



SAFEMA

OF PACKAGING

AgroParisTech

CONTAMINATION FROM FOOD CONTACT MATERIALS OVERVIEW, MIGRATION ISSUES REGULATION, RISK ASSESSMENT & MANAGEMENT

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L'emballage bienveillant, actif, intelligent, utile

L'emballage encombrant, inutile, dangereux

SCIENCE & IMPACT

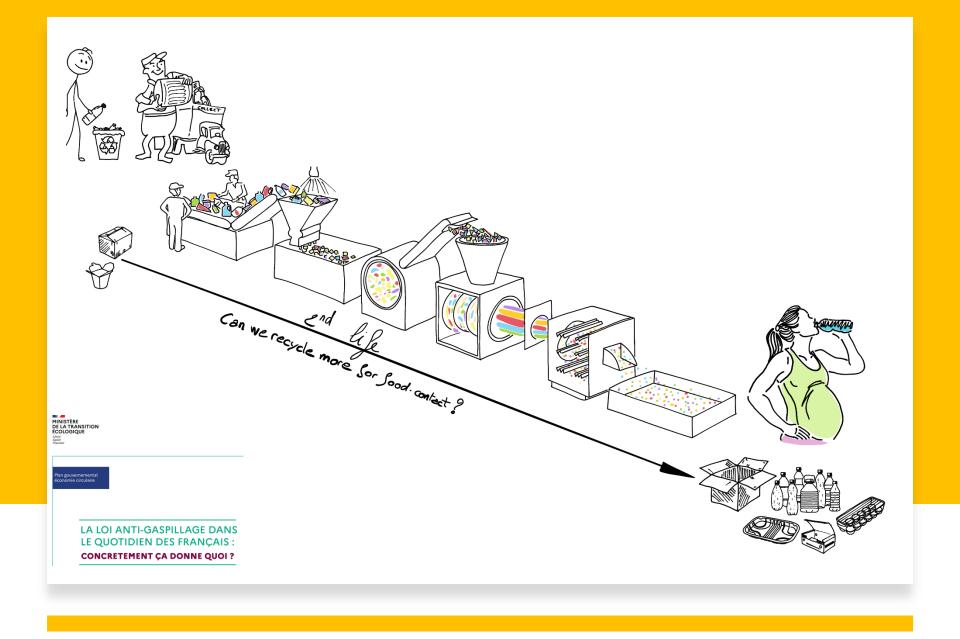
anon



MICRO PLASTICS ENTERING FOOD CH THROUGH ANIMAL INGESTIO

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GREEN

DEAL



Live events Food Packaging Materials: Safety, Active Packaging, & Sustainability: Safety of Food Contact Materials April 6, 2021

TOMORROW EVERYTHING SHOULD BE REUSABLE, REFILLABLE, RECYCLABLE

TURNING GREEN

We are sleeping on a volcano... A wind of revolution blows; the storm is on the horizon.

Alexis de Tocqueville (1848, just prior revolutions in Europe).

zero disposable plastic

TOMORROW EVERYTHING SHOULD BE REUSABLE, REFILLABLE, RECYCLABLE **100%** of packaging recycled by January 1, 2025 Banning packaging around fruit and vegetables in 2022 2026 2020 2022 A polluter-202 pays system free plastic toys banned in 2021 Mandatory for hygiene vater textiles from for a circular economy 2024 Inform on endocrine Disposable disruptors cutlery, straws Five-year O. X Plastic confetti Plastic tea bags ecodesign and swizzle 1 plans banned in 202 ticks banned in banned by 2022 (France) R Disposable Expanded Ban plastic dishes in fast-PS food containers

Cardboard

and packaging

to be

E)

bulk to

reduce packaging \mathbf{c}

Mixed deposit

for reuse and

5% packaging

reusable

recycling

202.

