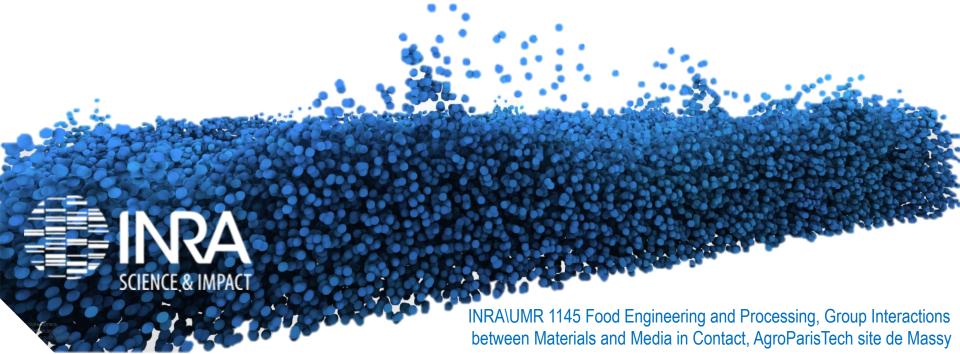
CONTAMINATION FROM FOOD CONTACT MATERIALS

OVERVIEW, MIGRATION ISSUES
REGULATION, RISK ASSESSMENT/MANAGEMENT

olivier.vitrac@agroparistech.fr















MICRO PLASTICS ENTERING FOOD CH THROUGH ANIMAL INGESTIO



Home > Law > Law-making process > Planning and proposing law > Impact assessments

Impact assessments

Impact assessments examine whether there is a need for EU action and analyse possible impacts of available solutions. These are carried out during the preparation phase, before the Commission finalises a proposal for a new law. They provide evidence to inform and support the decision-making process.

PAGE CONTENTS

The need for impact assessments

Better law-making

How to contribute

Cooperation between EU institutions

Subsidiarity and proportionality

The need for impact assessments

Impact assessments are carried out on initiatives expected to have significant economic, social or environmental impacts. These can be:

- legislative proposals
- non-legislative initiatives (e.g. financial programmes, recommendations for the negotiations of international agreeme
- implementing and delegated acts











 THIS LECTURE: http://modmol.agroparistech.fr/APT/

 MY LECTURES AT MSU (MI,USA): <u>http://www.fshn.msu.edu/events/event/Vitrac</u> DIFFUSION

https://mediaspace.msu.edu/media/dr.+olivier+vitrac +presentsa+diffusion+coefficients+of+organic+solut es+in+polymersa/1_zz20dgt9

PARTITIONING

https://mediaspace.msu.edu/media/Dr.+Olivier+Vitrac +presentsA+An+atomistic+Flory-

Huggins+formulation+for+the+tailored+prediction+of +activity+and+partition+coefficients/1_uzi6h91k SAFETY MANAGEMENT:

https://mediaspace.msu.edu/media/WorkshopA+Prediction+of+the+migrationA+beyond+conventional+estimates*/1 won1m7aw

 RISK ASSESSMENT: https://www.youtube.com/watch?v=7LMnc4czpuY



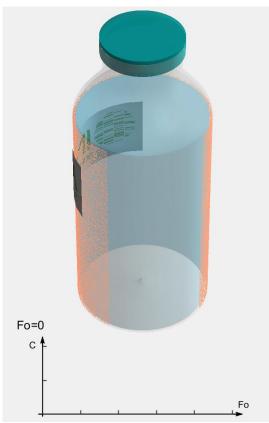
DESORPTION OF PACKAGING CONSTITUENTS (ADDITIVES, MONOMERS AND OLIGOMERS, NIAS...)

SELF-SIMILAR SITUATIONS WHICH OBEY
TO THE GENERAL MODEL OF DIFFSION-SOLUBILIZATION

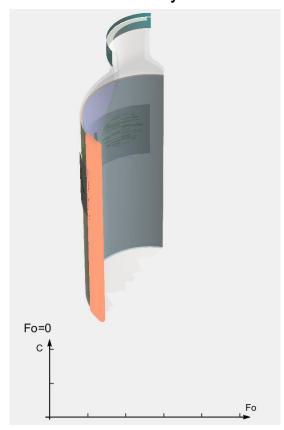
monlayer



with barrier to diffusion



multilayer



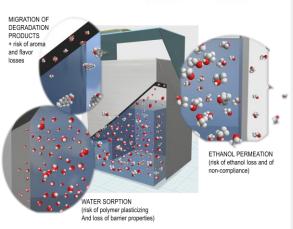


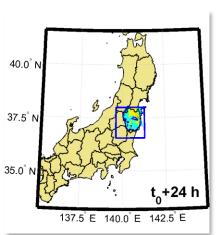
 $Fo = \frac{D_P t}{l_P^2}$

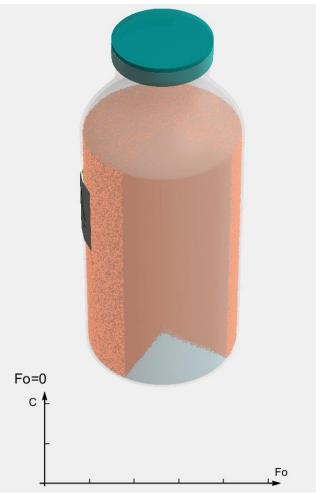
PERMEATION OFFOOD CONTENTS PERMEATION FROM ENVIRONMENT

alcoholic beverages

radionuclides



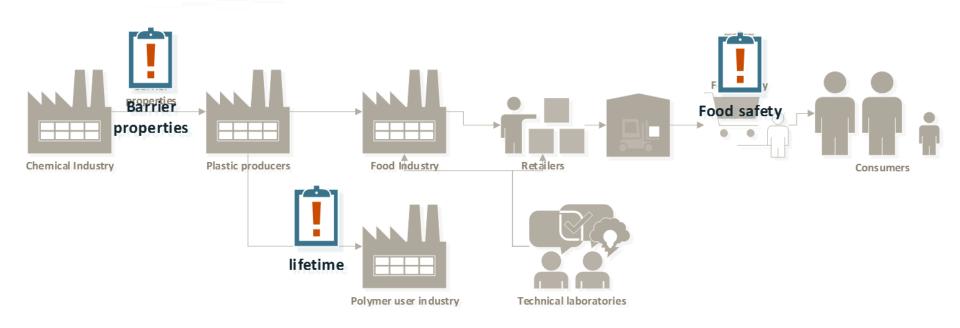








OUR MAIN APPLICATIONS Overview

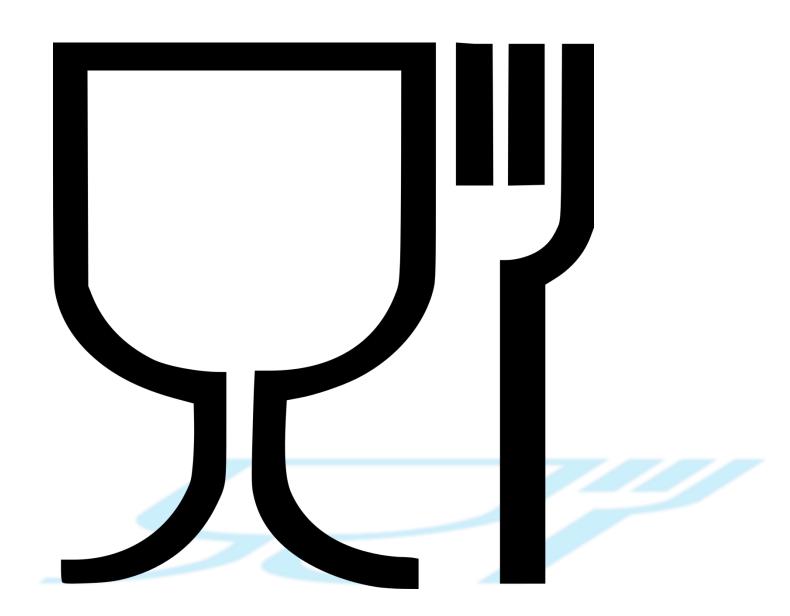




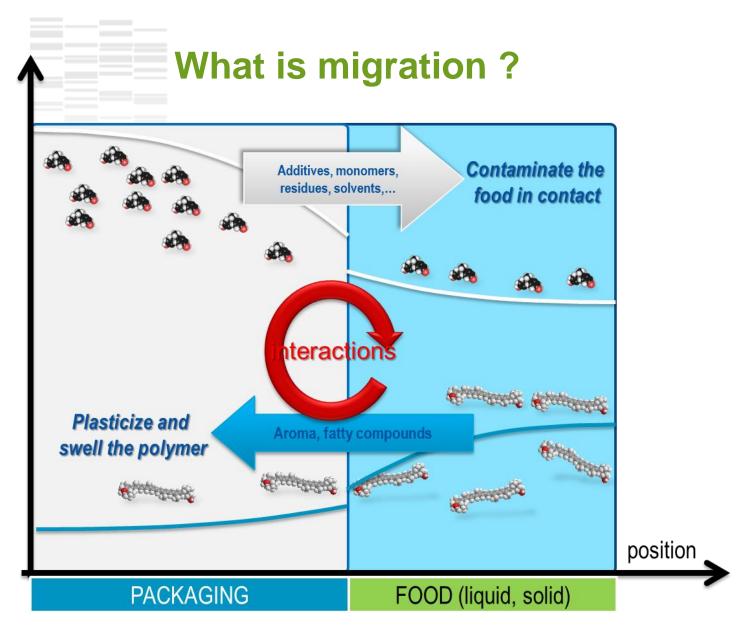








Concentration





FOOD PACKAGING INTERACTIONS

Example of sterilized product









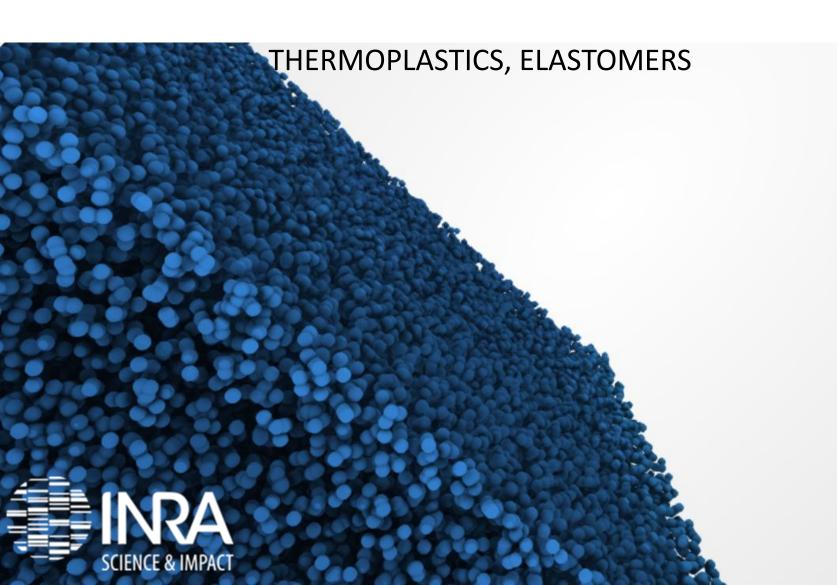
CONTENT



- FOOD PACKAGING OVERVIEW
- PERMEATION & BARRIER MATERIALS
- MIGRATION ISSUES
- TOXICITY
- REGULATION
- DIFFUSION IN POLYMERS
- CONCLUSIONS



FOOD PACKAGING MATERIALS



Classification of polymers

Thermoplastics: A thermoplastic, or thermosoftening plastic, is a polymer that melts, and returns to a solid state upon cooling.

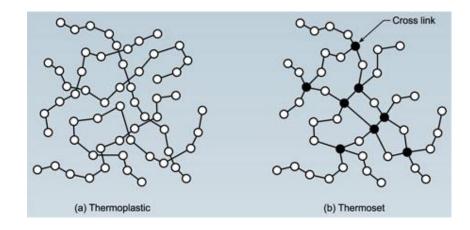
Examples: PE, PP, PS, PVC ...

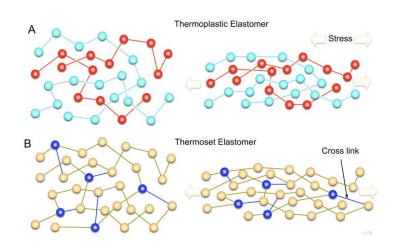
Thermosets: A thermosetting plastic, also known as a thermoset, is polymer material that irreversibly cures. The cure may be induced by heat, generally above 200 °C, through a chemical reaction, or suitable irradiation

Examples: Phenolic, epoxydes ...

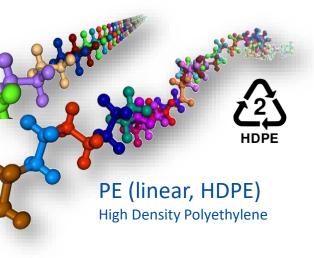
Elastomers: An elastomer is a polymer with viscoelasticity (colloquially "elasticity")

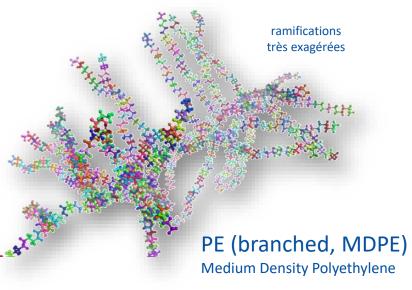
Exemples: Silicones, natural rubber ...

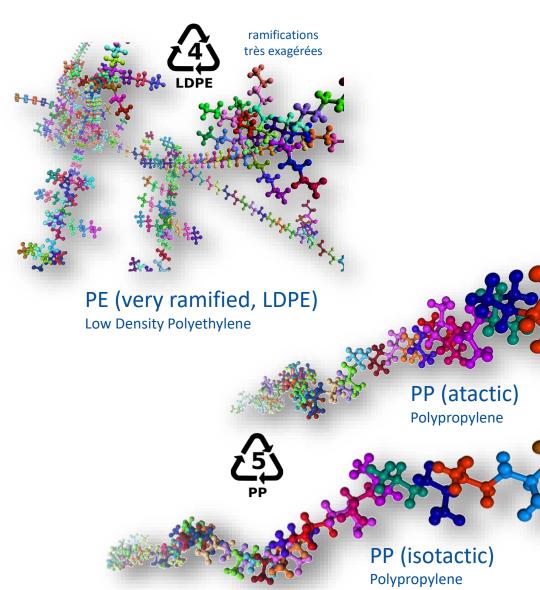




Polyolefins: PE – PP







POLYOLEFINSYLÈNE

LDPE

(Low density polyethylene)



- Vapour barrier
- Flexibility for seals
- Mouldability Tearability
- Flexibility Excellent stretchability • Sterilisation
- Chemical inertness
- Transparency Tactile effect

- Trays Boxing
- Screw or clip tops Nozzles
- Stretchable and retractable films for bundling (multiple-unit packs) and palletting • Bottles
- Stopper seals Carrier bags
- Small bags Tubes

HDPE

(High Density Polyethylene)



- Vapour barrier
- Mouldability Rigidity (for mechanical testing) • Impact resistance • Chemical inertness
- Resistance to stress-cracking
- Sterilisation Suitable for freezing (-40°C) • Opaqueness

- Large drums
- Screw or clip tops
- Bottles
- · Crates and cases · Covers
- Films for postal dispatch
- Flasks Drums and reusable
- containers Pots Tubes

Screw and clip tops

• Rigidity (Resistance to sterilisation)

(Polypropylene) • Resistance to cold • Vapour barrier



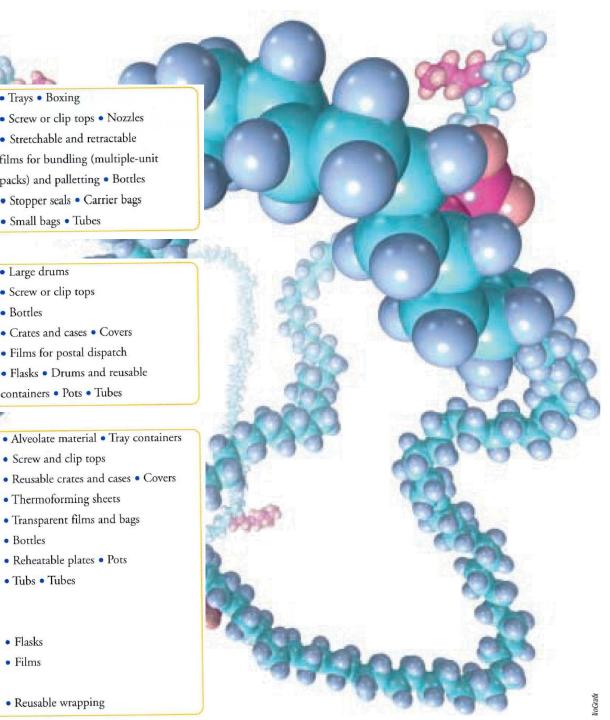
- Chemical inertness
- Suitable for freezing (-40°C)
- Suitable for micro-waves (+120°C)
- Low density
- · Resistant to stress-cracking
- Resistant to folding Thermal packing • Contact transparency

- Thermoforming sheets
- Transparent films and bags

• Reusable crates and cases • Covers

- Bottles
- Reheatable plates Pots
- Tubs Tubes

- Clarified PP
- OPP (oriented PP)
- EPP (expanded polypropylene: resistance to repeated impact)
- Flasks
- Films
- Reusable wrapping



POLYVINYLS PS Compact: Crystal PS: Transparency Tray containers (Polystyrene) with stretch film) • Brilliance • Rigidity • Egg containers • Stoppers PS (atactique) PS impact: opaque • Covers • Thermoforming sheets, • impact-resistance polystyrene pots for dairy products, • Brilliance • Cleavability cups for automatic drink machines Direct gassing: • Light • Heat sealable • Warm touch • Plates/trays **PVC** • Tray containers • Boxes PVC • Inertia • Good stretchability • Bottles • Flasks polyvinyl chloride (Polyvinyl Machinability Blister packs Excellent memory chloride) • Sheets for thermoforming Resistance to stress-cracking Food-contact films Transparency



Complexes (Combination

Structure adapted to application:

complementary properties

of materials using . Barrier to aroma,

perfume and gas

PET, EVOH,

PVDC, alumin-

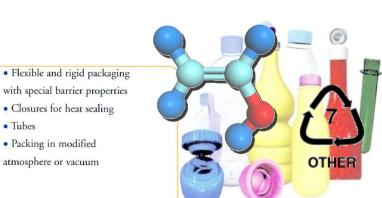
ium, paper or cardboard).

PE, PP, PVC,



with special barrier properties

- Closures for heat sealing
- Tubes
- Packing in modified atmosphere or vacuum



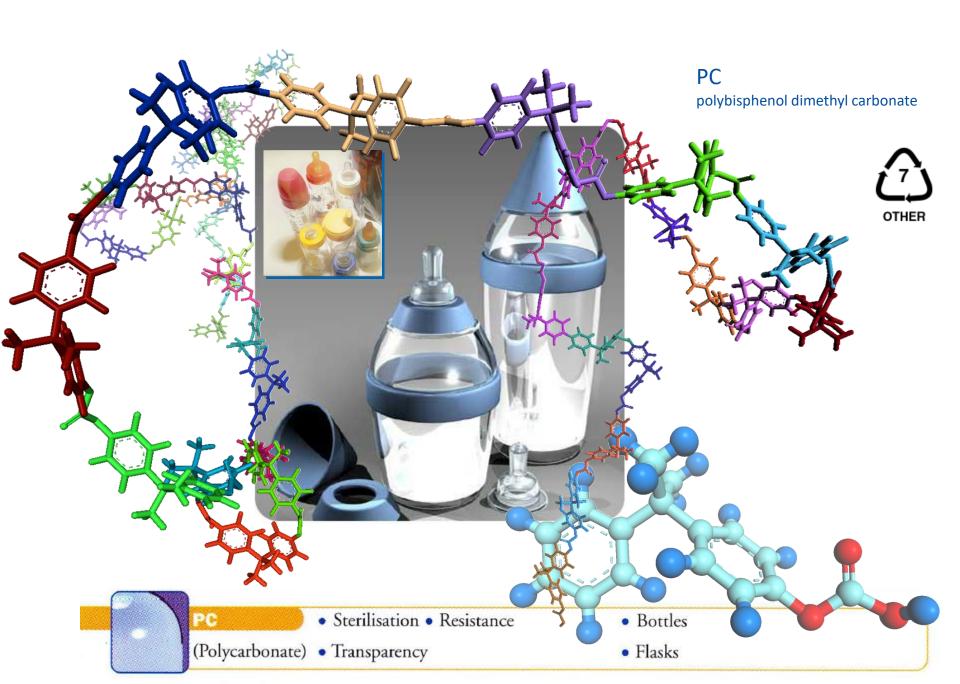


Polyethylene terepthalate

• Temperature resistant to 220° C

- PETG (glycol): amorphous,
 - Tray containers Lids
- same properties as (A)PET • Thermoforming sheets
- PET/PEN copolymer
- Gas barrier
- UV barrier
- Bottles
 - Flasks

POLYCARBONATES



MIGRATION CLASSES

Polymer	Formulation level	Degradation products	Interaction s with fatty food	Interaction s with alcohols and acids	Contamination risk
PET	+	++ (acetaldéhyde, cyclic trimer)	-	+	+
PE	++++	+++ (carbonyled compounds)	++++	-	+++++
PP	++++	+++ (carbonyled compounds)	+++	-	+++++
PS	+++	++ phenol, benzaldehyde, acetophenone	+++	non documente d	+++(+)
PVC	+++ à +++++ (si plastifié)	++ HCI	+++	non documente d	+++ to +++++





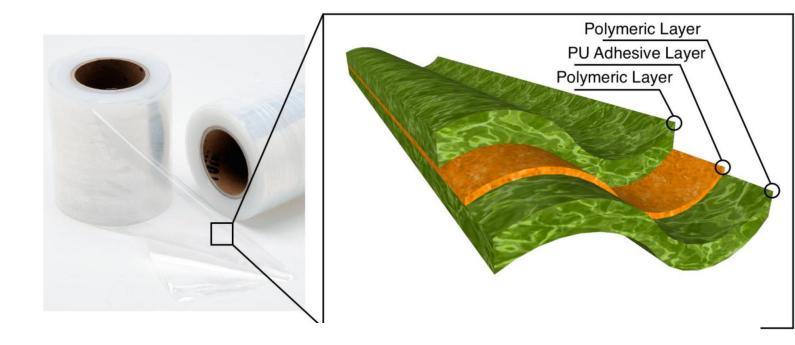
Polyurethane based
Sylil terminated polyether based
Butyl rubber based
Natural rubber water-based adhesives
Carboxylated-SBR water-based adhesives
Epoxies
Modified acrylics

