method	Yes	Yes	-	-
3MCP/UV/ICH BIR Method	Yes	-	-	-
Antimicrobials EN 1104	Yes	Yes	-	-
Heavy Metals Pb, Cd, Hg, CrVI FNV 12497 and FNV12498	Yes	Yes	-	-
Organoleptic inertness EN 1290	Yes	Yes	-	-
PCBs EN ISO 15318	-	-	-	Yes
Water extractables EN 647 (hot) and EN 920	-	Yes	Yes	-
Heptane extractables	-	-	Yes	-



Thank you for your attention

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