Prohibition

of the

Note: mention biodegradabl

TIT

Recycling bins in

No cups,

allowed

cotton swabs

restaurants

ABCDE

ENVIRONNEMENTA

and societal

labelling

Environmental

S

202

TURNING GREEN >



PARIS 2024



Ø REDUCE

Ø RENEW

@ REPLACE

202

10% reusable

packaging

for heating

infants and

food for

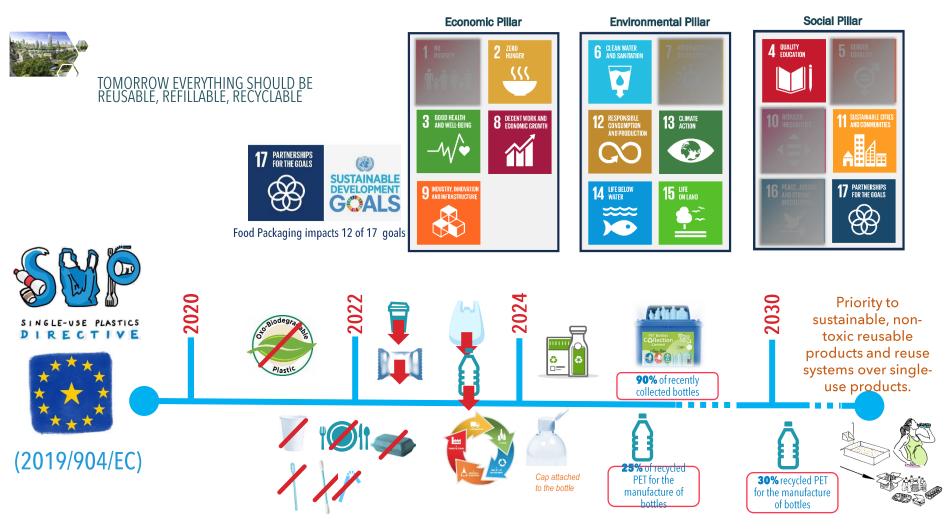
young

children.

2040

100% reusable

packaging



> The challenge of recycling plastics for food contact.

Can we recycle more for food contact?

All plastics including biosourced and biodegradable materials will need to be recyclable for the same use (food contact for food packaging).

Only PET is currently recycled at global scale, but with several challenges:

- Risk of misuse, cross-contamination (ex. from carboard)
- They can be used for direct contact after decontamination
- They could be used not decontaminated behind a functional barrier (e.g., made of decontaminated rPET)
- rPET can originate from various streams (food contact or not) and from various countries
- No harmonized standards

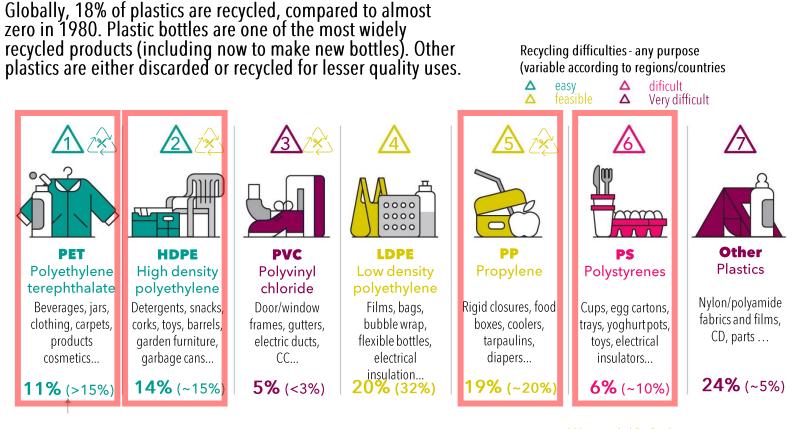


PET Polyethylene terephthalate

Beverages, jars, clothing, carpets, products cosmetics...

> Recycling more plastics beyond PET

% plastic wastes in 2015 (% food packaging wastes, Plastics Europe 2016)



Recycled for food

Could be recycled for food contact (polyolefins: PP, HDPE, LDPE)

p. 9

> Is the substitution of plastics by recyled paper & board a safer solution?

Recycled P&B are a very important source of mineral oils, which can contaminate food without contact and across a plastic layer.

- Germany recommends not to use recycled P&B in microwave oven.
- France requires an evaluation of the risk of contamination from secondary and ternary packaging.
- Detection limit ~10 mg/kg (Koster et al., 2020)



Maximum level of ∍ĺ Food type Origin contamination by Reference mineral oils 6. Chocolate and >100 mg·kg⁻¹ Cardboard (Lorenzini, 2010) approximate broducts ÷ 10-80 mg·kg⁻¹ **Baby milk** Cardboard (Droz, 1997) COFF Ö Cardboard and **Cereal Products** 30 mg·kg⁻¹ (Biedermann, 2013) printing inks 10 mg·kg⁻¹ Pasta cardboard box (Biedermann, 2011) 100-1000 mg·kg⁻¹ **Edible oil** Containers (Wagner, 2001)





OBJETIC GENERAL

recycler, reduire, reutiliser... de manière sûre

ATTITUTE .