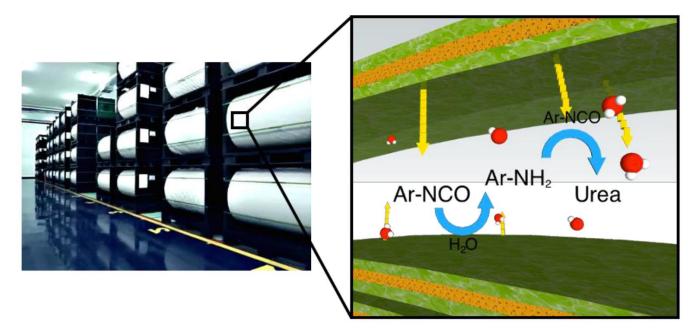
Cyanoacrylates

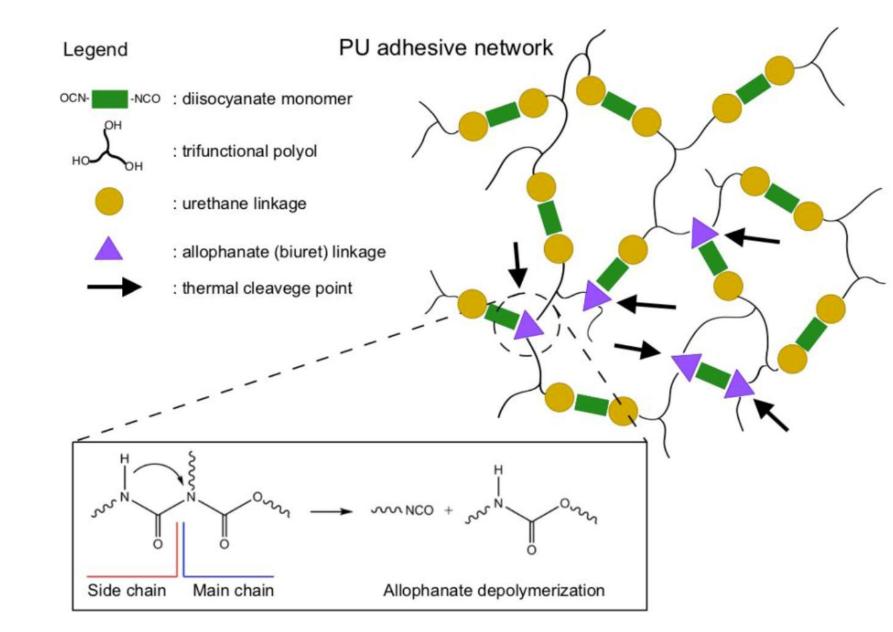


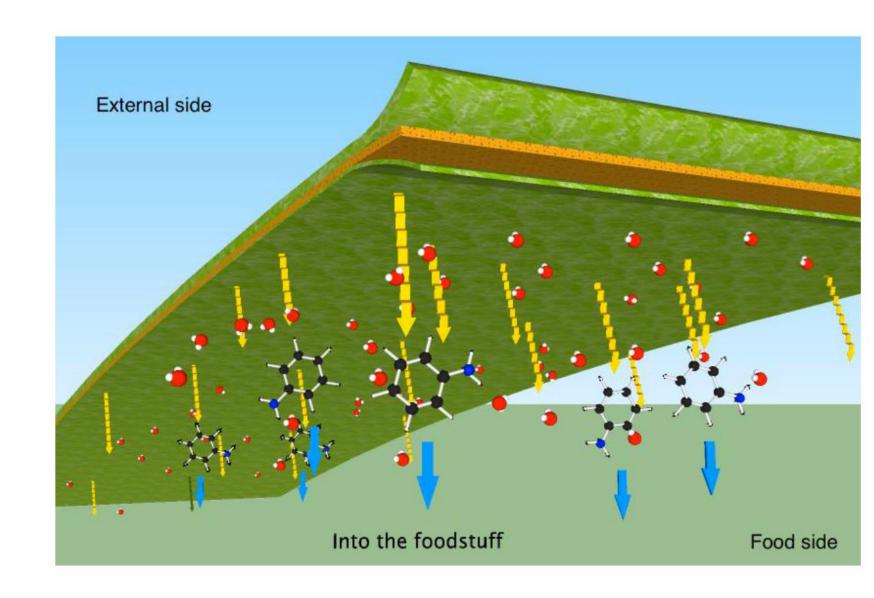


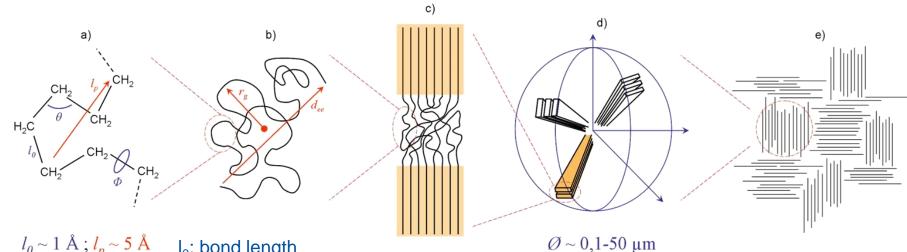
Component	Formulation level	Exposed contact surface	Interaction with food	Contaminatio n risk
Plastic layer in contact withfood	+++	+++++	+ to +++	+++++
Layer non-intented to be in contact with food	+++	+++++	-	+++
Cap, lid	+++	++	- to +	++
Gasket	+++++	+	- to +	+ to ++
Varnish	+++ to +++++	+++++	-	+++
Ink	+++++	+ to +++	-	+ to +++











 $l_0 \sim 1 \text{ Å}; l_p \sim 5 \text{ Å}$ I₀: bond length

I_p: persistence length

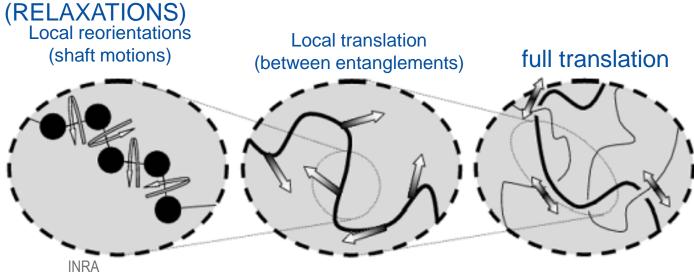
Φ: torsion angle

r_g: gyration radius

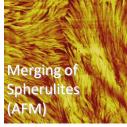
dee: end-to-end distance

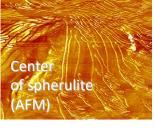
- Chemical structure a)
- b) Intermingled chains
- Semi-crystalline structure c)
- Poly-crystalline structure d)
- Heterogeneous material e)

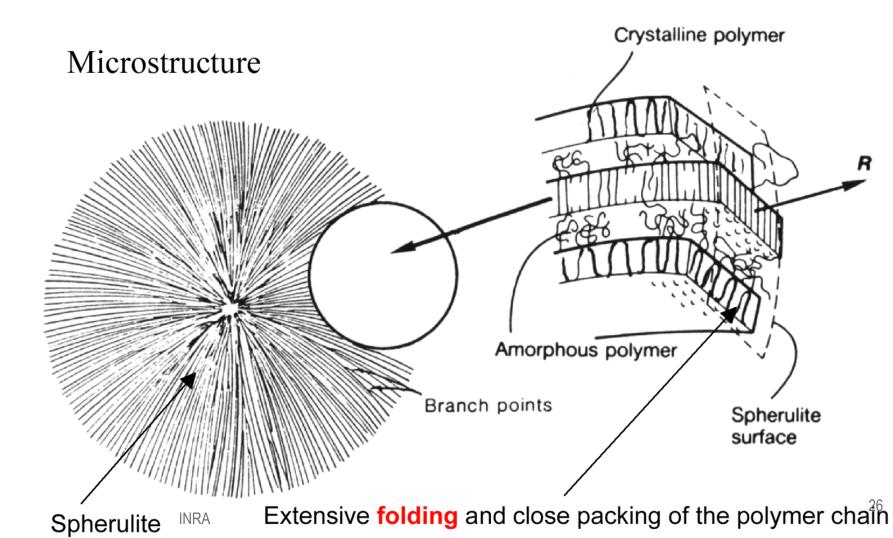






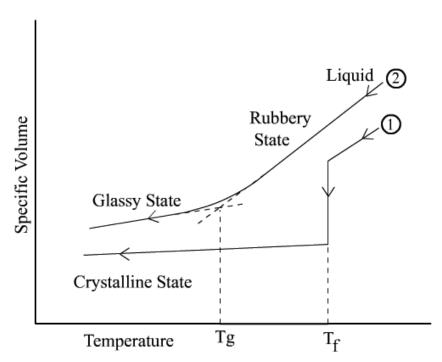




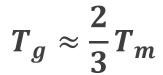


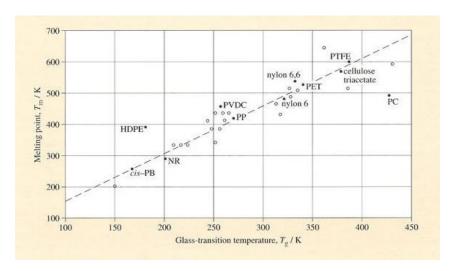
Critical temperatures for polymers

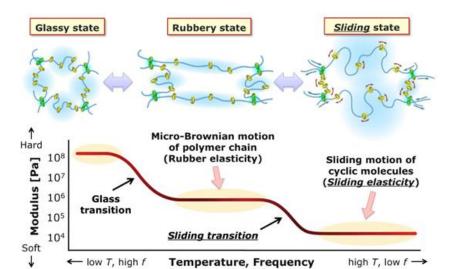
Glass transition temp. T_g Melting point T_m

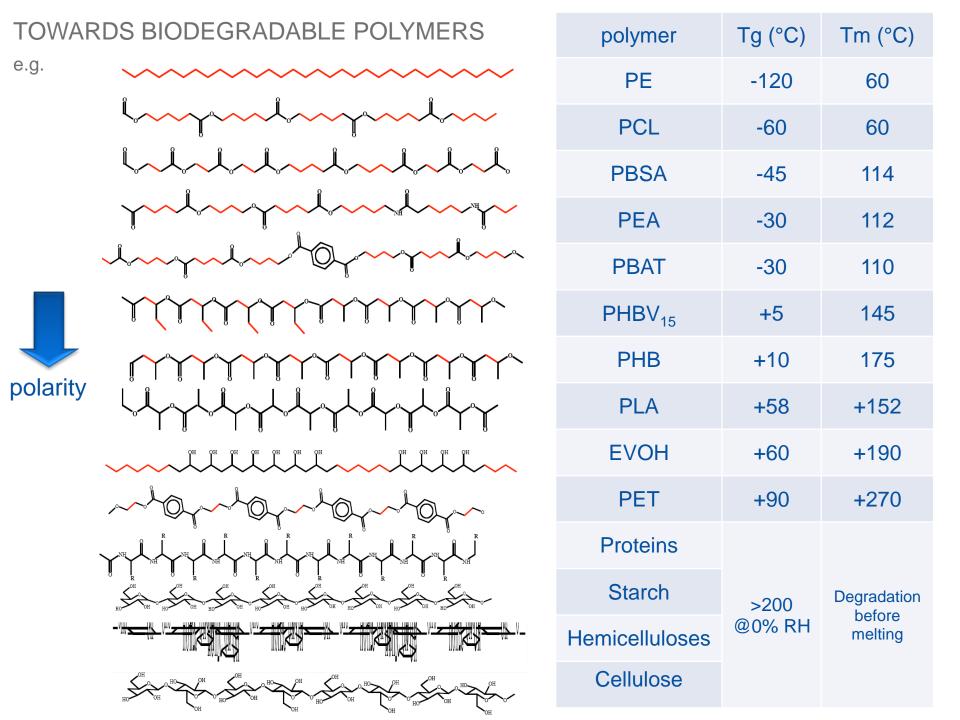


$$T_g = T_{g^{\infty}} - \frac{K}{\left\langle M_n \right\rangle}$$









ADDITIVES

THERMOPLASTICS, ELASTOMERS

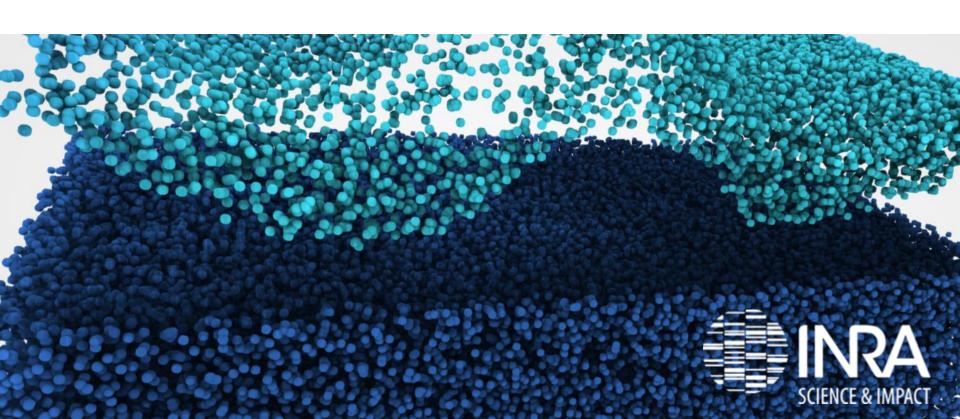




 Table 16.13
 Examples of Processing and Service Aids Used in Food-Packaging Materials

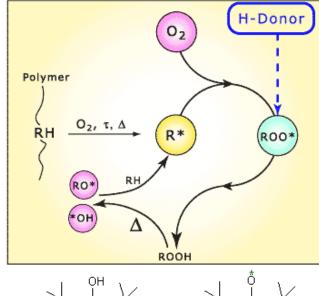
Technical function	Example	Use level, wt%, polymer
Antioxidant	Tetrakis[methylene (3,5-di- <i>tert</i> -butyl-4-hydroxyhydrocinnamate)]methane	0.25 (Polystyrene)
	Tris(2,4-di- <i>tert</i> -butylphenyl) phosphite	0.2 (Polyolefins)
Stabilizer	Di(n-octyl)tin S, S'-bis(isooctylmercaptoacetate)	1.5 (PVC)
	Epoxidized soybean oil	6 (PVC)
	Stearoylbenzoylmethane	0.5 (PVC)
	Cuprous iodide	0.01 (Nylon 6,6)
Plasticizer	Di(2-ethylhexyl) phthalate	40 (PVC)
	Di(2-ethylhexyl) adipate	20 (PVC)
	Acetyltributyl citrate	5 (PVDC)
Lubricant	N,N'-Ethylenebisstearamide	1 (PVC)
	Pentaerythritol adipate-stearate	1 (PVC)
Processing agent	Styrene/butadiene/methacrylate copolymer	2 (PVC)
Melt fracture eliminator	Vinylidene fluoride-hexafluoropropylene copolymer	0.1 (Polyethylene)
Slip agent	Fatty acid amides (erucamide, oleamide)	0.2 (Polyolefins)
Antistatic agent	N,N' -Bis (2-hydroxyethyl)alkyl- C_{14-18} -amine	0.15 (Polyolefins)
Blowing agent	Azodicarbonamide	0.15 (Polyethylene)
Antiblock agent	Silica, talc	0.2 (Polyethylene)
Impact modifier	Butadiene/styrene/methacrylate copolymers	10 (PVC)
Clarifying agent	Dibenzylidene sorbitol	0.25 (Polyolefins)
Light stabilizer	2-Hydroxy-4- <i>n</i> -octoxybenzophenone	0.5 (Polyolefins)
	Dimethylsuccinate-(4-hydroxy-2,2,6,6-tetra-methyl-1-piperidyl)-ethanol polycondensate	0.25 (Polyolefins)
Coupling agent	3-(triethoxylsilyl)propylamine	0.5 (Nylon 6,6)
Filler, extender	Calcium carbonate, clay, talc	>5 (Various polymers)
Reinforcing agents	Glass, fiber, mica, calcium silicate	>5 (Various polymers)
Colorant	Titanium dioxide, ferric oxide, carbon black, ultramarine blue, phthalocyanine blue	0.1–5 (Various polymers)

Source: Compiled from FDA (1987) and British Plastics Federation (1980).

COMMON ADDITIVES AND CONCENTRATION RANGES IN INITIAL MATERIALS

	PE	PP	PS	PVC	PET	PVA	PC	Ероху	PA
Antioxidant	В	В	В	X					В
Heat stabilizer				B/C		В			
UV stabilizer	B/C	B/C	С	С				С	
Antistatic agent	X	X	X	X	X	X	X		X
Shock agent	X	X	X	X	X	X	X		
Initiator			D	D		D			
Catalyst	D	D			D		D		D
Lubricant	X	X	X	X	X			X	
Plasticizer	Α		Α	Α		Α			
Charges	Α	Α	Α	Α	Α	Α	Α	Α	Α

A >10 000 mg·kg⁻¹ – B = 100-5000 mg·kg⁻¹ – C = 100-500 mg·kg⁻¹ D = 1-100 mg·kg⁻¹ – E < 1 mg·kg⁻¹, x ou X variable amounts (with x>X),



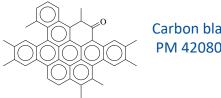
The 2,6-ditert-butyl-4-<u>hy</u>droxy<u>t</u>oluen (BHT, B12<u>1</u>) is the simplest phenolicantioxidant. It yields a stable phenoxical i) by mesomery, ii) steric effect due to large tert-butyl, and ii captodative effect.

	nom	CAS Formule M (g∙moſ¹)	Structure 3D	nom	CAS Formule M (g∙moſ¹)	Structure 3D
	2,6-Di(tert- butyl)hydroxytoluène (BHT)	128-37-0 C15 H24 O		Acide 3-(1,1- diméthyléthyl)-4- hydroxy-5-méthyl- Benzènepropanoïque	36443-68-2 C34 H50 O8	
		220.35	~~ <u>~</u>	(Irganox 245)	586.76	
	Monoacrylate de 2,2'- Méthylenebis(4-méthyl- 6-tert-butylphénol)	61167-58-6 C26 H34 O3 394.55	***	4,4',4"-[(2,4,6- triméthyl-1,3,5- benzènetriyl)tris(méthy lène)]tris[2,6-bis(1,1-	1709-70-2 C54 H78 O3 775.20	
	Irganox (3052)		***	diméthyléthyl)-phénol (Irganox 1330)	773.20	All Same
	2-méthyl-4,6- bis[(octylthio)méthyl]-	110553-27- 0 C25 H44 O S2	was a state of the	Isocyanurate de s- Triazine- 2,4,6(1H,3H,5H)-trione, 1,3,5-tris(3,5-di-tert- butyl-4-hydroxybenzyl)-	27676-62-6 C48 H69 N3 O6	
J	phénol (Irganox 1520)	424.75	- 2 %	(8CI); 1,3,5-Tri(3,5-di- tert-butyl-4- hydroxybenzyle) (Irganox 3114)	784.08	But the same
	3,4-dihydro-2,5,7,8- tetraméthyl-2-(4,8,12- triméthyltridecyl)- 2H-1- Benzopyran-6-ol (Irganox 231)	59-02-9 C29 H50 O2		Benzène propanoate de 3,5-bis(1,1- diméthyléthyl)-4- hydroxy-, 1,1'-[2,2- bis[[3-[3,5-bis(1,1- diméthyléthyl)-4-	6683-19-8 C73 H108 O12	
		430.71		hydroxyphényl]-1- oxopropoxy]méthyl]- 1,3-propanediyle] (Irganox 1010)	1177.63	15 15 15 15 15 15 15 15 15 15 15 15 15 1
	1,1-Bis(3,5-di-tert-butyl-	35958-30-6	868	bis[2,4-bis(1,1-	145650-60-8	0.0
	2- hydroxyphényl)éthane (Isonox 129)	C30 H46 O2 438.68		diméthyléthyl)-6- méthylphényl] éthyl ester (Irgafos 38)	C32 H51 O3 P 514.72	No. of the second
		2082-79-3	.92	2,4,8,10-Tetraoxa-3,9-	26741-53-7	
ne olic oxy	2,6-Di-tert-butyl-4- (octadécanoxycarbonylé thyl)phénol (Irganox	C35 H62 O3		diphosphaspiro[5.5]un décane, 3,9-bis[2,4-	C33 H50 O6 P2	200
	1076)	530.86		bis(1,1- diméthyléthyl)phénoxy]- (Ultranox 626,640)	604.69	
	Propionato do 2-3'	123-28-4	SOUTH AND A STATE OF THE STATE	Diphosphite de Bis(2,6-	80693-00-1	3. A. S. S.
	Propionate de 3, 3'- thiobis-, didodécyle (Irganox 800)	C30 H58 O4 S		di-tert-butyl-4- méthylphényl)pentaéry thritol (Mark PEP 36)	C35 H54 O6 P2	
ect	3,5-bis-(1, 1-	544			632.75	-9-
iii)	diméthyléthyl)-4- hydroxynenzène	32687-78-8 C34 H52 N2 O4	4 26 20	1,1',1"- Phosphite de 2,4-bis(1,1-	31570-04-4 C42 H63 O3 P	
	propionate d'hydrazine (Irganox 1024)	552.79		diméthyléthyl)-Phénol (Irgafos 168)	646.92	A STATE

nom	CAS Formule M (g·moſ¹)	Structure 3D	nom	CAS Formule M (g·moſ¹)	Structure 3D
Acide 4 <i>H-</i> 1-	248595-13- 3	. 9. 2	Adipate de Di(2-	103-23-1	-5
Benzopyran-2- carboxylique	C18 H20 O5		éthylhexyle (DEHA)	C22H42O4	30 35°
,,,,,	316.35		(= =:,	370.57	
4-	6160-78-7			77-90-7	3 3 2 5
Methylumbelliferyl- beta-D-	C16H18O8		Citrate de tributyl- acétyle	C20 H34 O8	
galactopyranoside	338.31		acetyle	402.88	
2-	117-81-7				
diéthylhexyl)phtalat e	C24H38O4				
(DEHP)	390.56	100 miles		-	
(DEHP)	TVALL AND CRINIANS RUPTORS		CLING Ell		



test containers with red drink after three days of UV exposure.



Benzo[a]pyrene,

carcinogenic impurity (< 0,25 mg/kg C)

specifications for the $\ensuremath{\mathsf{HAP}}$

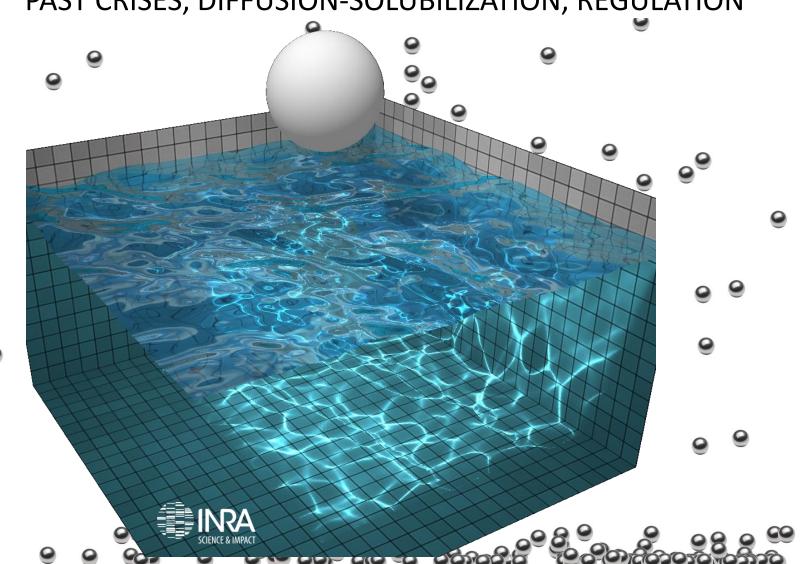


'	nom	CAS nom Formule Structure 3D M (g·moſ¹)		nom	CAS Formule M (g∙moſ¹)	Structure 3D
	2-Hydroxy-4- methoxybenzophénone (Chimassorb 90)	131-57-7 C14 H12 O3 228.24	****	Acide 3,5-bis(1,1- diméthyléthyl)-4-hydroxy- benzoïque (Cyasorb 2908)	67845- 93-6 C31 H54 O3 474.76	* A STATE OF THE S
·	1-(2-Hydroxyéthyl)- 2,2,6,6-tetraméthyl-4- hydroxypiperidine (Tinuvin 622)	52722-86-8 C11 H23 N O2 201.31		Décanoate de 1,10-bis(2,2,6,6- tetraméthyl-4-pipéridinyle) (Tinuvin 770)	52829- 07-9 C28 H52 N2 O4 480.72	**************************************
lack 80	2-(5-chloro-2H- benzotriazol-2-yl)-6- (1,1-diméthyléthyl)-4- méthyl-Phénol (Tinuvin 326)	3896-11-5 C17 H18 Cl N3 O 315.80		Didécanoate de 1,10- bis(1,2,2,6,6-pentaméthyl-4- piperidinyle) (Tinuvin 292)	41556- 26-7 C30 H56 N2 O4 508.78	
	2-(2H-benzotriazol-2- yl)-4,6-bis(1,1- diméthyléthyl)-Phénol (Tinuvin 320)	3846-71-7 C20 H25 N3 O 323.43		Poly[[6-[(1,1,3,3- tetraméthylbutyl)amino]-1,3,5- triazine-2,4-diyl][(2,2,6,6- tetraméthyl-4- piperidinyl)imino]-1,6- hexanediyl[(2,2,6,6-tetraméthyl- 4-piperidinyl)imino]] (Chimassorb 944)	71878- 19-8 (C35 H66 N8)n n·598.96	
-	2-hydroxy-4-(octyloxy)- (6CI,8CI); 2-Benzoyl-5- octyloxyphénol benzophénone (Chimassorb 81)	1843-05-6 C21 H26 O3 326.43		Didécanoate de 1,10-bis[2,2,6,6- tetraméthyl-1-(octyloxy)-4- piperidinyle] (Tinuvin 123)	122586- 52-1 C44 H84 N2 O6 737.15	28 Mary Mary
	2,2'-(2,5- thiophénediyl)bis[5- (1,1-diméthyléthyl)- Benzoxazole (Uvitex OB55)	7128-64-5 C26 H26 N2 O2 S 430.56		N2,N2'-1,2-ethanediylbis[N2-[3- [[4,6-bis[butyl(1,2,2,6,6- pentaméthyl-4- piperidinyl)amino]-1,3,5-triazin- 2-yl]amino]propyl]-N4,N6- dibutyl-N4,N6-bis(1,2,2,6,6- pentaméthyl-4-piperidinyl)- 1,3,5-Triazine-2,4,6-triamine (Chimassorb 119)	106990- 43-6 C132 H250 N32 2285.61	
	2-(3'-tert-Butyl-2'- hydroxy-5'-(2- octyloxycarbonyléthyl)p hényl)benzotriazole (Tinuvin 99)	84268-23-5 C27 H37 N3 O3 451.60	TO THE REPORT			



MIGRATION ISSUES

PAST CRISES, DIFFUSION-SOLUBILIZATION, REGULATION























http://ec.europa.eu/food/food/rapidalert/index en.htm



Site Map | What's New | A to Z Index | Contact | English (en)







Notifications List

New Search

Notifications list: 9 results

Search criteria

Subject *THIOXANTHONE* | Product type food contact material | Hazard category migration



Туре

FCM

FCM

XML 🚔



<< First <<

<< Previous 100 << Notifications 1 to 9 of 9 >> Next 100 >>

>> Last >>

	Classification	Date of case	Last change	Reference	Country	Subject	Product Catego
1.	information for attention	10/03/2011	16/03/2011	2011.0316	DE	migration of 2-methyl-4'-(methylthio)-2-morpholinopropiophenone, of ethyl-4-dimethylaminobenzoate and of 2.4-diethyl thioxanthone (DETX) (sum 685 µg/kg - ppb) from printing ink on drinking cups from Germany	food contact materials
2.	information for follow-up	21/01/2011	14/03/2011	2011.0088	DE	migration of 2-methyl-4'-(methylthio)-2-morpholinopropiophenone (54 µg/kg - ppb) and of 2.4-diethyl thioxanthone (DETX) (91 µg/kg - ppb) from plastic mugs from Greece	food contact materials
3.	information for attention	11/02/2011	10/03/2011	2011.0175	DE	migration of 2-methyl-4'-(methylthio)-2-morpholinopropiophenone, of ethyl-4-dimethylaminobenzoate and of 2.4-diethyl thioxanthone (DETX) (sum = 160) from printing on plastic cups from Germany	food contact materials
						migration of 2-methyl-4'-(methylthio)-2-morpholinopropiophenone	
4.	information	21/12/2010	10/03/201			Notification detail - 20	111 0316
5.	information	18/03/2010	10/03/201	grau	dieth	nethyl-4'-(methylthio)-2-morpholinopropiophenone yl thioxanthone (DETX) (sum 685 µg/kg - ppb) fron	
5.	information	18/03/2010	10/03/201	graa	dieth Re	ryl thioxanthone (DETX) (sum 685 μg/kg - ppb) from eference: 2011.0316	
5. 6.	information	18/03/2010 31/07/2009	10/03/201		dieth Re Notificat	yl thioxanthone (DETX) (sum 685 μg/kg - ppb) fron	
					dieth Re Notificat Last	ryl thioxanthone (DETX) (sum 685 μg/kg - ppb) from eference: 2011.0316 ion date: 10/03/2011	n printing ink on drinking cups f
					dieth Re Notificat Last Notificat	ryl thioxanthone (DETX) (sum 685 μg/kg - ppb) from eference: 2011.0316 ion date: 10/03/2011 t update: 16/03/2011	n printing ink on drinking cups f
6.	alert	31/07/2009	10/03/201		dieth Ro Notificat Last Notificat Action	eference: 2011.0316 ion date: 10/03/2011 t update: 16/03/2011 ion type: food contact material - information for attention - official	n printing ink on drinking cups f
6.	alert information	31/07/2009	10/03/201		dieth Ro Notificat Last Notificat Action	ryl thioxanthone (DETX) (sum 685 µg/kg - ppb) from eference: 2011.0316 ion date: 10/03/2011 t update: 16/03/2011 ion type: food contact material - information for attention - official on taken: withdrawal from the market ion from: Germany (DE)	n printing ink on drinking cups f
6. 7.	alert information alert	31/07/2009 11/04/2006 17/01/2006	10/03/201 02/02/200 02/02/200		Reconstruction Recons	ryl thioxanthone (DETX) (sum 685 µg/kg - ppb) from eference: 2011.0316 ion date: 10/03/2011 t update: 16/03/2011 ion type: food contact material - information for attention - official on taken: withdrawal from the market ion from: Germany (DE)	n printing ink on drinking cups f
6. 7.	alert information alert	31/07/2009 11/04/2006 17/01/2006	10/03/201 02/02/200 02/02/200	-	dieth Re Notificat Last Notificat Actic Notificati Distributio	ryl thioxanthone (DETX) (sum 685 µg/kg - ppb) from eference: 2011.0316 ion date: 10/03/2011 it update: 16/03/2011 ion type: food contact material - information for attention - official on taken: withdrawal from the market ion from: Germany (DE) in status: distribution restricted to notifying country	n printing ink on drinking cups f
6. 7.	alert information alert	31/07/2009 11/04/2006 17/01/2006	10/03/201 02/02/200 02/02/200	-	dieth Ro Notificat Last Notificat Actic Notificati Distributio	eference: 2011.0316 ion date: 10/03/2011 t update: 16/03/2011 ion type: food contact material - information for attention - official on taken: withdrawal from the market ion from: Germany (DE) in status: distribution restricted to notifying country Product: printing ink on drinking cups	n printing ink on drinking cups f

zoate and of 2.4from Germany

RASFF

ystem for Food and Feed

Hazards:

Substance / Hazard	Category	Analytical result	Units	Sampling date
migration of 2-methyl-4'- (methylthio)-2- morpholinopropiophenone	migration			
migration of 2.4-diethyl thioxanthone (DETX)	migration	sum 685	μg/kg - ppb	
migration of ethyl-4- dimethylaminobenzoate	migration			16/10/2010



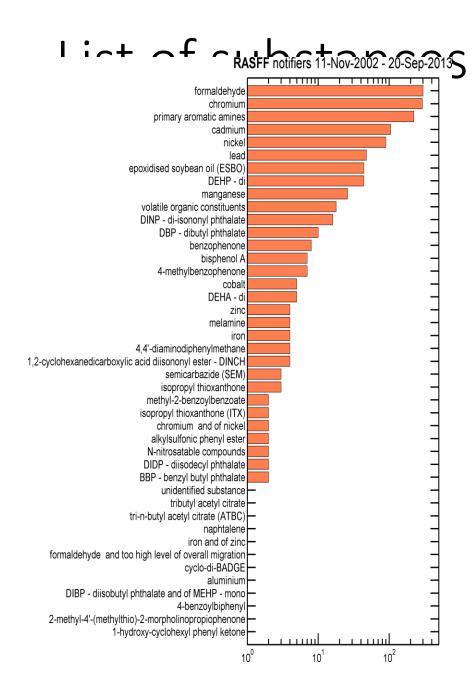


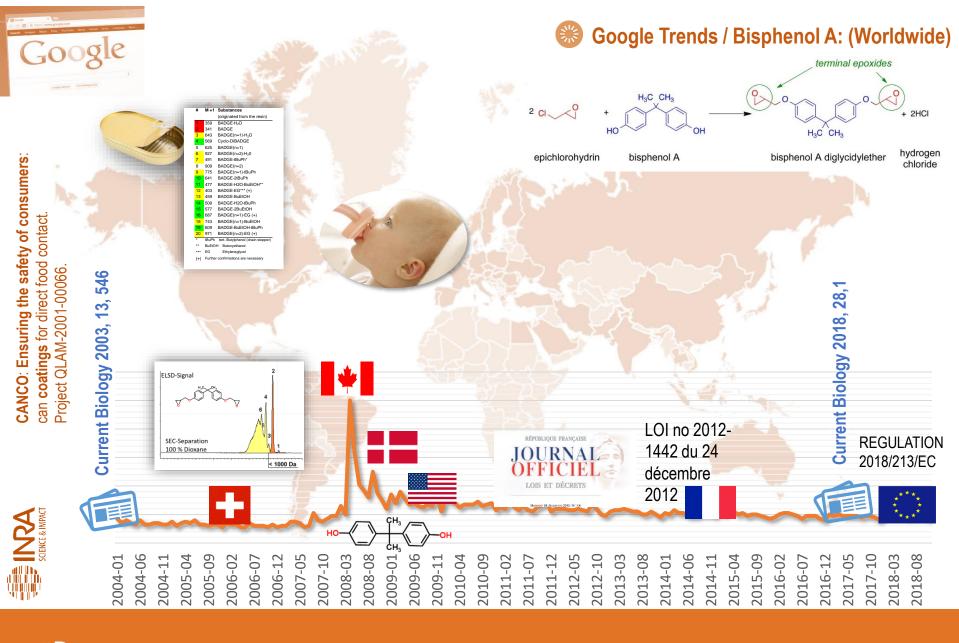
Table 6 - Migration of substances (except heavy metals) from food contact material

	substance	notications
migration of	1-hydroxy-cyclohexyl phenyl ketone	3
migration of	2.4-diethyl thioxanthone (DETX)	3
migration of	2-methyl-4'-(methylthio)-2-morpholinopropiophenone	3
migration of	4-methylbenzophenone	1
migration of	mineral oil	1
migration of	bisphenol A	8
migration of	epoxidised soybean oil (ESBO)	9
migration of	ethyl-4-dimethylaminobenzoate	3
migration of	formaldehyde	75
migration of	melamine	18
migration of	methyl-2-benzoylbenzoate	2
migration of	colour	6
too high level of	total migration	42
high content of	DBP - dibutyl phthalate	3
high content of	DEHP - di(2-ethylhexyl) phthalate	10
high content of	DINP - di-isononyl phthalate	5
migration of	DINP - di-isononyl phthalate	2
migration of	primary aromatic amines	33
migration of	volatile organic constituents	1
	inner coating peeling off	12
	deterioration of organoleptic characteristics of food in contact	17
	not suitable to contain food	2

2011 figures

BISPHENOLS

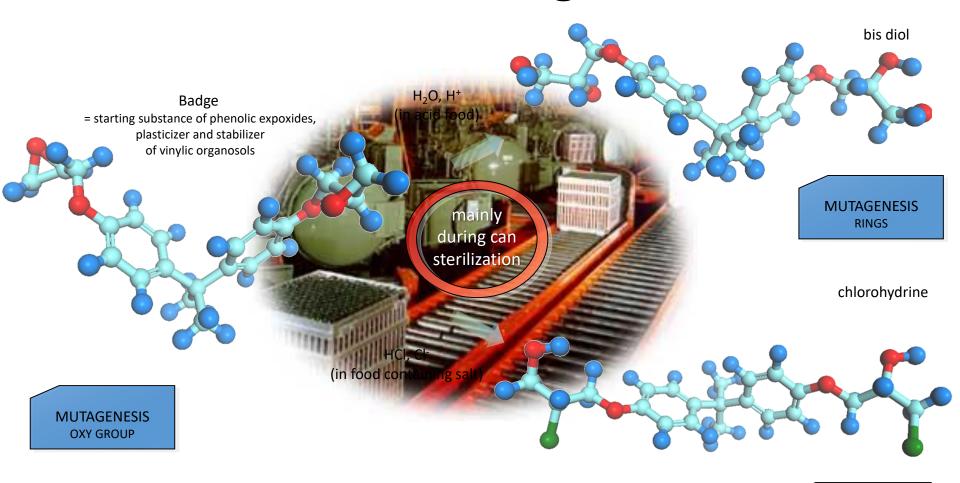








EPOXIDE=reactive migrants







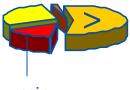
MUTAGENESIS CHLOROHYDRINES

SCREENING OF MIGRANTS FROM CAN COATINGS < 1000 Da

SAMPLE: STANDARD EPOXY-COATING, MECN-EXTRACT

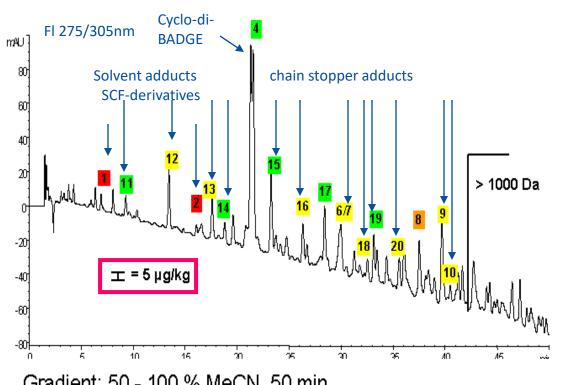


M +1 Substances



resin components < 1000 Da

> Structured Non-Target'-Screening



Gradient: 50 - 100 % MeCN, 50 min

π	IVI T I	Jubstances
		(originated from the resin)
1	359	BADGE·H ₂ O
2	341	BADGE
3	643	BADGE(n=1)·H ₂ O
4	569	Cyclo-DiBADGE
5	625	BADGE(n=1)
6	927	BADGE(n=2)· H_20
7	491	BADGE-tBuPh*
8	909	BADGE(n=2)
9	775	BADGE(n=1)-tBuPh
10	641	BADGE-2tBuPh
11	477	BADGE·H2O·BuEtOH**
12	403	BADGE-EG*** (+)
13	459	BADGE-BuEtOH
14	509	BADGE·H2O·tBuPh
15	577	BADGE-2BuEtOH
16	687	BADGE(n=1)-EG (+)
18	743	BADGE(n=1)-BuEtOH
19	609	BADGE-BuEtOH-tBuPh
20	971	BADGE(n=2)-EG (+)
*	tBuPh	tertButylphenol (chain stopper
**	BuEtO	H Butoxyethanol

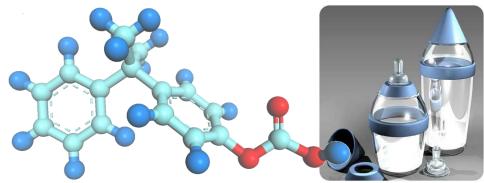
Ethyleneglycol

Further confirmations are necessary

Bisphenol A Exposure Causes Meiotic Aneuploidy in the Female Mouse

Background: There is increasing concern that exposure to man-made substances that mimic endogenous hormones may adversely affect mammalian reproduction. Although a variety of reproductive complications have been ascribed to compounds with androgenic or estrogenic properties, little attention has been directed at the potential consequences of such exposures to the genetic quality of the gamete.

Results: A sudden, spontaneous increase in meiotic disturbances, including aneuploidy, in studies of oocytes from control female mice in our laboratory coincided with the accidental exposure of our animals to an environmental source of bisphenol A (BPA). BPA is an estrogenic compound widely used in the production of polycarbonate plastics and epoxy resins. We identified damaged caging material as the source of the exposure, as we were able to recapitulate the meiotic abnormalities by intentionally damaging cages and water bottles. In subsequent studies of female mice, we administered daily oral doses of BPA to directly test the hypothesis that low levels of BPA disrupt female meiosis. Our results demonstrated that the meiotic effects were dose dependent and could be induced by environmentally relevant doses of BPA.



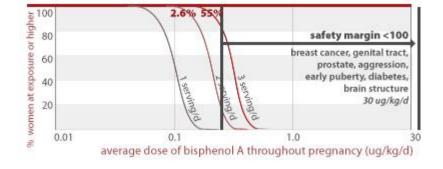
Conclusions: Both the initial inadvertent exposure and subsequent experimental studies suggest that BPA is a potent meiotic aneugen. Specifically, in the female mouse, short-term, low-dose exposure during the final stages of oocyte growth is sufficient to elicit detectable meiotic effects. These results provide the first unequivocal link between mammalian meiotic aneuploidy and an accidental environmental exposure and suggest that the oocyte and its meiotic spindle will provide a sensitive assay system for the study of reproductive toxins.

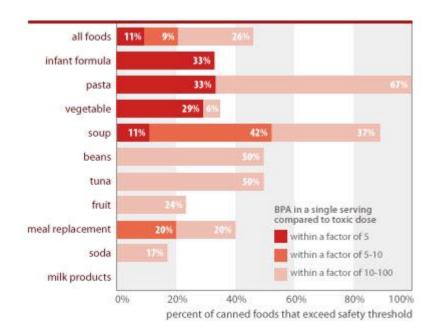


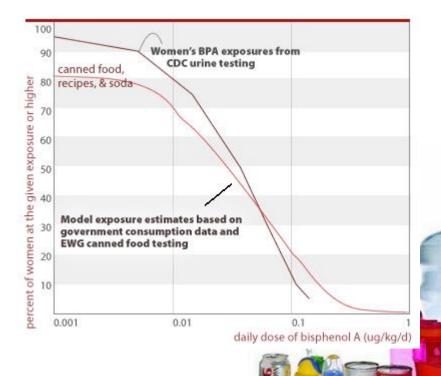




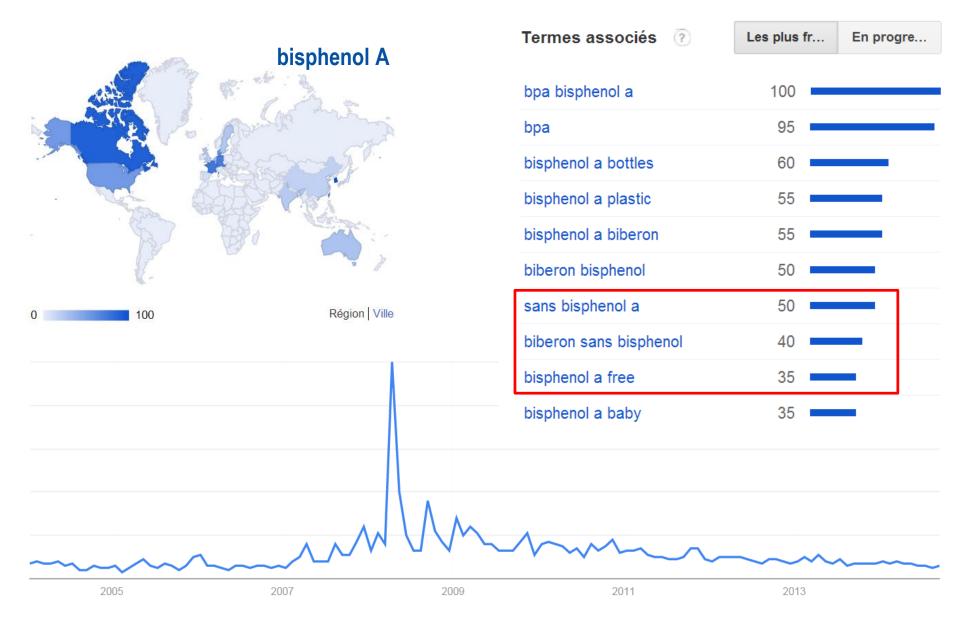
PRESENCE IN FOOD







Google Trends – 2003-present



Epilogue



ACTUALITÉ ÉCONOMIE FINANCE PE ENTREPRISE EMPLOI CULTURE ST

Actualité | Photos | Vidéos | Blogs | Express Yourself | Tendances | Elysée 2012

À la une | Politique | Monde | Economie | Société | Education | Médias | High-Tech | Sport | Sciences et si

Actualité > Politique



L'Assemblée unanime interdit les contenants alimentaires avec du bisphénol A

publié le 12/10/2011 à 17:11, mis à jour à 19:23



afp.com/Mychèle Daniau

PARIS - A l'unanimité, l'Assemblée a voté mercredi l'interdiction du bisphénol A dans les contenants alimentaires, objet d'une proposition de loi socialiste soutenue par le gouvernement.

La mesure s'appliquera à compter de 2014, mais dès 2013 pour les contenants alimentaires de produits destinés aux enfants de moins de 3 ans, conformément à un amendement introduit par le ministre de la Santé, Xavier Bertrand, lors des débats jeudi demier.

Le bisphénol A, composant chimique très répandu dans les objets de la

Toutes les dépêches

CAN: le Soudan qualifié, carton plein de la Côte d'Ivoire dans le

Wall Street finit en légère baisse: Dow Jones -0,05%, Nasdag -0,16%



Mercredi 26 décembre 2012 / N° 300

I Ol no 2012-1442 du 24 décembre 2012 visant à la suspension de la fabrication, de l'importation, de l'exportation et de la mise sur le marché de tout conditionnement à vocation alimentaire contenant du bisphénol A.

- « Cette suspension prend effet, dans les mêmes conditions, au 1er janvier 2015 pour tout autre conditionnement, contenant ou ustensile comportant du bisphénol A et destiné à entrer en contact direct avec des denrées alimentaires.
- « Avant le 1er juillet 2014, le Gouvernement remet au Parlement un rapport évaluant les substituts possibles au bisphénol A pour ses applications industrielles au regard de leur éventuelle toxicité.

EN

COMMISSION REGULATION (EU) 2018/213

of 12 February 2018

on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials

Article 2

- 1. The migration into or onto food of 2,2-bis(4-hydroxyphenyl)propane ('BPA') (CAS No 0000080-05-7) from varnishes or coatings applied to materials and articles shall not exceed a specific migration limit of 0,05 mg of BPA per kg of food (mg/kg).
- 2. By derogation from paragraph 1, no migration of BPA shall be permitted from varnishes or coatings applied to materials and articles specifically intended to come into contact with infant formula, follow-on formula, processed cereal-based food, baby food, food for special medical purposes developed to satisfy the nutritional requirements of infants and young children or milk-based drinks and similar products specifically intended for young children, as referred to in Regulation (EU) No 609/2013.

Article 7

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

It shall apply from 6 September 2018.

SUMMARY

Current Biology

Replacement Bisphenols Adversely Affect Mouse Gametogenesis with Consequences for Subsequent Generations

Highlights

- Replacement bisphenols are structural BPA variants with similar biological effects
- Common bisphenols are germline toxicants that induce meiotic effects in both sexes

Genotoxic bisphenol exposure effects may persist for several generations in males

Environmental contaminants can undermine science by affecting data and conclusions

B Bisphenol S (BPS)

Bisphenol S (BPS) HO CH3 CH3 CH4 CH3 Diphenyi sulfone

Authors

Tegan S. Horan, Hannah Pulcastro, Crystal Lawson, ..., Mary C. Gieske, Caroline V. Sartain, Patricia A. Hunt

Correspondence

pathunt@wsu.edu

In Brief

Horan et al. report changes in meiotic data in mice coinciding with physical damage to polysulfone cages. LCMS analyses implicate replacement bisphenols. Subsequent controlled experiments demonstrate that, like BPA, common replacement bisphenols induce meiotic effects in both sexes that, in males, may persist for several generations.

dangerous chemicals, exacerbates the regulatory burden of safety assessment, and increases environmental contamination. Our experience suggests that these environmental contaminants pose a risk not only to reproductive health but also to the integrity of the research environment. EDCs, like endogenous hormones, can affect diverse processes. The sensitivity of the germline allows us to detect effects that, although not immediately apparent in other systems, may induce variability that undermines experimental reproducibility and impedes scientific

advancement.

20 years ago, accidental bisphenol A (BPA) expo-

sure caused a sudden increase in chromosomally

abnormal eggs from our control mice [1]. Subsequent rodent studies demonstrated developmental

effects of exposure with repercussions on adult health and fertility (e.g., [2-9]; reviewed in [10-17]).

Studies in monkeys, humans, fish, and worms sug-

gest BPA effects extend across species (e.g., [18-30]; reviewed in [31-33]). Widespread use has re-

sulted in ubiquitous environmental contamination

and human BPA exposure. Consumer concern resulted in "BPA-free" products produced using struc-

turally similar bisphenols that are now detectable environmental and human contaminants (e.g.,

[34-41]). We report here studies initiated by meiotic changes mirroring our previous BPA experience

and implicating exposure to BPS (a common BPA replacement) from damaged polysulfone cages.

Like with BPA [1, 2, 5], our data show that exposure to common replacement bisphenols induces germ-

line effects in both sexes that may affect multiple generations. These findings add to growing evidence

of the biological risks posed by this class of chemicals. Rapid production of structural variants of BPA and other EDCs circumvents efforts to eliminate

"Horan et al., 2018, Current Biology 28, 1–7

PHOTOINITIATORS



Food and Feed borne crises throughout the food chain





destroy consumer's confidence in food

But what about food packaging





Nonylphenol NP





residues



Semicarb Nide/SEM



Bisphenol A diglycidyl ether (BADGE)

Italian police seize contaminated Nestle baby milk

22 Nov 2005 16:45:09 GMT Source: Reuters



← PREVIOUS | NEXT →

Forest Ranger officials check a package of baby milk made by Swiss food group Nestle in a supermarket in Italy November 22, 2005, Italian police seized around 30 million litres of baby milk produced by Nestle on Tuesday after tests showed traces of ink, and the company said it was recalling the infant food in four European countries. REUTERS/HO

(Adds Tetra Pak comment in paragraph 11)

By Massimiliano Di Giorgio and Isabel Strassheim

ROME/ZURICH, Nov 22 (Reuters) -Italian police seized around 30 million litres of baby milk produced by Swiss food giant Nestle <NESN.VX> on Tuesday after tests showed it was contaminated with traces of ink used in the packaging.

Nestle said the chemical substance was not harmful, but announced it was recalling the infant food in four European countries, including Italy, because of the problem, which related to Tetra Pak cartons.

Italian Agriculture Minister Gianni Alemanno demanded tests to see if babies given the contaminated milk over a prolonged period faced health risks.

"It is incredible that such defenceless

beings as babies should face such serious risks in a product as widely used as milk." Alemanno said in a statement.

Italian officials said they had already seized about 2 million litres of Nestle baby milk earlier this month after finding traces of isopropylthioxanthone (ITX), an ink component used in the offset printing process of the Tetra Pak cartons.

They broadened their net on Tuesday, sweeping hundreds of packets of milk off supermarket shelves and out of depots around Italy. Police said they also searched lorries in their effort to root out the four Nestle products under investigation.

Nestle, the world's biggest food company, said it had decided to recall all liquid infant formula milks packed in offset printed cartons in Italy, France, Spain and Portugal.



BOTTOM LINE SAFE

A spokesman at Nestle's corporate headquarters in Switzerland said a new packaging process had been put in place to prevent the contamination and that the recall would not have a significant impact on the company's results at a group level.

Nestle shares were down 0.5 percent at 1615 GMT in a slightly higher overall Swiss market

Tetra Pak spokeswoman Patricia O'Hayer said ITX was not recognised as a toxic substance on any official list and was not on the World Health Organisation lists of toxic substances that should not come into contact with food.

"We have studied the toxicological data available, and that confirms that it is not toxic," she told Reuters.

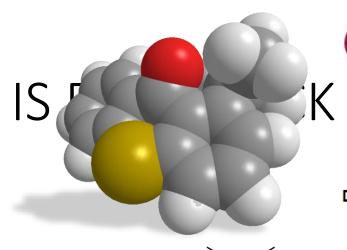
O'Hayer said Tetra Pak removed the printing technology in question in October to prevent any printing compound, even if not dangerous, from seeping into a product.

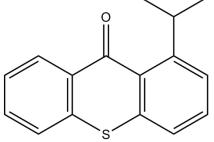
"We had no indication that this was in any way a cause for concern," she said.

This is the second time Nestle has run foul of Italian authorities this year.

In October, Italy's antitrust authority fined seven producers of baby formula including Nestle a total of 9.743 million euros for running a cartel in Italy to keep prices much higher than in many European countries.







isopropyl thioxanthone

photoinitiator used in UV, curing resins, inks, coatings and adhesives $M=241 \text{ g·mol}^{-1}$

















December 15, 2005

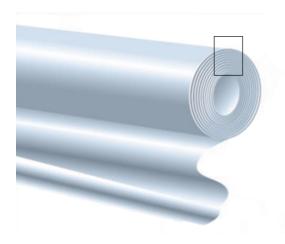
DETAILS EMERGE IN TAINTED NESTLÉ FORMULA SCANDAL

The discovery of contamination in various Nestlé baby food brands has caused a huge stir in Europe. Millions of litres of formula have been pulled from the shelves and a top official in the Italian government has threatened legal action against the corporation's CEO. It is now clear that the contamination was caused by IsopropilThioxanthone (ITX), a fixative of printing ink used on liquid milk cartons (produced by TetraPack, a large company that serves many other food companies for different kinds of foods and beverages). It is also apparent that Nestlé has been less than responsible is recalling potentially contaminated baby formula, prompting government intervention and seizures of the product. This episode demonstrates yet again Nestlé's willingness to preserve its own profits at the expense of infant health, and the inherent dangers presented by mass-produced baby food.

July 2005: First tests of Nestlé ready-to-feed liquid formula in the Marche region of Italy show contamination by ITX. Further tests were ordered on other Nestlé products: Nidina 1 for infants, Nidina 2 for babies 6 to 12 months, Latte Mio and Mio Cereali for children 1 to 3 years.

RAPPEL







← PREVIOUS | NEXT →

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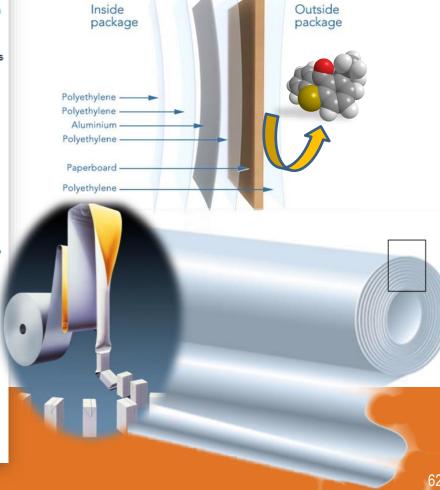
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AlertNet

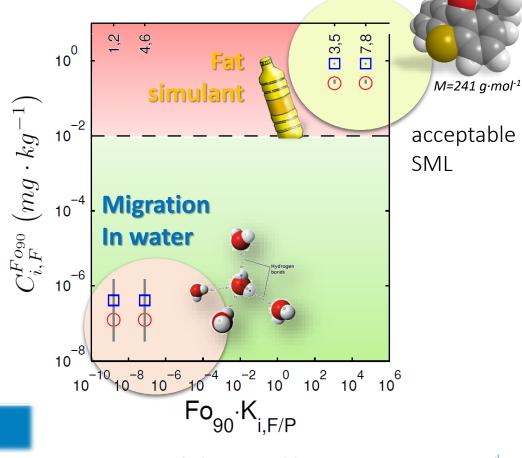
REUTERS



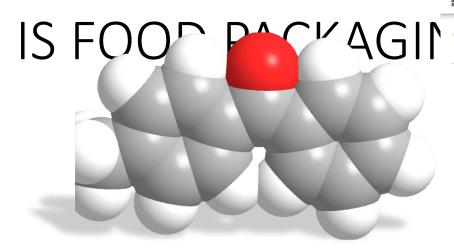
Modeling would have been able to predict ITX values in food?

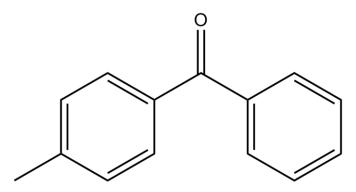
.Food Additives and Contaminants Part a-Chemistry Analysis Control Exposure & Risk Assessment, 2009, 26(12), 1556-1573.

	2-ITX	
	not available	
	Polymer	LDPE ^{††}
PARAMETER	notation (unit)	
Thickness	l _P (µm)	50
Volume dilution ratio	L _{F/P} (-)	360
Biot mass number	Bi (-)	10³
Contact Time	t (days)	90
Temperature	(°C)	4
Likely initial concentration ^a	$\overline{C}_{i,P}^{\scriptscriptstyle 0}$ a (mg·kg-1)	100 ± 10
Conservative initial concentration ^b	$\left(C_{i,P}^{0}\right)^{\!+}{}^{\mathrm{b}}\left(\mathrm{mg}\!\cdot\!\mathrm{kg}^{\!-\!1}\right)$	300
Likely diffusion coefficient	$\overline{D}_{\scriptscriptstyle i,P}$ ° (m².s ⁻¹)	8.4·10 ⁻¹⁶ [7.6·10 ⁻¹⁶ 9.2·10 ⁻¹⁶]
Conservative diffusion coefficient ^d	$D_{i,P}^{+}$ d (m².s ⁻¹)	3.9·10 ⁻¹⁴
Likely partition coefficient	$\overline{K}_{i,F/P}$ (-)	1.4·10 ⁻⁹ [3.7·10 ⁻¹⁰ 5.1·10 ⁻⁹]
Conservative partition coefficient	$K_{i,F/P}^+$ (-)	10³



		Date of case	Last change	Reference	Country	90 ^{·K} i,F/P
	6.	08/09/2005		2005.631	ITALY	food contact materials
RASH PAMAI			migration of isopropyl thioxanthone (250 μg/l) from packaging of milk for babies from Spain			





4-methyl benzophenone



Contact

Accueil > Actu, France > Lidl a rappelé des milliers de boîtes de céréales en février

Lidl a rappelé des milliers de boîtes de céréales en février

02/04/2009



Allez aux commentaires - 🥋 Commenter





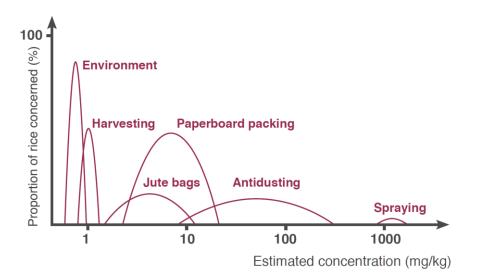
Des milliers de paquets de céréales pour le petit déjeuner "muësli" ont été retirés en février des rayons des 1 400 magasins Lidl de France, suite à la contamination de ces céréales par une composante toxique utilisée dans l'encre des emballages, indique, jeudi 2 avril, Lidl. "Nous avons été informés le 6 février par notre maison-mère qu'il fallait retirer de la vente deux références, des muesli au chocolat et des muesli aux fruits. Les marchandises ont été retirées le 9 février", déclare Jérôme Gresland, directeur des achats de Lidl pour la France, confirmant une information du Canard enchaîné. Des sites comme 60 millions de consommateurs ou rappelsproduits.fr permettent aux

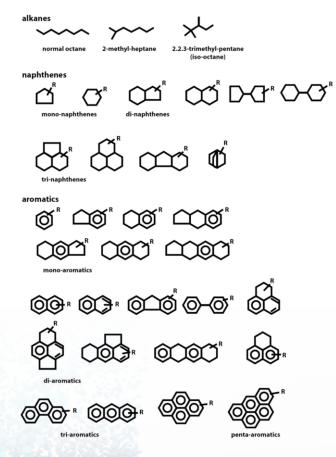
consommateurs s'informer sur les produits - steaks hachés avariés, circuits hydrauliques de voiture défectueux, saucisson contenant des salmonelles - rappelés par les constructeurs et fabricants.

Le signalement de la maison-mère était consécutif à une alerte du système d'alerte européen pour les denrées alimentaires (RASFF), après qu'un contrôle sanitaire a mis en évidence en Allemagne la présence de 4-méthyle benzophénone (4-MBP) dans des céréales, a précisé M. Gresland. L'EFSA a fait savoir le 4 mars que "la consommation régulière de produits fortement contaminés" par la molécule incriminée pouvait présenter "dans des cas extrêmes un risque pour certains enfants". La branche française de Lidl a décidé de son propre chef de retirer les produits de ses rayons, "par précaution", a souligné M. Gresland.

"A aucun moment la Direction générale de la concurrence, de la consommation, et de la répression des fraudes (DGCCRF) ne nous a demandé de procéder à un rappel des produits" déjà vendus, a-t-il dit. "La DGCCRF a pris contact avec nous début mars, trois semaines après le retrait des produits de la vente", a-t-il.





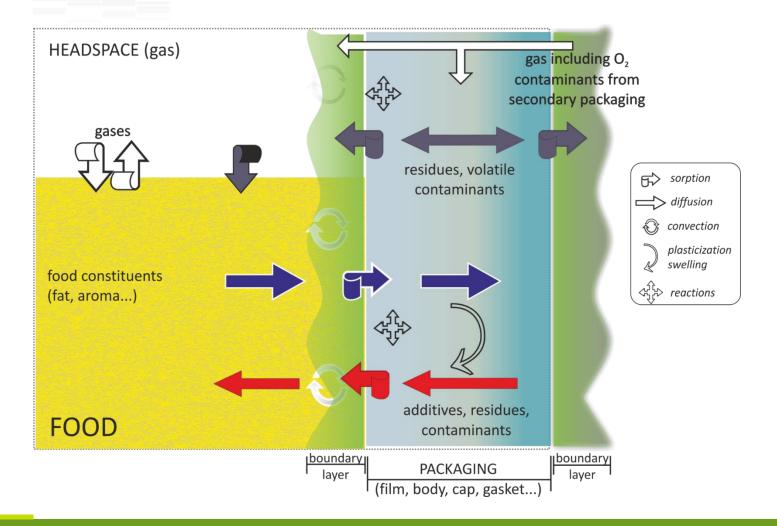


MINERAL OILS



Coupled mass transfer

between the food product and the packaging material





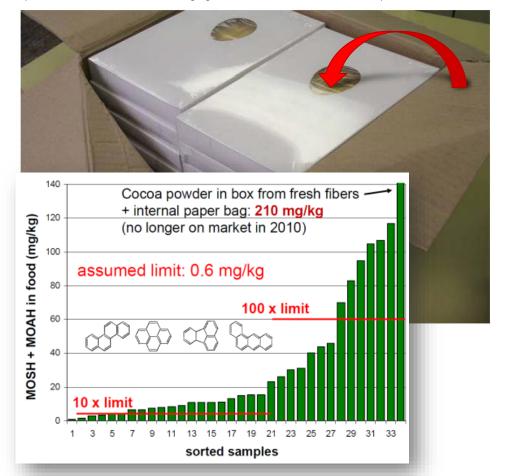
CONTEXT: EXAMPLES NOT COVERED BY SPECIFIC MEASURES: NON-

SPECIFICALLY REGULATED MATERIALS, DRY AND AQUEOUS FOOD FALSELY CONSIDERED SAFE

CONTAMINATION OF NODDLES BY RECYCLED FIBERS OF SECONDARY PACKAGING

After 65 days of contact, 6.1 mg/kg of paraffins found in noodles stored in boxes in top and bottom positions. Estimated migration at shelf life (2 years): 10 mg/kg

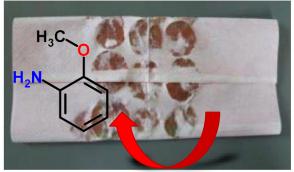
(Biedermann et al., 2011; Packaging Technol & Sci 2011, 24, 281-290)



CONTAMINATION OF FRESH FRUITS BY PRINTED TABLE NAPKIN

Migration of o-anisidine (primary aromatic amine): printed paper 17.5 μ g/l \rightarrow kiwi: 5.3 μ g/l (migration rate: 17 %) (Helling, 2011)





MOH SURVEY

FOOD WATCH - October 2015

SOURCES DE CONTAMINATION DES ALIMENTS PAR LES HUILES MINÉRALES



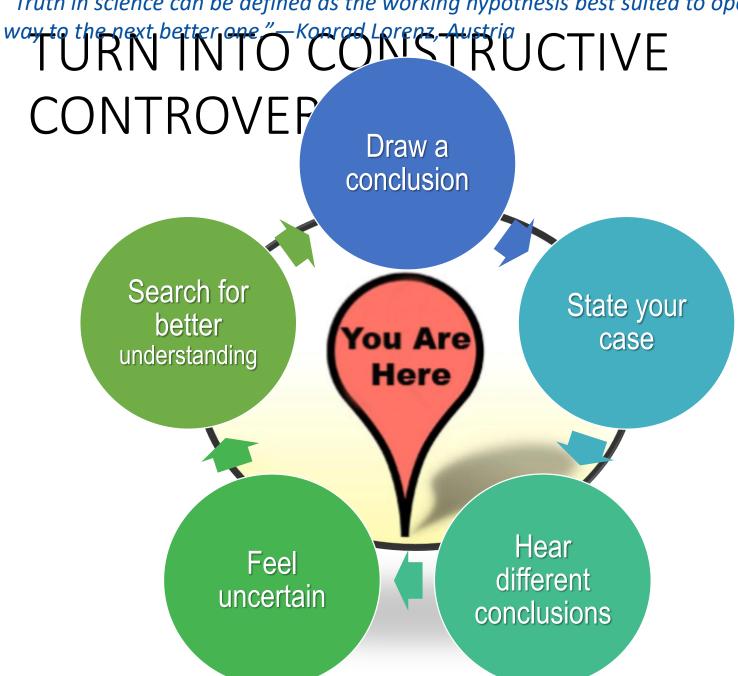




TOXICITY



"Truth in science can be defined as the working hypothesis best suited to open the



theguardian

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News \rightarrow World news \rightarrow Food safety

Chemicals leaching into food from packaging raise safety concerns

Scientists, in BMJ paper, warn of potential long-term damage of exposure to synthetics, including formaldehyde in drinks bottles

Sarah Boseley, health editor

The Guardian, Wednesday 19 February 2014

Jump to comments (449)



Packaged burger and chips. Synthetic chemicals in packaging include phthalates, known to disrupt hormone production. Photograph: Martin Godwin for the Guardian

Synthetic chemicals which are used in the processing, packaging and storing of the food we eat could be doing long-term damage to our health, environmental scientists warn.

The concerns have been raised in the Journal of Epidemiology and Community Health, part of the British Medical Journal group.

The scientists claim that tiny amounts of synthetic chemicals leach into food. While these minute quantities in themselves do no harm, no one knows how safe we are from a lifetime's exposure to the chemicals, such as formaldehyde, through eating food previously wrapped or stored in plastics.

In a commentary piece in the journal the scientists note that some of the chemicals that could cause concern are regulated but this does not prevent their being used widely in food packaging. They say that people who eat packaged or processed foods are likely to be chronically exposed to low levels of these substances throughout their lives.

Far too little is known about the long-term impact and especially about our exposure to such chemicals at critical points in human development, such as in the womb and during early childhood.

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Environment Pollution - Plastic bags

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China's toxic air pollution resembles nuclear winter, say scientists Air pollution now impedina photosynthesis and potentially wreaking havoc on country's food supply, experts warn

Air pollution: European commission launches legal action against the

Air pollution: how big a problem is it for





Geoffrey Kabat

Contributor FOLLOW

I write about the science and politics of health full bio --









How Abysmal Scientific Research Is Used To Scare America's Parents



14 comments, 2 called-out + Comment Now + Follow Comments

Much that is published in scientific journals is of astonishingly poor quality.

We have become accustomed to a steady barrage of reports of hazards lurking in our environment that MAY pose a threat our health and that of our children.

These include, among others, low-level radiation exposure from nuclear power plants and nuclear waste; possible water contamination from hydraulic fracturing; and exposure to a wide range of chemicals, including pesticides and industrial pollutants, in food, water, air, and consumer products.

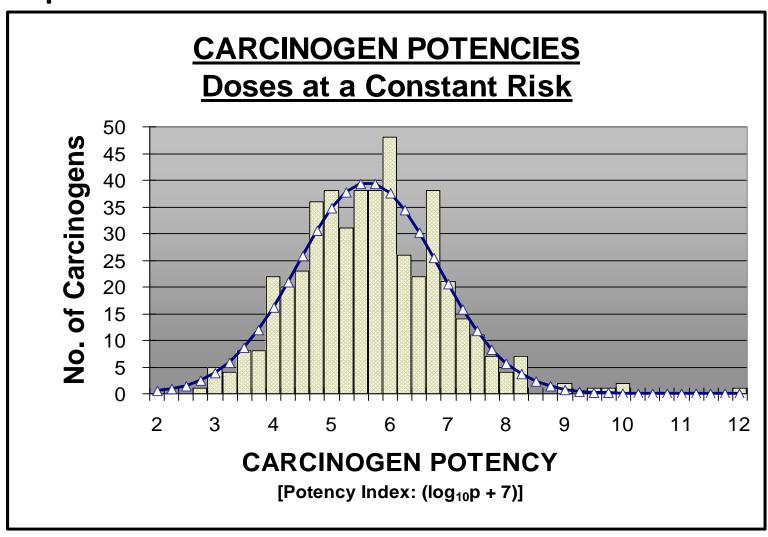
Potential hazards like these need to be studied and will be studied, but the public needs to realize that much that is published in scientific journals, and even in reputable journals, can be of astonishingly poor quality and is of absolutely no relevance to nonresearchers. But, far from these papers being ignored, they often get seized on by the media and high-lighted as if they provided serious, actionable evidence of a hazard.

How can this happen? How do mediocre or plain-wrong studies get accepted for publication in scientific journals? In essence the explanation is simple. Scientists and scientists-in-training need to find questions to work on and need to publish their results in order to put themselves on the map and to advance in their careers. Journals want to publish articles on topics that appear to be important and that will engage readers.

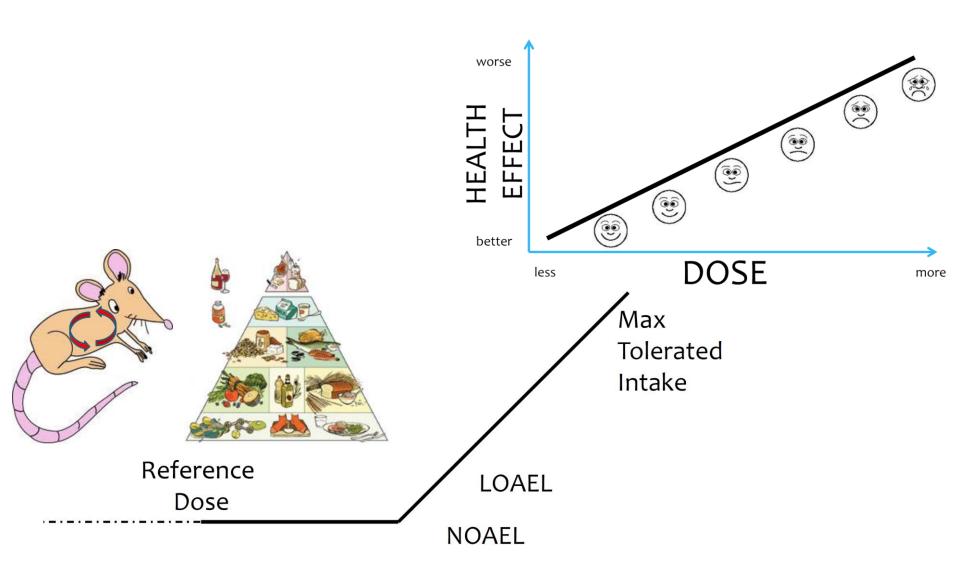
△ CONFERENCES AND MORE

based on acute toxicology concepts





ACUTE TOXICOLOGY



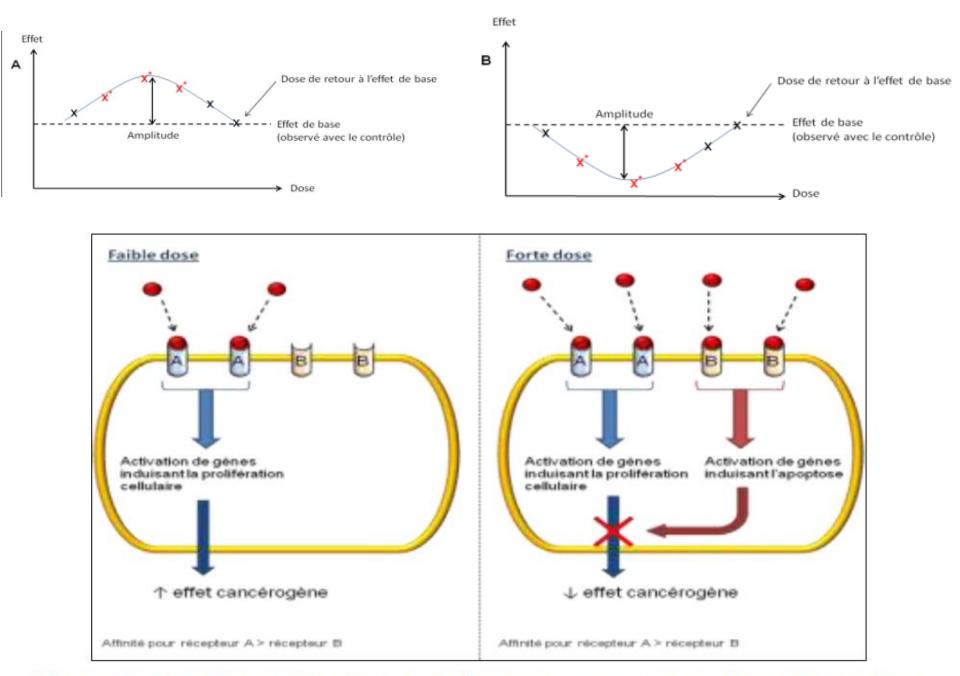
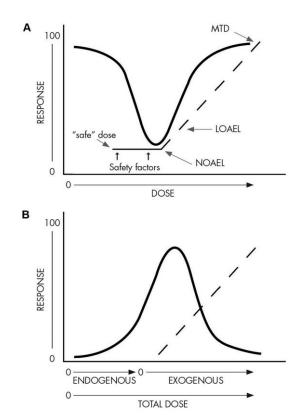


Figure 3 : Equilibre entre effets prolifératifs et pro-apoptotiques selon la dose

800 studies



Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses

Laura N. Vandenberg, Theo Colborn, Tyrone B. Hayes, Jerrold J. Heindel, David R. Jacobs, Jr., Duk-Hee Lee, Toshi Shioda, Ana M. Soto, Frederick S. vom Saal, Wade V. Welshons, R. Thomas Zoeller, and John Peterson Myers

Center for Regenerative and Developmental Biology and Department of Biology (L.N.V.), Tufts University, Medford, Massachusetts 02155; The Endocrine Disruption Exchange (T.C.), Paonia, Colorado 81428; Laboratory for Integrative Studies in Amphibian Biology (T.B.H.), Molecular Toxicology, Group in Endocrinology, Energy and Resources Group, Museum of Vertebrate Zoology, and Department of Integrative Biology, University of California, Berkeley, California 94720; Division of Extramural Research and Training (J.J.H.), National Institute of Environmental Health Sciences, National Institutes of Health, U.S. Department of Health and Human Services, Research Triangle Park, North Carolina 27709; Division of Epidemiology and Community Health (D.R.J.), School of Public Health, University of Minnesota, Minneapolis, Minnesota 55455; Department of Preventive Medicine (D.-H.L.), School of Medicine, Kyungpook National University, Daegu 702-701, Korea; Molecular Profiling Laboratory (T.S.), Massachusetts General Hospital Center for Cancer Research, Charlestown, Massachusetts 02129; Department of Anatomy and Cellular Biology (A.M.S.), Tufts University School of Medicine, Boston, Massachusetts 02111; Division of Biological Sciences (F.S.v.S.) and Department of Biomedical Sciences (W.V.W.), University of Missouri-Columbia, Columbia, Missouri 65211; Biology Department (T.Z.), University of Massachusetts-Amherst, Amherst, Massachusetts 01003; and Environmental Health Sciences (J.P.M.), Charlottesville, Virginia 22902

TABLE 1. Low-dose definitions and cutoff doses: BPA and DEHP as examples

Chemical	Estimated range of human exposures	Doses below the NOAEL	Doses below the LOAEL	Administered doses (to animals) that produce blood levels in typical humans
BPA	0.4–5 μ g/kg · d (679)	No NOAEL was ever established in toxicological studies (38)	<50 mg/kg · d (38)	\sim 400 μ g/kg · d to rodents and nonhuman primates (4, 253)
DEHP	0.5–25 μ g/kg · d (680)	<5.8 mg/kg · d (681, 682)	<29 mg/kg · d (681, 682)	Unknown

Estimates of human exposure are made from consumer product consumption data but do not take into account that there are unknown sources of these chemicals. DEHP, Bis(2-ethylhexyl) phthalate.

Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses

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LOW-DOSE EFFECT SUBSTANCES

TABLE 4. Select examples of EDCs whose potential low-dose effects on animals remain to be studied

Chemical	Use	EDC action	Low-dose cutoff
Antiseptics and preservatives			
Butyl paraben Propyl paraben	Preservative (cosmetics) Antimicrobial preservative found in pharmaceuticals, foods, cosmetics, and shampoos	Estrogenic, antiandrogenic Estrogenic activity	2 mg/kg · d (EPA) LOAEL 10 mg/kg · d, NOEL 6.5 mg/kg · d (Europa)
Cosmetics and personal care products			
2,4-Dihydroxybenzophenone	UV absorber in polymers, sunscreen agent	Estrogenic activity	Not identified
3-Benzylidene camphor	UV blocker used in personal care products	Estrogenic activity	0.07 mg/kg · d (710)
4,4'-Dihydroxybenzophenone	UV light stabilizer used in plastics, cosmetics, adhesives, and optical fiber	Estrogenic activity	Not identified
Benzophenone-2	Used in personal care products such as aftershave and fragrances	Estrogenic activity, changes in T_4 , T_3 , and TSH levels, alterations in cholesterol profile	NOEL 10-333 mg/kg · d (711)
Benzophenone-3 Multiple use (other)	UV filter	Estrogenic, PPARγ activator	200 mg/kg · d (Europa)
Melamine	Flame-retardant additive and rust remover; used to make laminate, textile, and paper resins; metabolite of cyromazine	Affects voltage-gated K ⁺ and Na ⁺ channels and Ca ²⁺ concentrations in hippocampal neurons	63.0 mg/kg · d (FDA)
Resorcinol	Used in the manufacturing of cosmetics, dyes, flame retardants, hair dye formulations, pharmaceuticals, skin creams, and tires	Alters T_4 and TSH levels	80.00 mg/kg · d (Europa)
Pesticides			
Aldrin ^a	Insecticide	Estrogenic activity	0.025 mg/kg · d (Health Canada)
Alachlor	Herbicide	Decreases serum T ₄ , binds PR, weakly binds ER	1 mg/kg·d (EPA)
Amitrole	Herbicide	Decreases thyroid hormone	0.12 mg/kg · d (FAO)
Bitertanol	Fungicide	Alters aromatase	30 mg/kg · d (EPA)
Carbendazim	Fungicide	Affects FSH, LH, and testosterone levels; alters spermatogenesis and Sertoli cell morphology	8 mg/kg • d (712)
Diazinon	Insecticide	Alters glucocorticoids	0.065 mg/kg · d (CDC)
Endrin ^a	Insecticide	Stimulates glucocorticoid receptor	0.025 mg/kg · d (CDC)
Fenoxycarb	Insecticide	Alters acetylcholinesterase	260 mg/kg · d (CDC)
Mirex ^a	Insecticide	Decreases testosterone levels	0.075 mg/kg · d (CDC)
Zineb	Fungicide	Alters T ₄ and dopamine levels	LOAEL 25 mg/kg · d (EPA)
Ziram Resins	Fungicide	Alters norepinephrine levels	1.6 mg/kg · d (EPA)
Bisphenol F	Used in polycarbonates	Alters T ₄ , T ₃ , and adiponectin levels, has estrogenic activity	LOAEL 20 mg/kg · d (713)
Styrene	Precursor to polystyrene	Alters dopamine	200 mg/kg · d (EPA)

• HIGH DOSE: 10 000 PPB EXPOSURE • LOW DOSE: 1 PPB EXPOSURE





Newbold RR, Padilla-Banks E, Jefferson WN, Heindel JJ 2008 Effects of endocrine disruptors on obesity. Int J Androl 31:201-208

CONTROVERSY O

Nat. Rev. Endocrin. 6 (2010), 237

Editorial

Nature Reviews Endocrinology 6, 237 (May 2010)

Subject Category: Epidemiology

The perils of plastic

Vicky Heath About the author

A 'round-robin' spam e-mail that is circulating on servers worldwide claims that drinking bottled water that has been left in a warm car can cause breast cancer. Is this warning just an urban myth or does it hold a grain of truth? The FDA, it seems, is erring on the side of caution; earlier this year, the organization revised its position on the safety of bisphenol A (BPA), a chemical used in the manufacture of plastics. Previously deemed safe for food-contact use, the FDA has now expressed "some concern" about the potential health risks that BPA poses to fetuses, infants and young children.

ENDOCRINOLOGY

66The plastics industry has a responsibility to ensure that its products are safe..."

Is society compromising its health for the conveniences of modern living? Industrial chemicals, such as BPA, are literally everywhere: in homes, in the workplace, even the great outdoors. They cannot possibly all be avoided. Given the current recommendations of the FDA and the Endocrine Society, a multidisciplinary approach is clearly needed—one that involves scientists, clinicians, policy makers and the chemicals industry—with the aim of gathering reliable data to form the basis of national and international public-health policies. In the meantime, the use of plastics and other man-made substances should be closely monitored in groups known to be at the greatest risk. Perhaps that e-mail is not spam after all.



Water Research 46(2012), 571-583



[...]

Genotoxic and estrogenic activities in PETbottled water have been reported. Chemical mixtures in bottled water have been suggested as the source of these toxicological effects. [...]

Formaldehyde, acetaldehyde and antimony are clearly related to migration from PET into water. However, several studies have shown other theoretically unexpected substances in bottled water. The origin of these compounds has not been clearly established (PET container, cap-sealing resins, background contamination, water processing steps, NIAS, recycled PET, etc.).

[....]

ESTROGENIC COMPOUNDS FROM PET??

MABC Science

△ Recherche

2 RECENT STUDIES (Italian and German) on drinking water turbateurs endocriniens: restons vigilants»

1) involving a recombinant yeast-based in vitro assay (March 2009 in International Journal of Hygiene and Environmental Health) → estrogenic activity was assessed in 30 PET-bottled mineral water samples. Ninety percent of the samples tested negative for estrogenic activity. Of the remaining samples, most showed measurements corresponding to a range of 14–23 ng/L estradiol equivalents—similar to the estrogen burden posed by treated drinking water derived from groundwater and river water (15 and 17 ng/L estradiol equivalents, respectively).

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2) Involving mud snails (*Potamopyrgus antipodarum*) (10 March 2009, Environmental Science and Pollution Research) → PET-housed snails produced up to twice as many embryos as glass-housed snails..

RPA and phthalates do

"What we found was really surprising to us." says Wagner.

Common plastic ingredient linked to birth defects. Science Online, 01 Apr 2003

Reference = glass bottle water with same water.

The study adds to growing concerns about products that

epidemiologist at the University of Rochester School of Medicine and Dentistry in New York.

"This is coming at a good time because the use of bottles for consuming water is getting very bad press now because of its carbon footprint," she says. "It's just another nail in the coffin of bottled water, the way I see it."

Wagner and a colleague used genetically engineered yeast to analyse 20 samples of mineral water. Nine samples came out of glass bottles, nine were bottled in PET plastic and two were in cardboard, juice-like boxe

The specialised yeast, which change colour in the presence of estrogen-like compounds, revealed estrogenic activity in seven of the nine plastic bottles (and both cardboard samples), compared with just three of the nine glass ones.

Overall, Wagner says, levels of these compounds in the water were surprisingly high

thyroīde qui seraient l
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Plusieurs centaines de substances sont actuelleme

raugmentation du niveau d'obésité dans les populations occidentales.
Plusieurs centaines de substances sont actuellement classées parmi les perturbateurs endocriniens.

Où les trouve-t-on ?

Ces molécules sont principalement détectées dans l'eau, puis dans toute la chaîne alimentaire. De plus, comme viennent de le montrer Martin Wagner et Jörg Oehlmann de l'université Goethe de Frankfort [1], peut-être aussi dans le plastique des bouteilles d'eau minérales en polyéthylène téréphtalate (PET).



RISK ASSESSMENT





European Food Safety Authority

INRA

http://www.efsa.europa.eu

Scientific Committee

Senior scientists, with experience of work within scientific bodies, covering all disciplines across EFSA's areas of responsibility.

CONTAM



Panel on Contaminants in the Food Chain

Experts in chemistry, exposure assessment, toxicology, epidemiology, and statistics

Panel on Animal Health and Welfare Experts in toxicology, toxicity, epidemiology, chemistry, exposure assessment, and microbiology.

Panel on Food Additives and Nutrient

Sources Added to Food Experts in toxicology, toxicity, epidemiology, chemistry, exposure assessment, and



Panel on Biological Hazards Experts in epidemiology, microbiology, pathology, and exposure assessment.





Panel on Food Contact Materials, **Enzymes, Flavourings and Processing** Aids

Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids





Panel on Genetically Modified Organisms Experts in food and feed safety assessment, environmental sciences, molecular characterisation, and plant science.



Panel on Dietetic Products, Nutrition and Allergies Experts in nutrition, human medicine,

exposure assessment, toxicology



Panel on Plant Health Experts in pest risk assessment, plant pathology, epidemiology, and ecology.



Panel on Additives and Products or Substances used in Animal Feed Experts in animal nutrition, toxicology, microbiology, exposure assessment, and



Panel on Plant Protection Products and their Residues Experts in chemistry, toxicology,



> 60% of ingested Chemicals are coming from Packaging (exposome)

Compliance
(contaminations)
of 70% of plastics
tested by
Modeling

Contaminations from non-plastic Materials not considered

CIRCULAR ECONOMY VS SAFETY



Workshop "Predicting the safety of food contact articles" - New science and digital opportunities 4 October 2018, Zurich, Switzerland

https://www.foodpackagingforum.org/events/predicting-the-safety-of-food-contact-articles-new-science-and-digital-opportunities





REGULATION



PRINCIPLES OF FOOD INERTIA: A LONG HISTORY

L'ART DE CONSERVER.

8 a. Année. — Nº 19

JUILLET 1910

PE I

LA CONSERVE ALIMENTAIRE

TOUTE

Rulletin mensuel de Vulgarisation Théorique et Pratique de Fabrication

Bedige par un groupe de Habricants-Industriels et de Chefs d'Emplois de cette Industrie

Ouvr Mani stir l

Proprie ancie la M



Nicolas APPERT (1750-1841)

École Nationale D'INDUSTRIE ALIMENTAIRE

Nicolas Appert

COMITÉ DE DIRECTION
Bourse du Commerce

- Paris -

CHEZ P

L'idée de la création de cette école dont nous avons été les plus fervents propagandistes vient d'être mise définitivement au point par un groupe de praticiens, de chimistes et d'agronomes distingués qui vont en assurer le fonctionnement. L'enseignement sera tout à la fois théorique et pratique.

Dans la voie pratique, le Comité de Direction se propose, non pas d'organiser une usine de fabrication de conserves et de produits alimentaires divers, destinée à concurrencer l'industrie libre, mais de créer des laboratoires d'essais et d'enseignement que dirigera un praticien qualifié et où chaque fabricant pourra venir se documenter et concourir aux progrès de la science alimentaire

Les essais théoriques seront dirigés par un technologue éminent, M. Crolbois, chef de laboratoire à l'Institut Pasteur.

Une très large place sera réservée, dans l'enseignement à la question des machines, appareils et ustensiles employés par l'Industrie alimentaire. Un ingénieur diplòmé, M. RAY-MONO MONOT, des usines de Diétrich, est chargé d'organiser cette partie du programme.

M. Moréal de Brévans, le distingué sousdirecteur du laboratoire municipal, a bien voulu se charger de l'enseignement si important de la chimie appliquée à l'alimentation.

Enfin M. Ed. Jacquet, ingénieur-agronome, administrateur de l'école, occupera la chaire de professeur d'« Alimentation Commerciale ».

Ajoutons que notre bulletin transformé en revue bi-mensuelle à laquelle collaboreront désormais les personnalités ci-dessus, devient le Bulletin Officiel de l'Ecole.

En un mot et suivant l'exemple d'autres pays, une l'niversité nouvelle et bien moderne vient de naître en France, celle de l'Industrie Alimentaire. Cette industrie quitte ainsi, définitivement, le domaine empirique pour rentrer dans celui des sciences exactes, où elle avait LA CONSERVE ALIMENTAIRE

sa place déjà marquée par les exigences et le progrès sans cesse grandis-ants de la vie contemporaine.

290

Pour le Comité de Direction : Aug. Corthay.

Causerie Professionnelle

par Nicolas APPERT

Méfions-nous des Conserves Étrangères

Nous donnons ci-dessous la traduction d'un extrait du passage que M. Hamel consacre à la législation et l'inspection des conserves alimentaires au Canada, dans le traité qu'il publie en ce moment. (Modern practice of canning meats):

« Comparés avec les règlements qui régissent l'inspection des conserves alimentaires aux Etats-Unis et en Europe, ceux du Canada sont encore à l'état embryonnaire.

Pour protéger les fabricants Canadiens contre la concurrence des Etats-Unis, il était nécessaire de créer une législation, au moins sur le papier.

- « Je ne parle pas ici de l'inspection des viandes fraiches qui est soumise à un groupe de savants et de vétérinaires de valeur.
- « Mais l'acheteur éclairé de conserves alimentaires quelles qu'elles soient, viandes, poissons, fruits ou légumes est loin d'avoir obtenu la mêm. sécurité.

«Le règlement en date de 1908 qui régit l'ins-

pection des conserves alimentaires nous dit:
Aucune substance alimentaire ne doit contenir
de produit nuisible, produits chimiques, colorants ou antiseptiques, et plus loin on noudit: Il sera fourni aux Inspecteurs par les
soins du Ministère de l'Agriculture les noms
des antiseptiques et colorants inoffensifs dont
l'emploi est permis. L'addition de tout autre
empèchera le produit de recevoir l'étiquette
constatant l'inspection.

- « Nous comprenons bien que les chimistes du Ministère sont là pour condamner tout produit alimentaire où l'analyse révèlerait la présence d'un produit chimique dangereux, mais pour ceux qui sont au courant des discussions en cours entre les hygiénistes les plus distingués du monde entier au sujet de la plus ou moins grande nocivité de tel ou tel antiseptique, la satisfaction est maigre.
- « Je répète que le fabricant de conserves en bottes n'a pas besoin d'antiseptiques pour assurer la conservation indéfinie de ses produits. La stérilisation lui suffit.
- « Pourquoi donc ne pas faire comprendre au monde entier que les mots « CANADA APPROVED » de l'étiquette signifient absence entière de susbstances nuisibles, aussi bien dans les conserves que dans les viandes fraiches.
- « Que si quelques antiseptiques sont considérés comme inoffensifs par le Ministère de l'Agriculture, pourquoi ne pas faire connaître au public comme aux fabricants le nom de ce qui est permis et de ce qui est prohibé?
- « Le règlement de 1908 ne prend nullement en considération la qualité de la soudure employée, pas plus que celle de l'acide, et il semble que sur ce point les japonais sont bien en avance sur nous lorsqu'ils donnent les commandes pour leur armée.
- « Pour en finir, il semble que des instructions plus complètes auraient été pour le plus grand intérêt du fabricant lui-même, en donnant au public consommateur une garantie parfaite de sécurité. La consommation en aurait été accrue en regagnant la confiance des consommateurs qui sont peu confiants dans les conserves, généralement sans raisons, d'ailleurs. »

G. T. HAMEL, ingénieur.

L'auteur faisant une œuvre purement technique et non de polémique est évidemment très modéré. Mais pour qui lit entre les lignes et pour nous qui savons combien sont rares parmi le personnel de l'inspection les gens compétents, toutes les places étant prises par les politiciens, nous ne nous sentons pas rassu-



YOUR ROLE

	ASSESSMENT
RUI	ASSESSIVIENT
	AUGEOUNEIT

		Risk balancing	Conflicts
role	Scientifc risk assessment	Conflict Evaluative	cognitive, evaluative, normative
Routine	Conflict: cognitive	Targets: BFR Risken erkennen – Gesundheit schützen OLAMUS SAMPLERIORER DI SAMPLERIORER	Targets:DG SANCO, industry stakeholders
Target: industry	Target: professional associations	FOOD STANDARDS AGENCY European Food Safety Authority	
Discourse: internal	Discourse: cognitive	Discourse: reflective	Discourse: participatory
Outcome: simple	Outcome: complex	Outcome: uncertain	Outcome: ambiguous



Risk Tradeoff

WHAT IS RISK?

Risk is a function of perception and representation





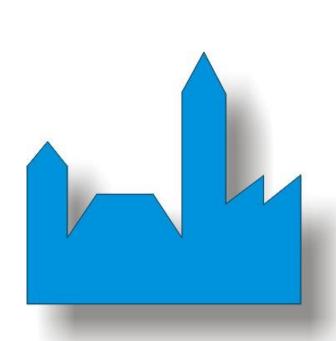


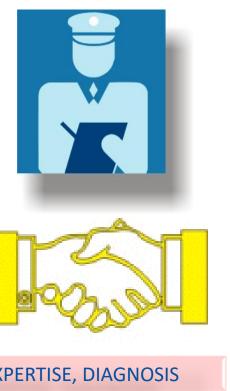






REGULATION=TRANSFER OF RESPONSABILITIES











FOOD

https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials_en

European Commission > Food Safety > Food > Chemical safety > Food Contact Materials

HEALTH

FOOD

ANIMALS

PLANTS

CHEMICAL SAFETY

Contaminants

Residues of Veterinary Medicines

Hormones in Meat

Pesticide Residues

Food Contact Materials

Legislation

Authorisations

Non-harmonised

Consultation

ALL TOPICS



Food comes into contact with many materials and articles during its production, processing, storage, preparation and serving, before its eventual consumption. Such materials and articles are called Food Contact Materials (FCMs). Food contact materials are either intended to be brought into contact with food, are already in contact with food. or can reasonably be brought into contact with food or transfer their constituents to the food under normal or foreseeable use. This includes direct or indirect contact. Examples include:

- · containers for transporting food
- machinery to process food
- · packaging materials
- · kitchenware and tableware

The term does not cover fixed public or private water supply equipment.

FCMs should be sufficiently inert so that their constituents neither adversely affect consumer health nor influence the quality of the food. To ensure the safety of FCMs, and to facilitate the free movement of goods, EU law provides for binding rules that business

The EU Rules on food contact materials can be of general scope, i.e. apply to all FCMs or apply to specific materials only. EU law may be complemented with Member States national legislation if specific EU rules do not exist.

The safety of FCM is evaluated by the European Food Safety Authority (EFSA). At EFSA's website you can search for opinions on substances to be used in food contact

The safety of Food Contact Materials is tested by the business operators placing them on the market, and by the competent authorities of the Member States during official controls. Scientific knowledge and technical competence on testing methods is being maintained by the European Reference Laboratory for Food Contact Materials (EURL-FCM). Its website provides guidelines and other resources concerning the testing of food contact materials.

Principles for EU legislation

Union legislation on food contact materials at EU level aims to:

- Protect consumers' health
- . Ensure the effective functioning of the internal market

Contacts

- SANTE-fcm@ec.europa.eu
- · European professional organisations
- . European Reference Laboratory on Food Contact Materials (EURL-FCM)
- · European Food Safety Authority

Training

For government officials engaged in food and feed safety inspection of selected countries training on food contact materials is provided free of charge under BTSF. Also refer to the European Training Platform for Safer Food.

Share

RELATED LINKS

- Food Contact Materials <u>Database</u>
- Multi-language versions of brochures and guidance

RELATED DOCUMENTS

- EU guidelines on conditions and procedures for the import of polyamide and melamine kitchenware originating in or consigned from China and Hong Kong J
- EU Guidance to the Commission Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food J

OUICK LINKS



Rapid Alert for Food and Feed (RASFF)



Health and food audits and analysis



European Food Safety Authority (EFSA) Better Training for Safer



Food (BTSF)



F-News



Legislation

I. General legislation

The framework Regulation

Regulation (EC) No 1935/2004 provides a harmonised legal EU framework. It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs).

The principles set out in Regulation (EC) No 1935/2004 require that materials do not:

- · Release their constituents into food at levels harmful to human health
- · Change food composition, taste and odour in an unacceptable way

Moreover, the framework provides:

- · for special rules on active and intelligent materials (they are by their design not
- · powers to enact additional EU measures for specific materials (e.g. for plastics)
- · the procedure to perform safety assessments of substances used to manufacture FCMs involving the European Food Safety Authority
- · rules on labelling including an indication for use (e.g. as a coffee machine, a wine bottle, or a soup spoon) or by reproducing the appropriate symbol. For more information, please refer to the following document on Symbols for labelling food contact materials.
- for compliance documentation and traceability

Regulation on Good Manufacturing Practices

Regulation (EC) No 2023/2006 ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation:

- · premises fit for purpose and staff awareness of critical production stages
- · documented quality assurance and quality control systems maintained at the
- · selection of suitable starting materials for the manufacturing process with a view to the safety and inertness of the final articles

Good manufacturing rules apply to all stages in the manufacturing chain of food contact materials, although the production of starting materials is covered by other legislation.

II. EU legislation on specific materials

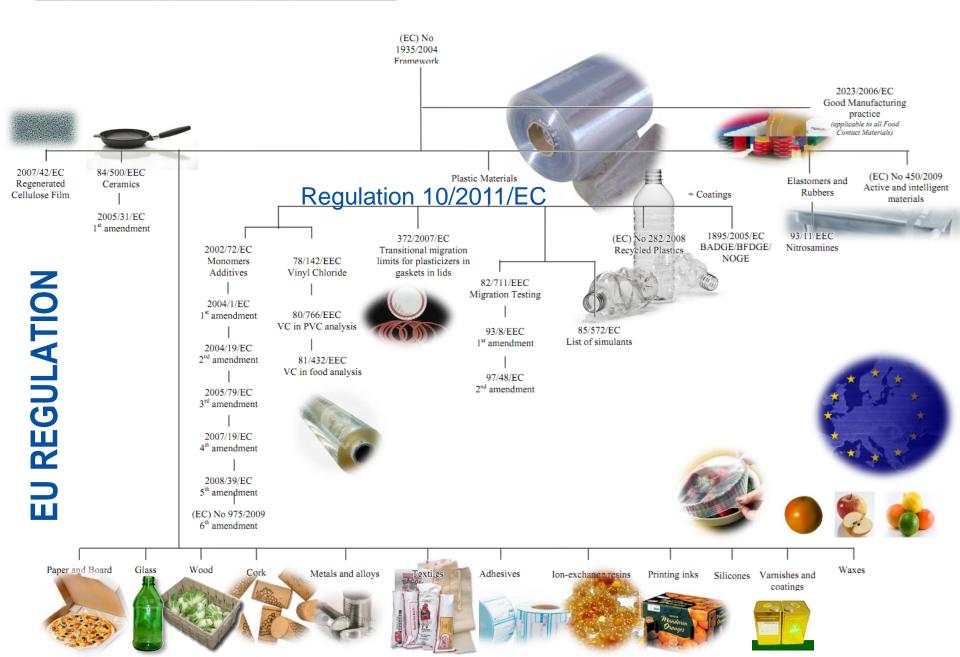
In addition to the general legislation, certain FCMs — ceramic materials, regenerated cellulose film, plastics (including recycled plastic), as well as active and intelligent materials - are covered by specific EU measures. There are also specific rules on some starting substances used to produce FCMs.

Plastic Materials	
Active and Intelligent Materials	
Recycled Plastic Materials	
Ceramics	
Regenerated Cellulose Film	

III. Other Legislation

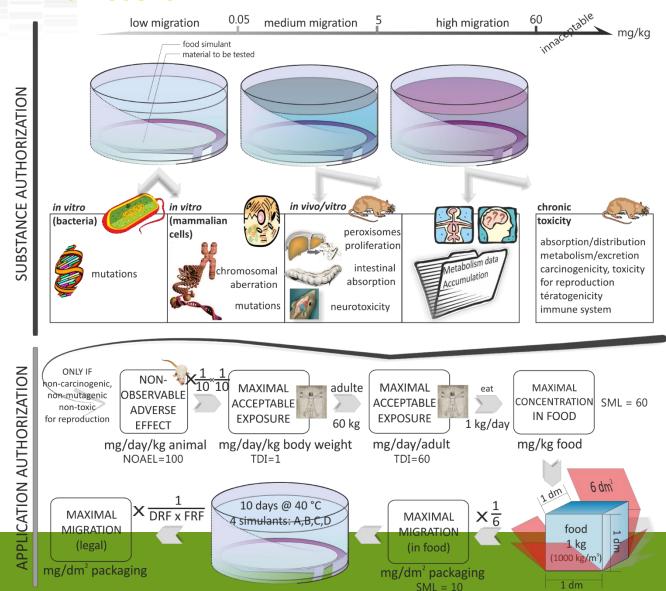
Legislation on Specific Substances

- · Regulation 1895/2005/EC restricting use of certain epoxy derivatives in materials and articles intended to come into contact with food
- . Directive 93/11/EEC release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers



SPECIFIC RULES FOR PLASTICS

COMPLIANCE ISSUES





Risk assessment vs risk management

502 substances (including 230 monomers and 272 additives) among the 937, which are positively listed in EU directives on plastics in contact with food, are subjected to (SML)

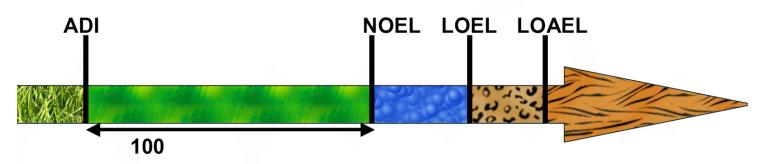
EFSA: Risk Assessment

ADI = NOEL/100 (per kg body weight)

DG SANCO: Risk Management

SML= 60 * ADI (mg intake per person per day

from an assumed 1 kg packaged food)



ADI = Acceptable Daily Intake NOEL = No Observed Effect Level

SML = Specific Migration Level LOEL = Lowest Observed Effect Level

LOAEL = Lowest Observed Adverse Effect Level



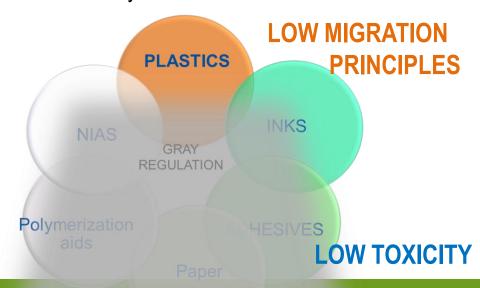
SPECIFIC EU RULES FOR PLASTICS FOR FOOD CONTACT

Materials can be regulated alone or in combination with other materials

- list of substances
- purity standard for substances
- overall migration limits: OML (60 mg/kg or 10 mg/dm²)
- specific migration limits: SML
- other rules ensuring safety and inertness
- compliance, sampling, analytical methods, migration modeling
- traceability
- declaration of compliance

Plastic materials

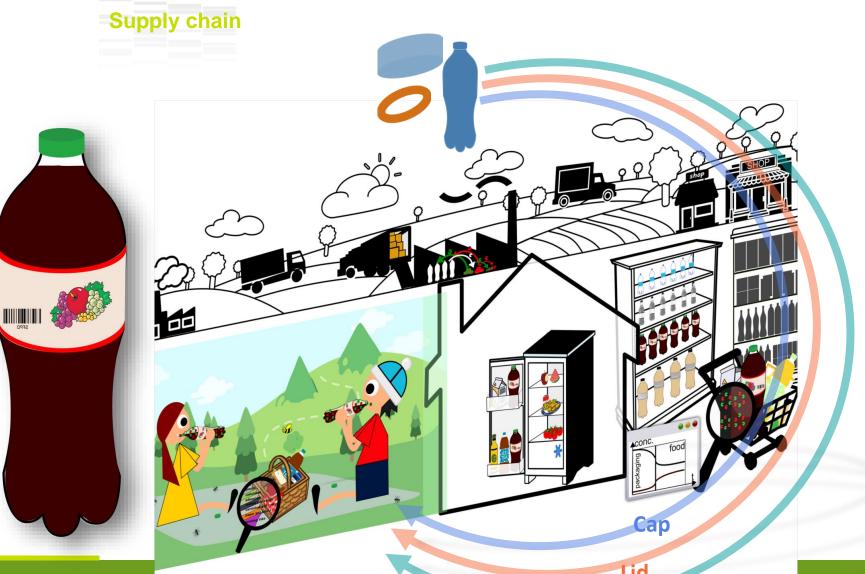
- exclusively plastics
- Plastic multilayers or layers tied with adhesives
- Plastic layers, coatings forming gaskets
- Plastic layers in multi-materials





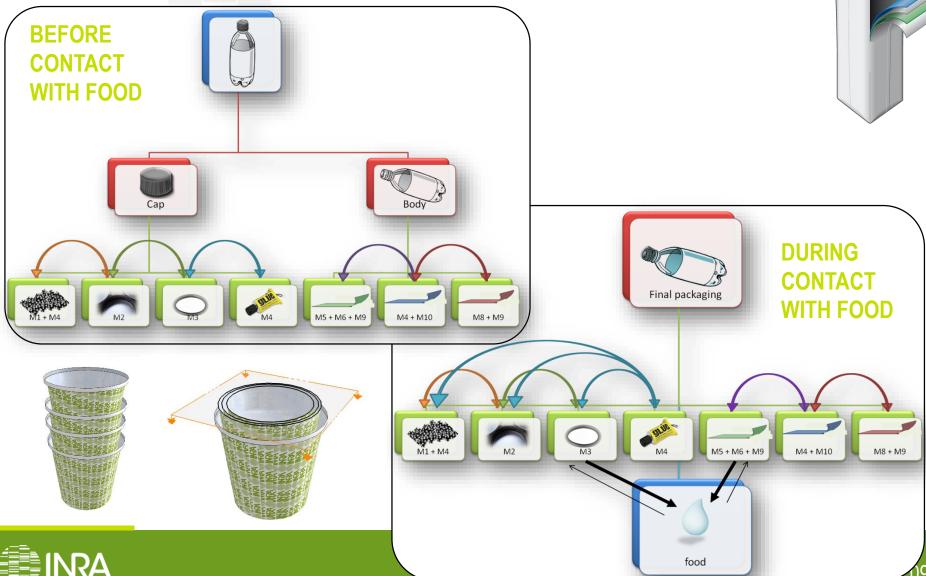


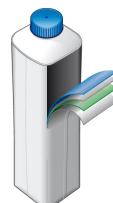
CHAINED STEPS, COMBINED MATERIALS





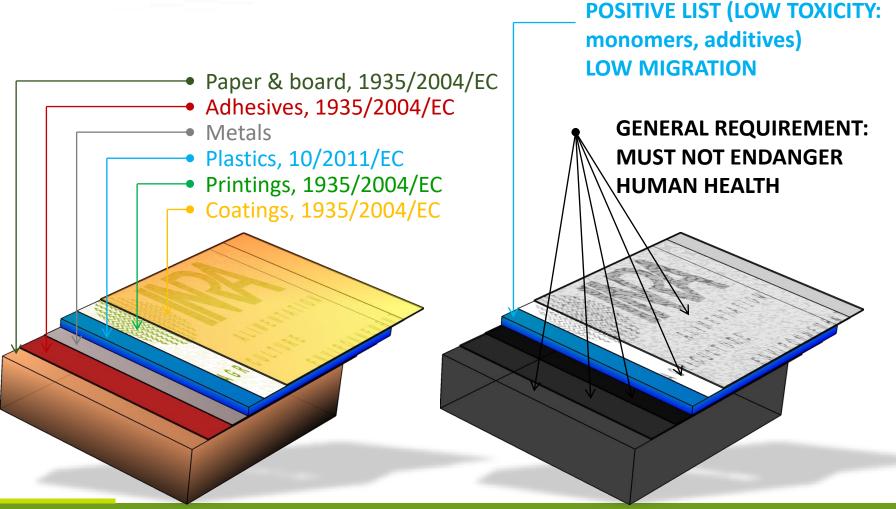
CROSSED-MASS TRANSFER BETWEEN MATERIALS



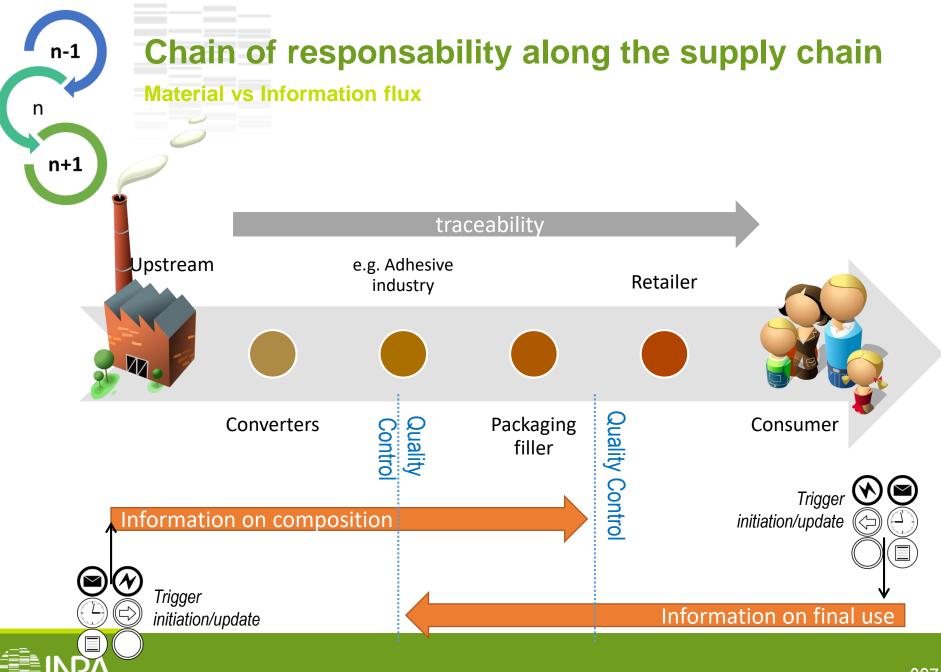


HETEROGENEOUS EU REGULATIONS

Variable concepts









Home > Law > Law-making process > Planning and proposing law > Impact assessments

Impact assessments

Impact assessments examine whether there is a need for EU action and analyse possible impacts of available solutions. These are carried out during the preparation phase, before the Commission finalises a proposal for a new law. They provide evidence to inform and support the decision-making process.

PAGE CONTENTS

The need for impact assessments

Better law-making

How to contribute

Cooperation between EU institutions

Subsidiarity and proportionality

The need for impact assessments

Impact assessments are carried out on initiatives expected to have significant economic, social or environmental impacts. These can be:

- legislative proposals
- non-legislative initiatives (e.g. financial programmes, recommendations for the negotiations of international agreements)
- · implementing and delegated acts



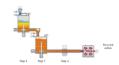




EFSA has issued upward of 140 positive scientific opinions on the safety of processes to recycle plastics for use in food contact material.



ONLY recycled PET is authorized in EU.



500 M€ have been invested in plants capable of converting recycled plastic materials into materials suitable for packaging and food contact applications

In 2014, more than 50% of the recycled PET in Europe was used in food contact applications.



The lack of harmonisation amongst Member States generates legal uncertainty and unnecessary burden for the industry using recycled materials.

It also sets up obstacles for the Circular Economy

Recyling plastics for food contact







Misuse issues (post-use contaminations) of Polyethylene terephthalate (PET) can be easily handled : glassy polymer, it is mainly contaminated by small contaminants which can be removed by a devolatilization step above T_q

1. Filling and use of HDPE milk bottles
2. Recollection
3. Sorting

Recycling

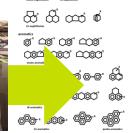
Foodgrade HDPE milk bottles

Contact in Judy layout 21 Judy la

Polyolefins are rubber polymers which can be easily contaminated by high molecular weight contaminants after use.







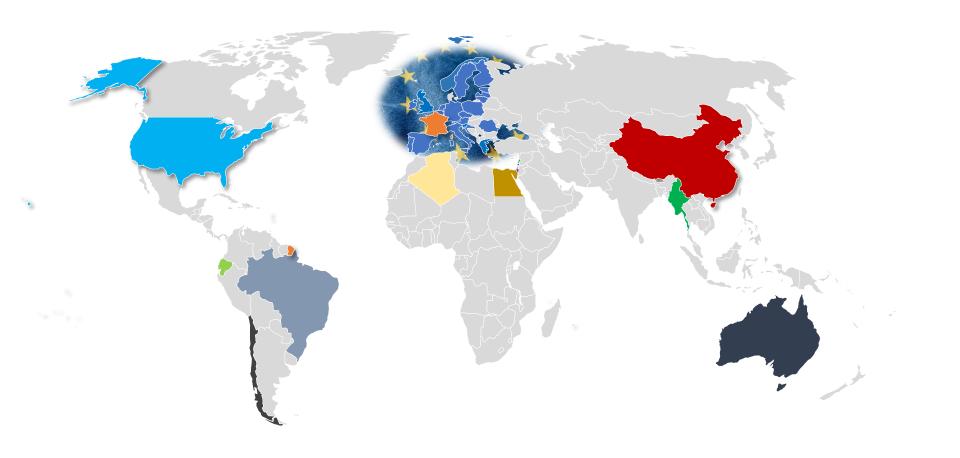
Paper and board contains large amount of residues from printing inks: aromatic (carcinogenic) and aliphatic mineral oils can be transferred without contact and lead to cross-contamination between materials

J. of Chromatography A. 2013;**1293:107-19.**

RECYCLED PET FOR FOOD CONTACT IS ATHORIZED (282/2008/EC)
RECYCLED POLYOLEFINS IS AUTHORIZED ONLY IN GERMANY
RECYCLED PAPER AND BOARDS IS SOURCE OF RECURING CRISES IN EU







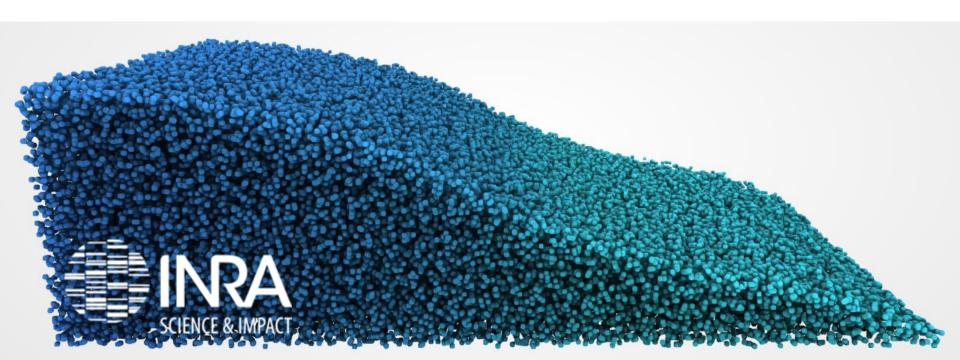
Our approaches developed jointly with EU are a model for several countries and industries (medical devices, biotechnology, cosmetics...





DIFFUSION IN POLYMERS

OVERVIEW, BARRIER PROPERTIES, MIGRATION ISSUES

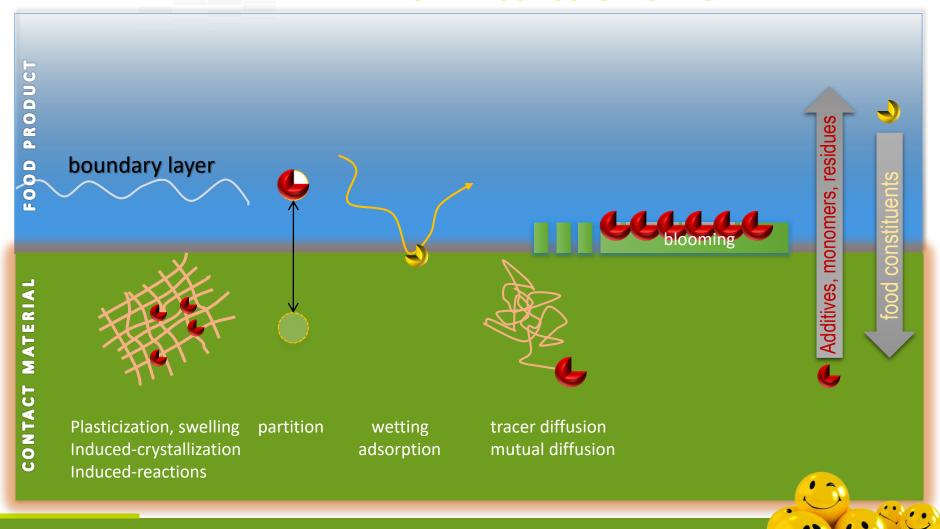




MIGRATION ISSUES

CROSSED MASS TRANSFER OF FOOD CONTACT MATERIALS AND FOOD CONSTITUENTS

16/01/2020





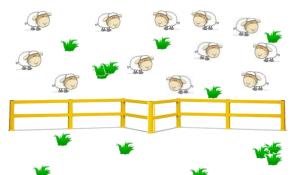


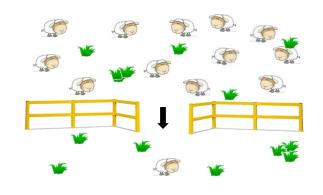
 $t_0 = 0$ hour

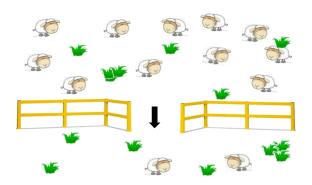
 $t_1 = 10$ hours

= 30 hours

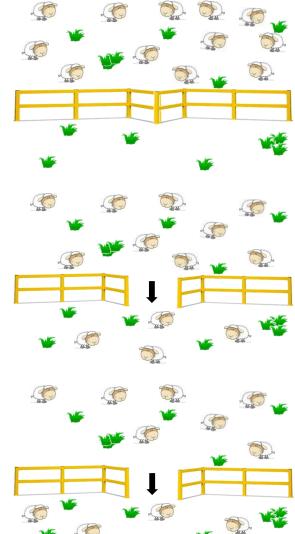


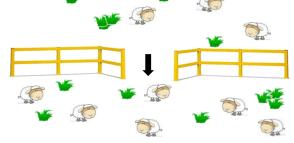




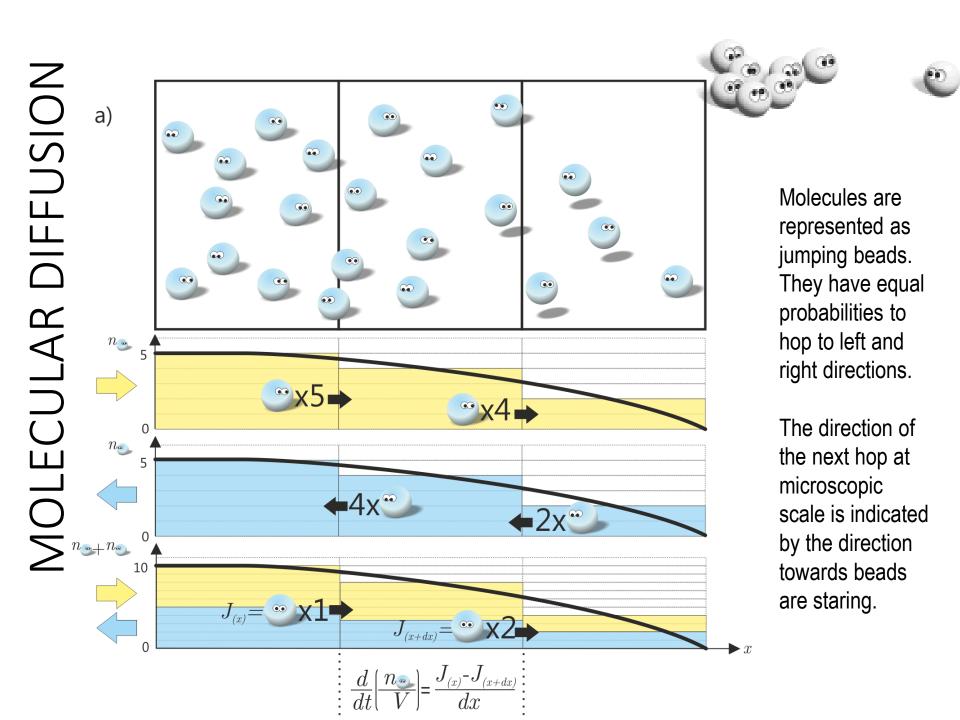




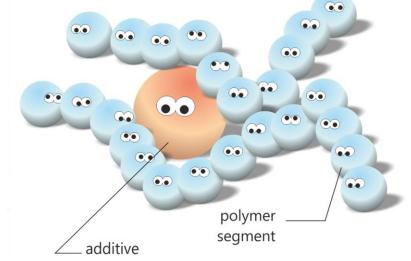


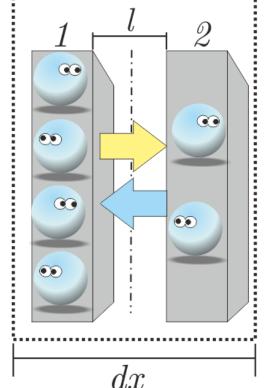






Mutual diffusion of additive Among polymer segments





$$j_{\bullet} = \mathbf{v} \cdot n^{1} = \frac{1}{2} \cdot \mathbf{v} \cdot n^{1}$$

$$j_{\bullet} = \mathbf{v} \cdot n^{2} = \frac{1}{2} \cdot \mathbf{v} \cdot n^{2}$$

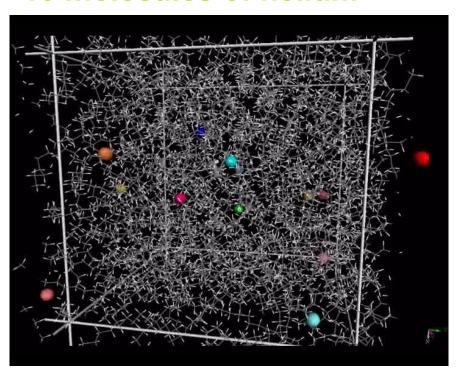
$$\frac{d}{dx} c_{\bullet} = \frac{n^{2}}{l} / l - n^{1} / l$$

$$J = j_{\bullet} - j_{\bullet} = -\frac{1}{2} \cdot \mathbf{v} \cdot l^{2} \cdot \frac{d}{dx} c_{\bullet}$$

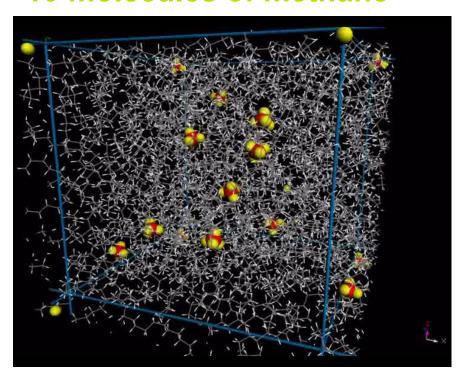
Interpretation of the net flux J (first Fick Law) as the microscopic exchange of molecules at frequency v between states 1 and 2 separated by a distance dx.

DIFFUSION IN POLYETHYLENE (0.5 NS SIMULATION, T=298 K)

10 molecules of helium



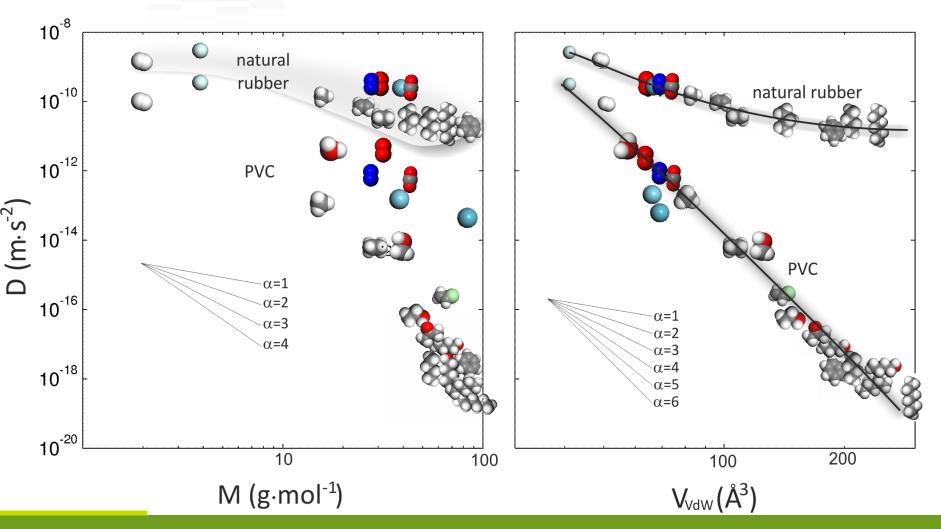
10 molecules of methane





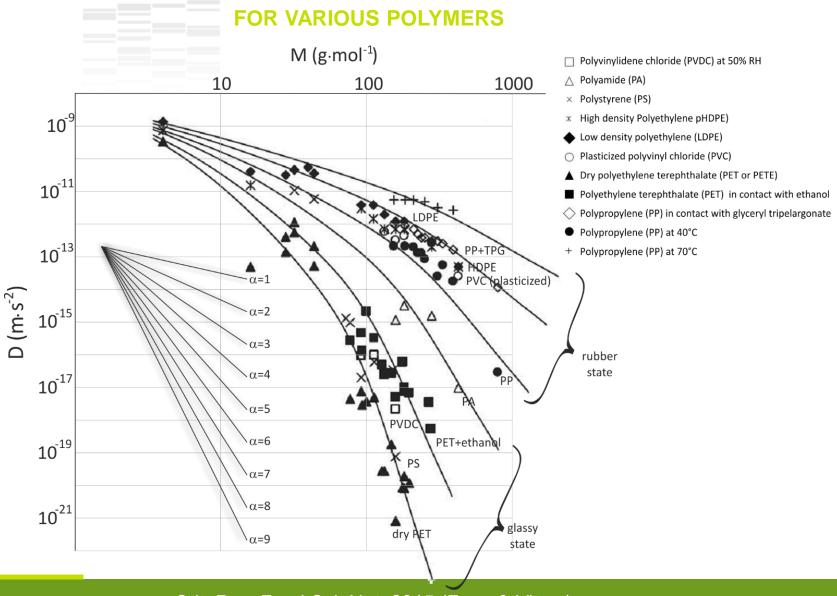
SCALING D WITH SOLUTE SIZE

STIFF DIFFUSANTS





SCALING EXPONENTS

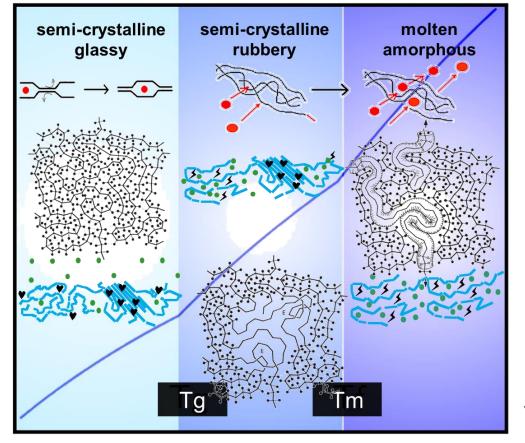




ACTIVATION OF DIFFUSION BY TEMPERATURE

BELOW TG, ABOVE TG

log(D)





Т



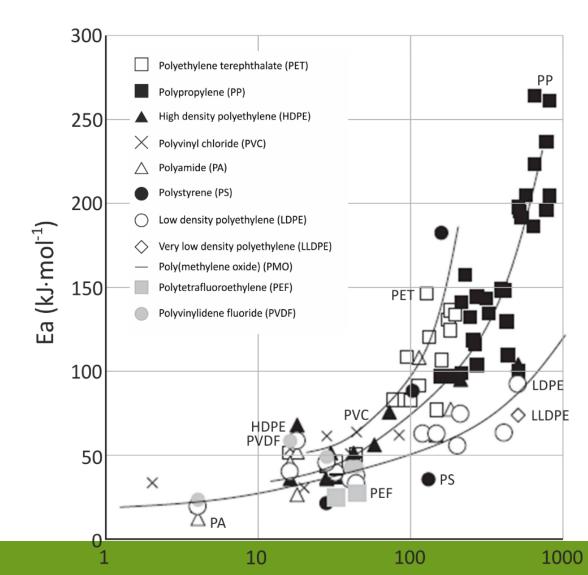


SCALING ACTIVATION ENERGY

VARIOUS DIFFUSANTS IN VARIOUS POLYMERS

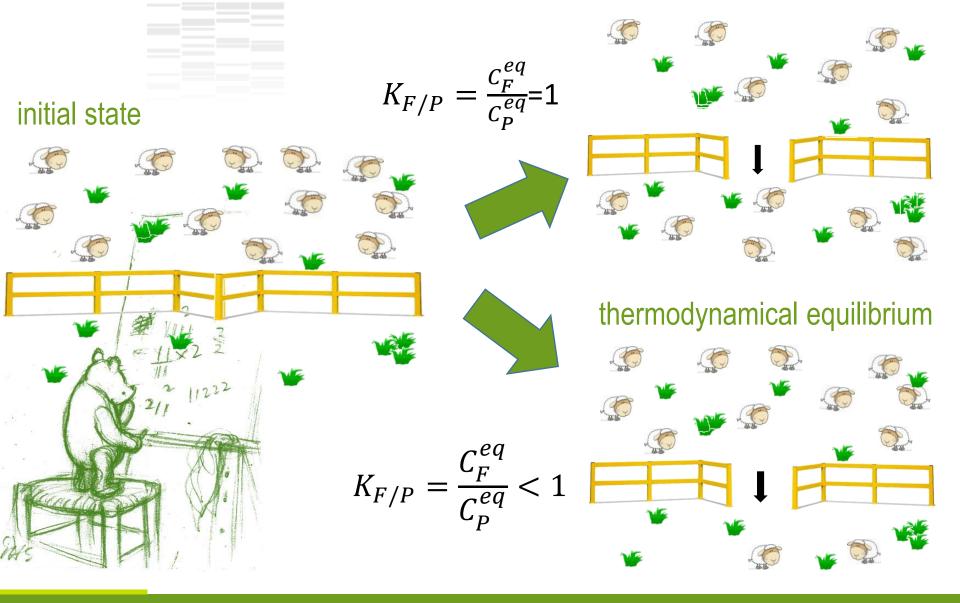
Ea(M) \approx Ea(M_0) + $ln(M/M_0)$

Crit. Rev. Food Sci. Nut. 2015 (Fang & Vitrac) http://www.tandfonline.com/doi/full/10. 1080/10408398.2013.849654





INTUITIVE DEFINITION OF PARTITION COEFFICIENTS

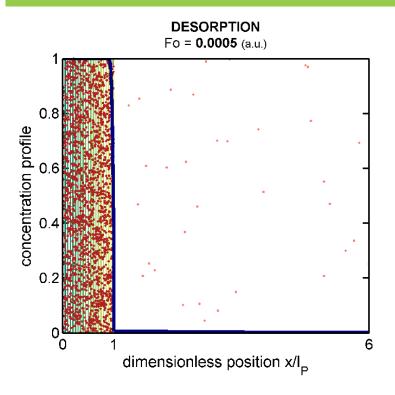


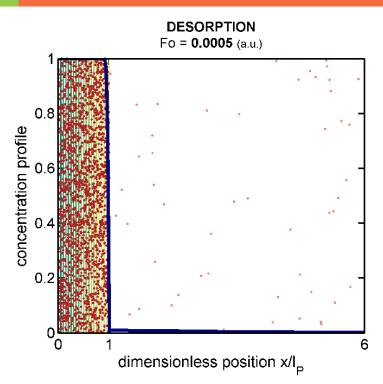


EFFECT OF PARTITION COEFFICIENT ON MIGRATION

50 times for chemical affinity for P 50 times for chemical affinity for F









$$K_{i,F/P} = rac{C_{i,F}^{eq}}{C_{i,P}^{eq}} = rac{1}{1 - crystallinity} rac{oldsymbol{\gamma_{i,P}^{v}}_{amorphous}}{oldsymbol{\gamma_{i,F}^{v}}}$$

MIGRATION MODELING AUTHORIZED IN EU, US, China

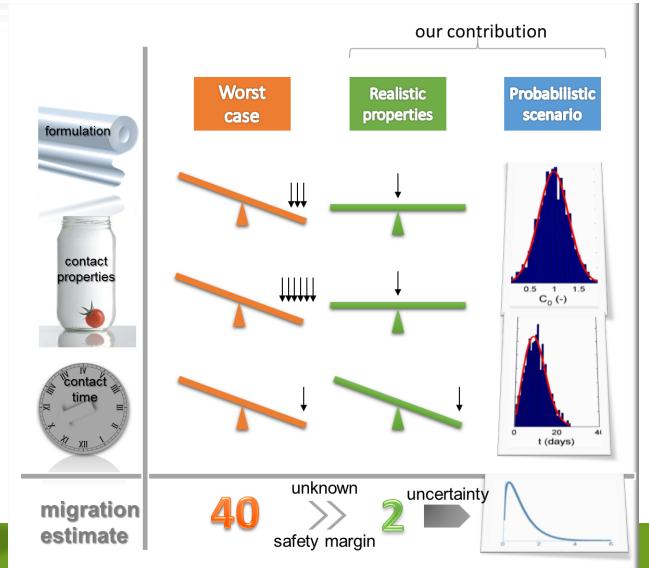
At each stage of manufacture, supporting documentation, substantiating the declaration of compliance, should be kept available for the enforcement authorities. Such demonstration of compliance may be based on migration testing. As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculations, including modelling, other analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing. Test results should be regarded as valid as long as formulations and processing conditions remain constant as part of a quality assurance system.

To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed such as to overestimate real migration.



HOW TO OVERESTIMATE MIGRATION

MODELING CAN DEMONSTRATE COMPLIANCE BUT NOT NON-COMPLIANCE





MIGRATION MODELING

STATE OF THE ART (from lab to industry, from lab to food safety agencies)

properties

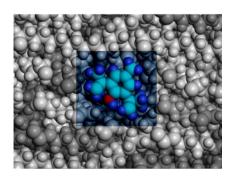
migration

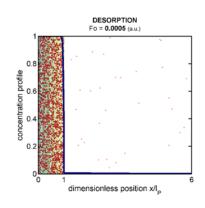
exposure

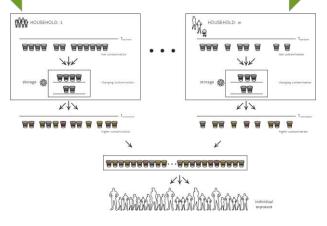
Probabilistic (equilibrium)

Probablistic/deterministic



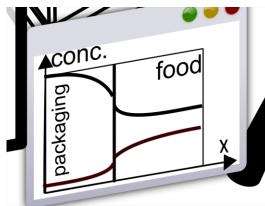


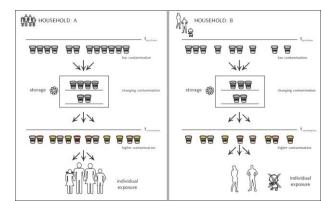




Free energy perturbation

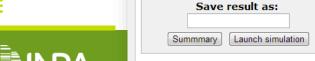
$$\exp\left(-\frac{F_1 - F_0}{k_B T}\right)$$
$$= \left\langle \exp\left(-\frac{U_1 - U_0}{k_B T}\right) \right\rangle$$





ALL SOFTWARE ARE BUILT ON SIMILAR ASSUMPTIONS

My Information	l 	Archived simulations or templates		
user: demouser (change user) project: common (change project) database: common2013a.sfpp3.database Application: Diffusion_1DFV2n (change a		geometry for Import a concentration p Clear all propertie form reset	from a previous result file in the current form mulation contact conditions transport prop. all ration profile rofile is in the current form	
Contact conditions	Layer selecto	_	Help	
L_FP 100	V Layer 1	import import T import T import T	Acetaldehyde Name: Acetaldehyde (Acetic aldehyde; Ethanal; Ethyl aldehyde; CH3CHO; Acetaldehyd; Aldehyde acetique; Aldeide acetica; NCI-C563) CAS: 75-07-0 REF: 10060 InChIKey: IKHGUXGNUITLKF-UHFFFAOYSA-N Formula: C2H4O M: 44.053 g/mol SML: 6 ppm EFSA: Group TDI = 0.1 mg/kg b.w. (calculated as acetaldehyde (including 10060 and 23920) Toxicity profiles similar to methaldehyde. A 2- year oral rat study and a 3-generation oral rat study including teratogenicity with methamethaldehide. The reports on nasal carcinogenicity after inhalation were considered without relevance for effects from oral intake of smaller doses, (adopted at 113rd SCF meeting)(17-18 September 1998) http://europa.eu.int/comm/food/fs/sc/scf/out 16 en.html	



Acceptable threshold or specific migration limit 6 ppm



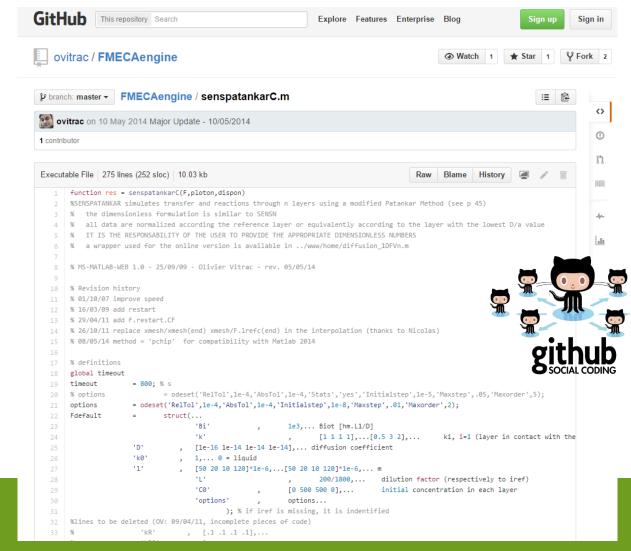


New trends: OPEN-SOURCE codes

https://github.com/ovitrac/FMECAengine



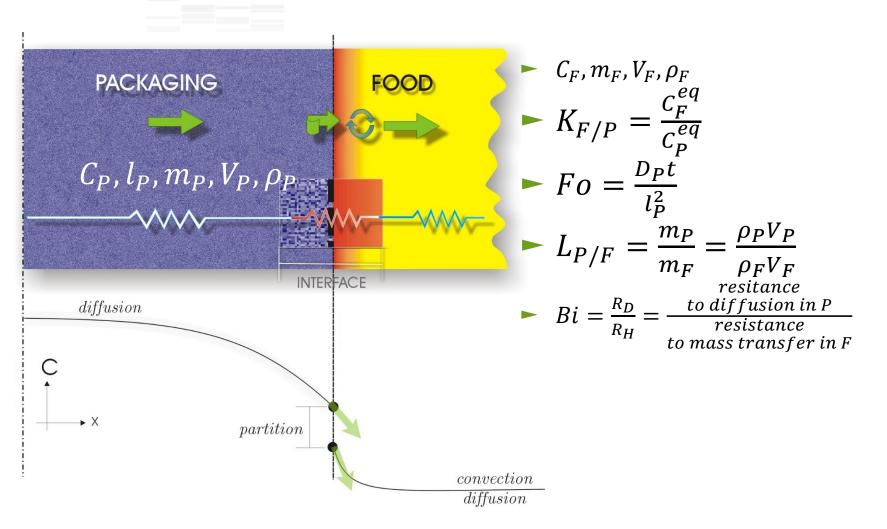






DIMENSIONLESS FORMULATION

MONOLAYER / DIFFUSION + SORPTION





MASS BALANCE

FROM TOTAL MIGRATION TO PARTITION CONTROLLED MIGRATION

packaging

Intial state

$$\rho_P \cdot V_P \cdot C_P^{t=0}$$

SI=kg⋅m⁻³

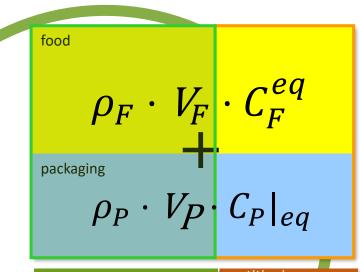
food

SI=m³

SI=kg⋅kg⁻¹

Equilibrium state

$$C_F^{eq} = \frac{1}{\frac{1}{L_{P/F}} + \frac{1}{K_{F/P}}} C_P^{t=0}$$



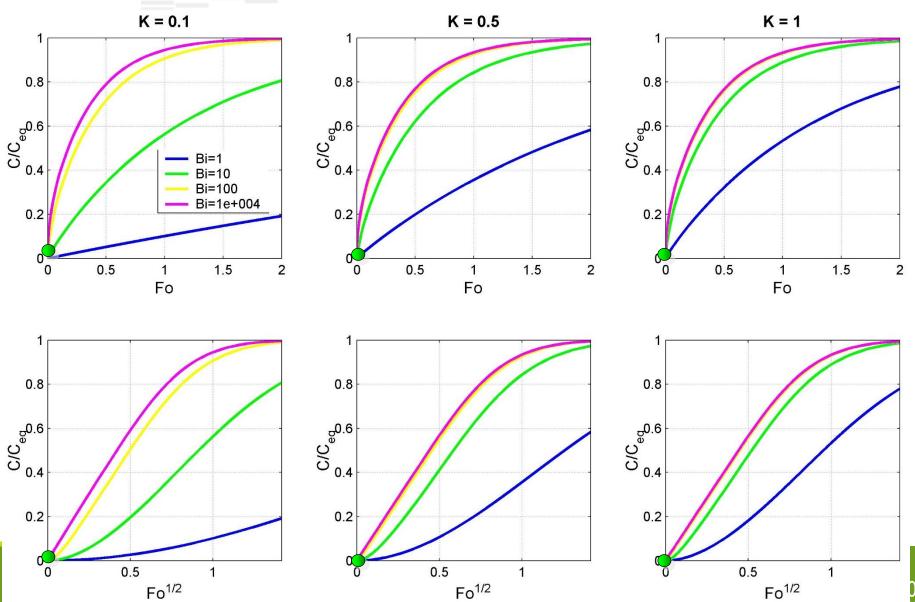
geometry effect $L_{P/F} = rac{
ho_P V_P}{
ho_F V_F}$

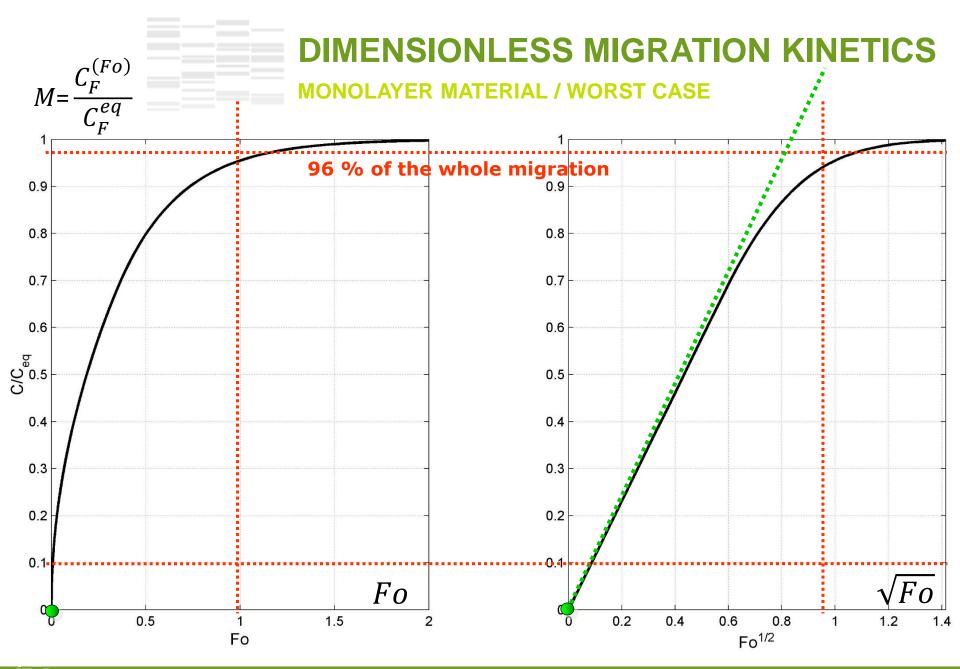
 $K_{F/P} = \frac{C_F^{eq}}{C_P^{eq}}$



DIMENSIONLESS MIGRATION KINETICS

MONOLAYER MATERIAL

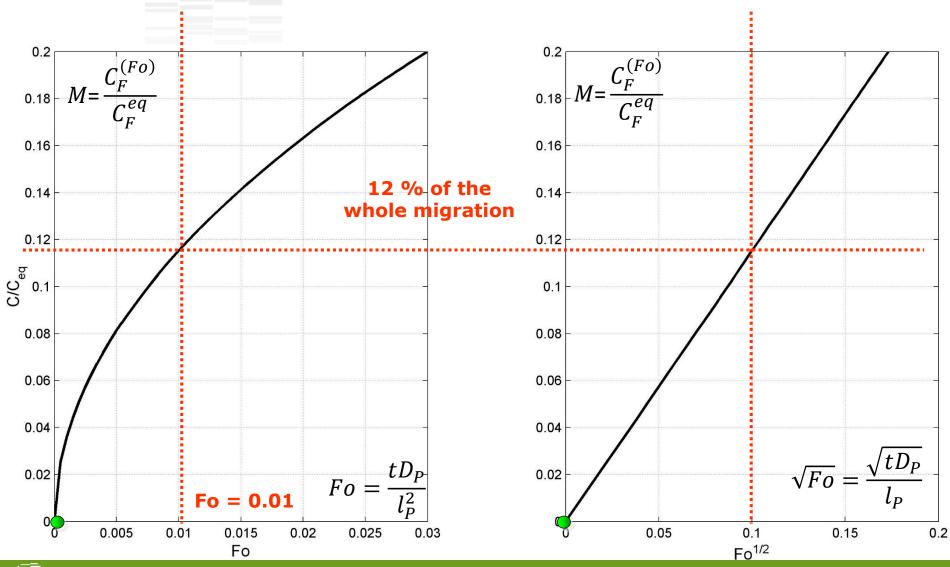






DIMENSIONLESS MIGRATION KINETICS

MONOLAYER MATERIAL





F MC

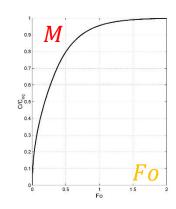
RULES OF THUMB FOR WORST CASE SCENARIOS

MONOLAYER MATERIAL

$M = \frac{C_F^{(Fo)}}{C_F^{eq}}$ Dimension-less migration (migration ratio)	$Fo = \frac{tD_P}{l_P^2}$ Dimension-less time
≈ 100%	1
≈ 50%	0.2
≈ 10%	0.01

Time to reach a given migration ratio: $t = Fo \frac{l_P^2}{D_P}$

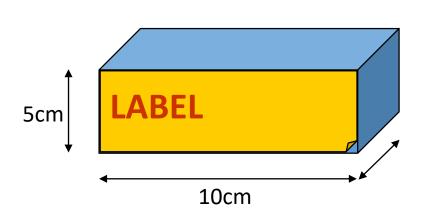
Concentration in food at time t: $C_F(t) = M(Fo) \cdot C_F^{eq} = M(Fo) \cdot \frac{K \cdot L}{K + L} \cdot C_P^{t=0}$





MODELING EXISTS ALSO FOR

MULTILAYERS
ARBITRARY COORDINATE SYSTELS
CHAINED STEPS



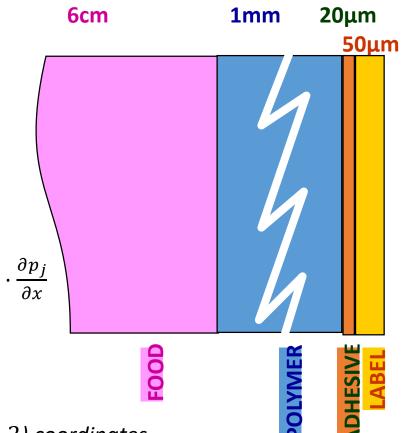
Henry isotherm: p = kC, k=Henry coefficient

Diffusive flux:
$$J_j = -D_j \cdot \rho_j \cdot \frac{\partial c_j}{\partial x} = -\frac{D_j \cdot \rho_j}{k_j} \cdot \frac{\partial p_j}{\partial x} = -\alpha_j \cdot \frac{\partial p_j}{\partial x}$$

Transport equation:
$$\delta_j \cdot \frac{\partial p_j}{\partial t} = \frac{1}{x^m} \frac{\partial}{\partial x} \left(x^m \cdot \alpha_j \cdot \frac{\partial p_j}{\partial x} \right)$$

$$\alpha_j = \frac{D_j \cdot \rho_j}{k_i} = D_j \cdot \delta_j$$

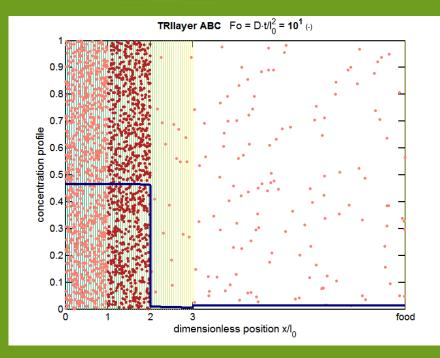
cartesian (m=0), cylindrical ((m=1), spherical (m=2) coordinates





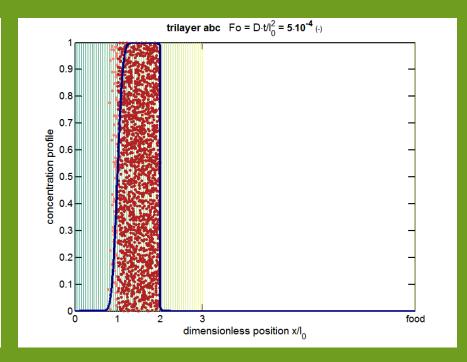
SIMULATION OF MULTILAYER MATERIALS

Functional barrier = barrier to diffusion + sorption



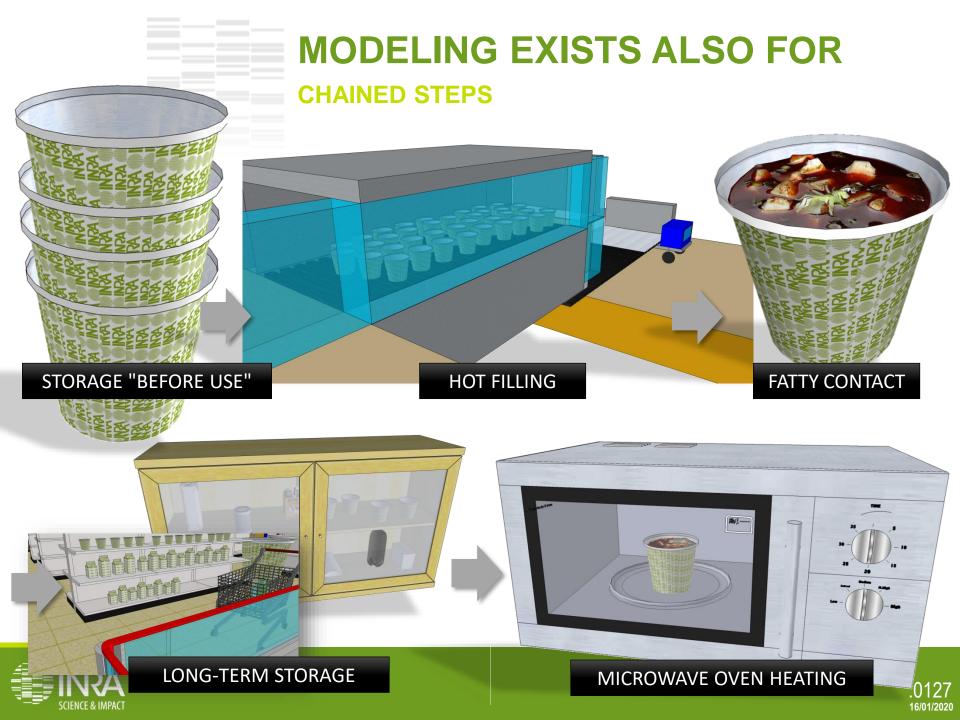
prop	Layer 3	Layer 2	Layer 1	Food
C_0	0	1	0	0
I/I _o	1	1	1	100
D/D ₀	1	1	0.1	10 ⁴
k/k ₀	1	50	1	1

Idem + low chemical affinity for the food

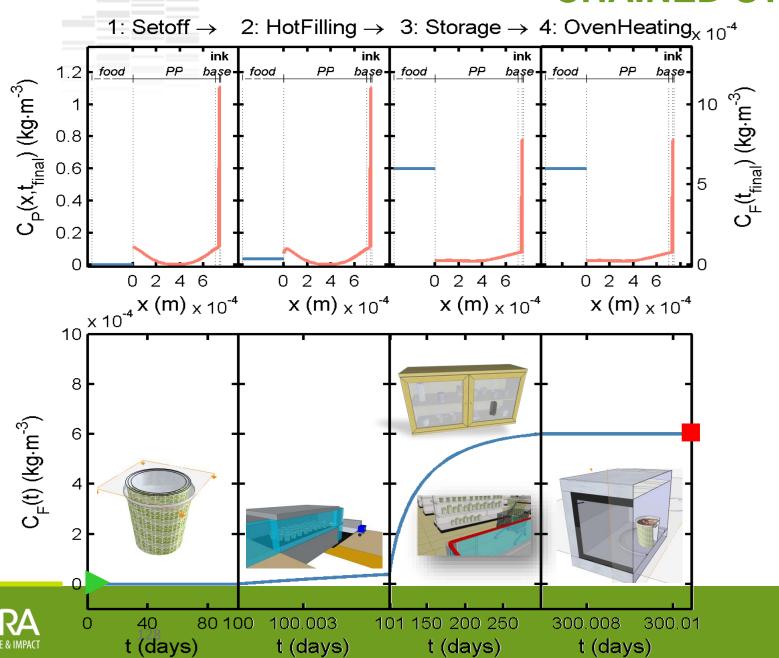


prop	Layer 3	Layer 2	Layer 1	Food
C ₀	0	1	0	0
I/I _o	1	1	1	100
D/D ₀	1	1	0.1	10 ⁴
k/k ₀	1	50	1	20





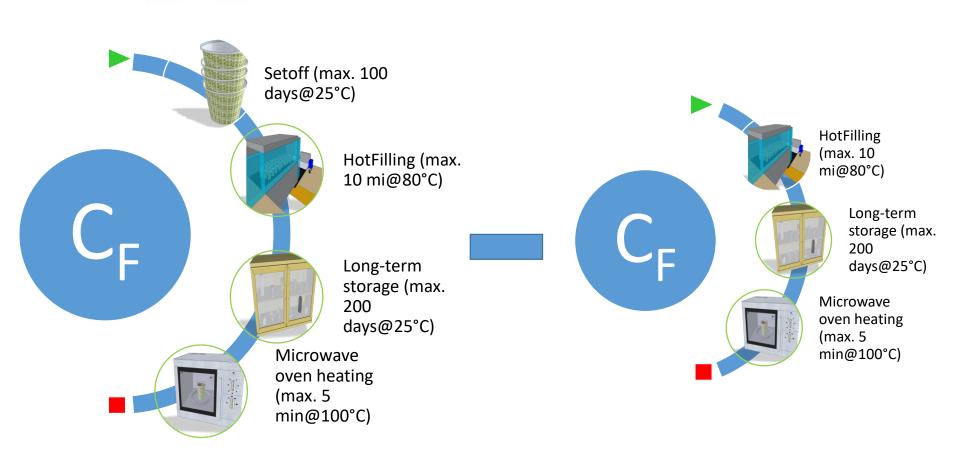
CHAINED STEPS



ASS SINC CASE

ASSESSING THE SEVERITY OF A SINGLE STEP

CASE OF "SETOFF" STEP

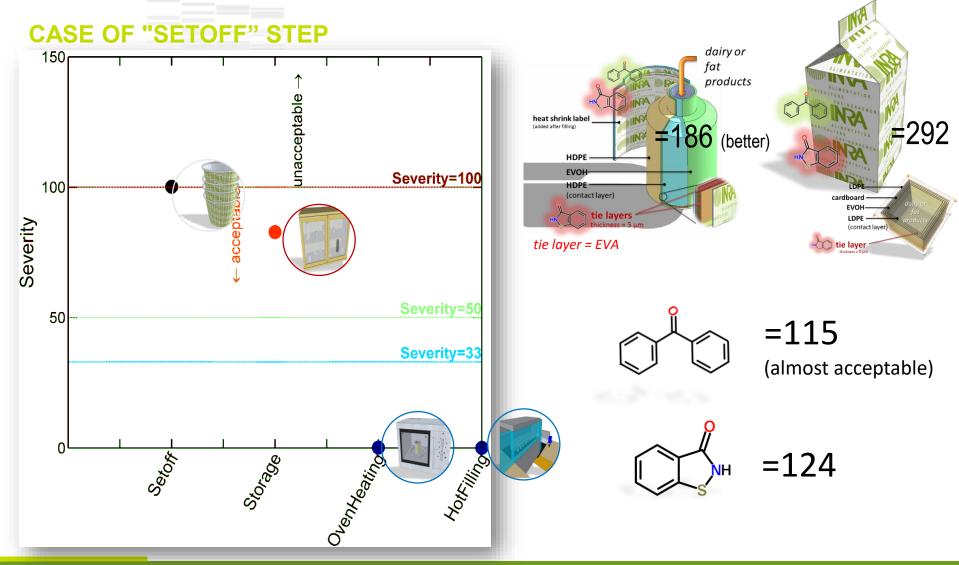


Full methodology described in *AIChE J.* 2013, **59**(4), 1183-1212



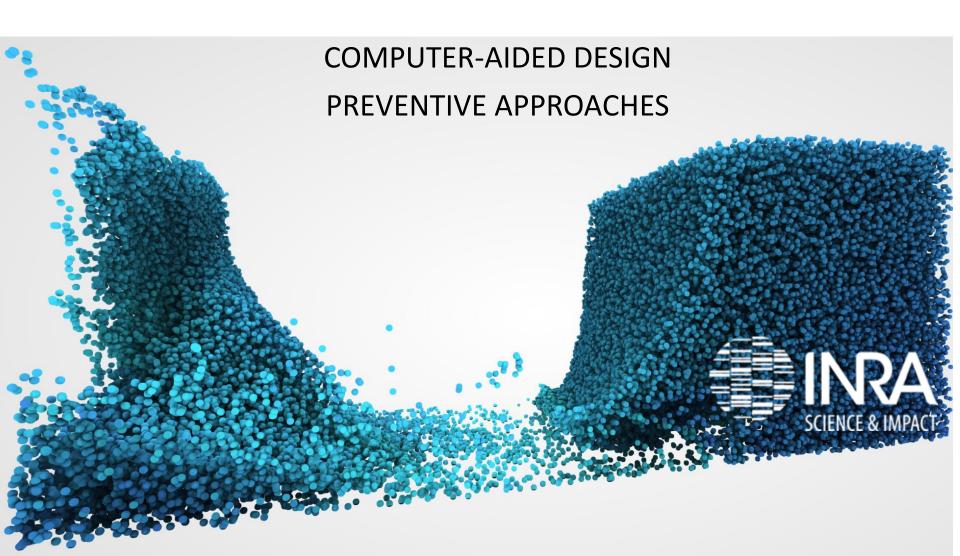
Severity $(\hat{C}_F(\text{step }i)) = f \left| \max_{C_{F_M}} \left| \underbrace{C_{F_M}}_{1 \to 2 \to \cdots \to M} - C_{F_M} \right|_{1 \to 2 \to \cdots \to M/i}, C_{F_i} \right|_{i}$

COMPARING THE SEVERITY OF A SEVERAL STEPS, PACKAGING DESIGNS, SUBSTANCES...





CONCLUSIONS

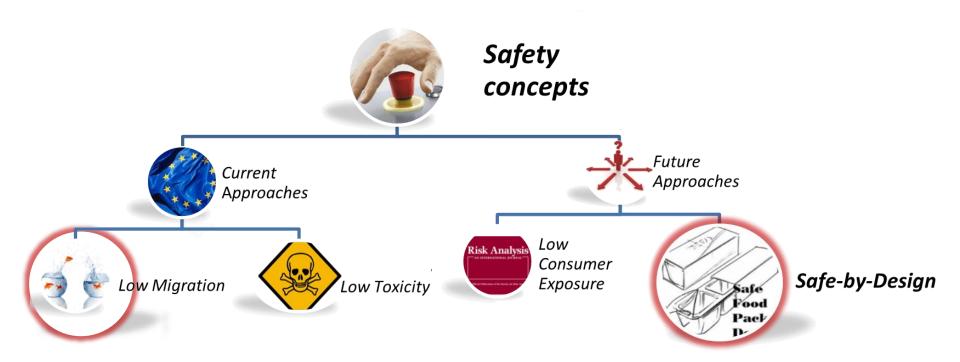






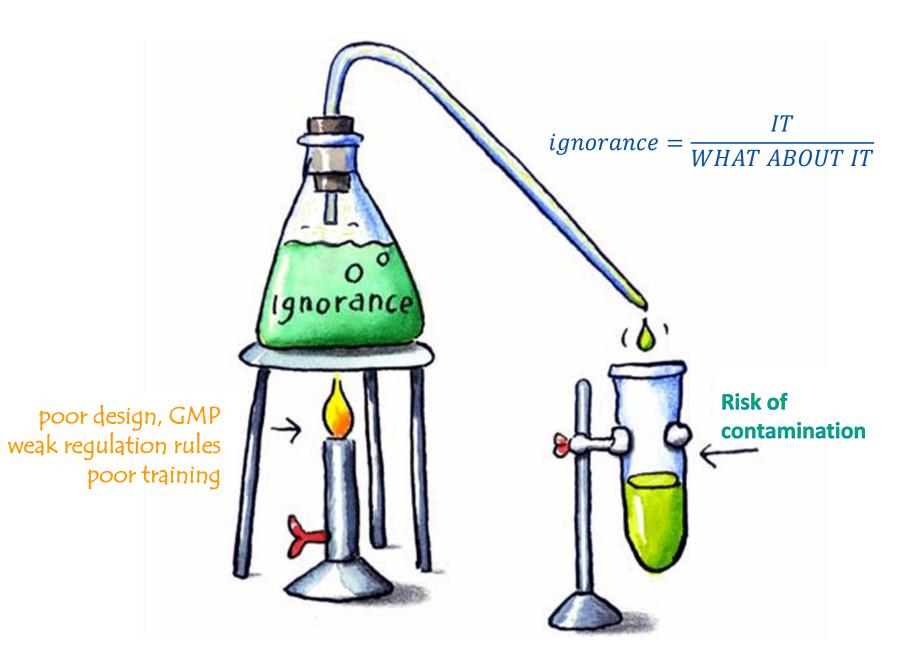
TOWARDS NEW CONCEPTS

PREVENTIVE APPROACHES OF FOOD SAFETY





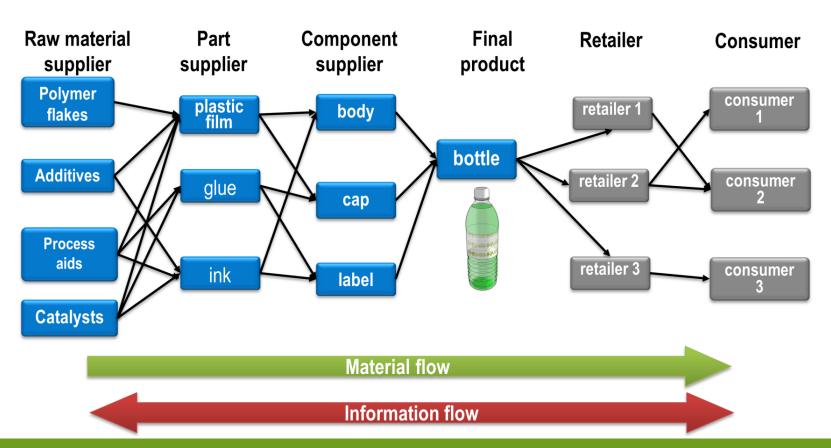
HUMAN RISK





TOWARDS NEW CONCEPTS

DEVELOPING COOPERATION BETWEEN STAKEHOLDERS

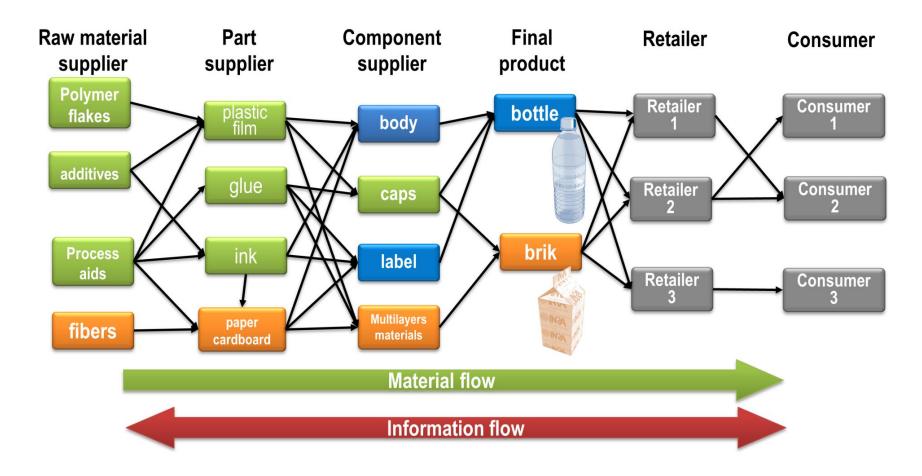






TOWARDS NEW CONCEPTS

DEVELOPING COOPERATION BETWEEN STAKEHOLDERS





MAIN STEPS TO REVIEW

	Safe Food Pack Design
Lyon 1 LNE	FRANCE SAG EMBALLAGE



0

Collaborative research project SAFEFOODPACK DESIGN

liérarchisation

FMECA « milk for infants stored in a brick » **Formulation** Design





Process



Informations



Mechanisms

Described mechanisms

monomers (plastics, adhesives)

Formulation

- catalysts
- antioxidants
- **lubricants**
- biocides (cardboard, ink)
- mineral oil (cardboard)
- solvents
- photoinitiators
- other residus (NIAS)

- two components:
- brick body (4 materials, 5 lavers)
- cap (two materials incl. the sealing system)
- six materials
- LDPE, PP (cap)
- aluminum foil
- cardboard (origin)
- « ink »
- « adhesives »

- production, storage, assembly of materials
- assembly and storage of components
- printing (printing technology, curing/drying....)
- storage of empty packaging
- aseptic packaging filling (temperature, pretreatment...)
- storage and retailing of the bricks
- filled with milk conditions of use or storage by the consumer/end-user: chilled. ambient, oven heating?
- Consumption-type (bottle feed with direct contact between the mouth and the neck...)

- identity and nature of materials in assemblies
- formulation of materials (substances specifically regulated or not)
- test conditions used to evaluate the risk of contamination
- conditions of preparation. packaging filling, storage, consumption of packaged food
- communication of revisions and modifications in la formulation, design, process and in the final use

- diffusion across layers
- set-off
- cross-contamination between materials and with the storage ambience
- effects of poor drying and curing on printing inks

Highly concentrated

- antioxidants, lubricants, biocides
- mineral oils, photoinitiators
- monomers, catalysts. solvents
- other residues

Barrier material

aluminum foil

Materials acting as reservoir of low molecular weight contaminants

- ink
- adhesive

Materials acting as reservoir of high molecular weight of contaminants

- PP. LDPE
- paper and board

steps associated to long-time contact

- storage of materials
- storage of components
- storage of finished products

steps associated to high temperatures

- aseptic filling
- oven heating

steps which may lead to crosscontamination

- storage
- printing
- assembling / laminating

non-documented or missing information

- accessible information
- documented information, which follow each component and materials
- verifiable and auditable information
- frequency of update of information: regular, when a change occur, only when the design is modified,...

- mass transfer, which can be evaluated rapidly from calculations: from, trough LDPE, PP layers
- mass transfer, which can be tested experimentally in a simple manner: set-off
- mass transfer, which require a depth expertise: crosscontamination, aging



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PRINTING INKS (EUPIA guidelines to be revised)

- Exclusion/Negative lists
- Recommended substances
- Purity/traceability requiremed
- Migration (less than 10 ppb for non evaluated substances) and risk assessments
- Inks prepared according to GMP
- No-direct contact with food
- No "visible' Set-off in stacks and reels



MINERAL OILS

- No recycled paper or paperboard
- No MOSH below C20, migration <2 ppm for C20-C35
- Migration of MOAH (C16-C35)<0.5 ppm</p>
- List of raw materials and production aids
- No holding/reheating above 90°C
- No microwave uses
- With internal bag