TITTT

- mission d'intérêt public
- secteur non-compétitif,
- appuyer la transition écologique,

l'innovation et les futures règlementations



LES NOUVEAUX AXES R&D recycler, reduire, reutiliser... de manière sûre

AXE 1 ALIMENTARITE DES RECYCLATS

(reconnu)



AXE 2 VIEILLISSEMENT DES MATERIAUX RECYCLES, REUTILISES, REEMPLOYES, COMPOSTABLES

(à construire)



AXE 3 INGENIERIE INTEGRANT LE COUPLE EMBALLAGE-PRODUIT

(à fédérer)





Mission d'intérêt public, secteur non-compétitif, appuyer la transition écologique, l'innovation et les futures règlementations

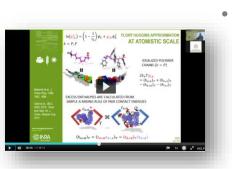
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• THIS LECTURE:

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THE SCHOOL OF PACKAGING MICHIGAN STATE UNIVERSITY





MY LECTURES AT MSU (MI,USA): http://www.fshn.msu.edu/events/event/Vitrac 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+Pred iction+of+the+migrationA+beyond+conventional+esti mates*/1_won1m7aw

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



> Train yourself to become green



Three months online curriculum on packaging design https://fitness.agroparistech.fr/

🞧 Main menu 🔑 About Us

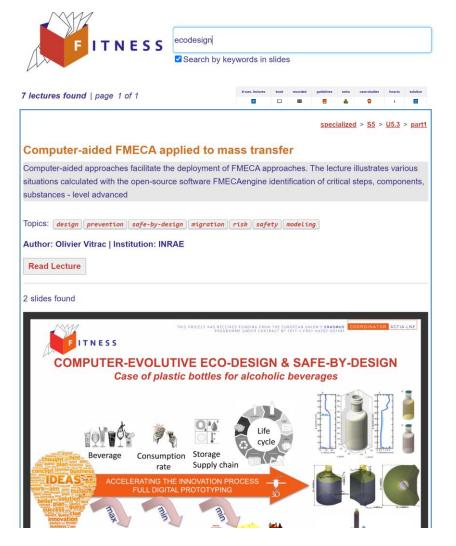


tia France Germany Portugal Spain

All lectures, interactive contents and Quizz are provided "AS S". The content (85 lectures from Common to Specialized Modules) is under development and may contain inconsitencies and inaccuracies. It will be updated regularly.



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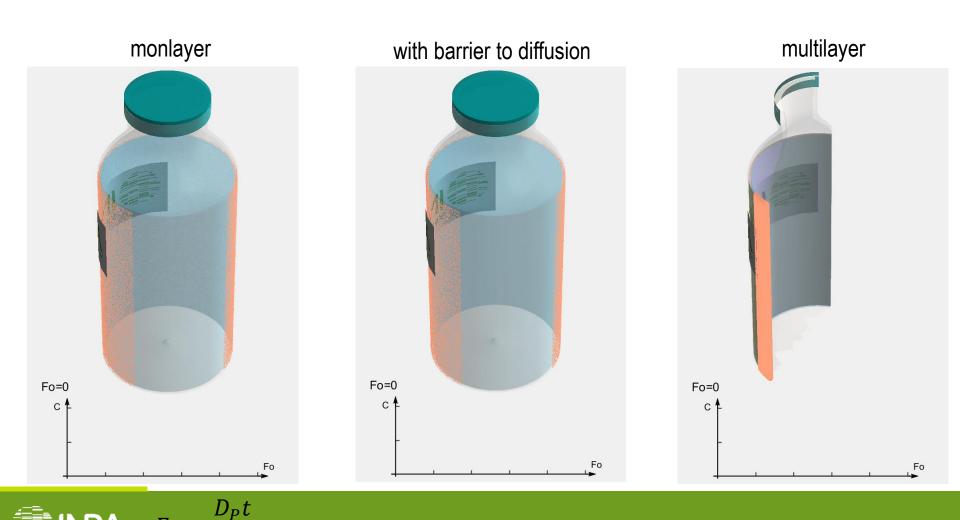


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This lecture

DESORPTION OF PACKAGING CONSTITUENTS (ADDITIVES, MONOMERS AND OLIGOMERS, NIAS...) SELF-SIMILAR SITUATIONS WHICH OBEY

TO THE GENERAL MODEL OF DIFFSION-SOLUBILIZATION

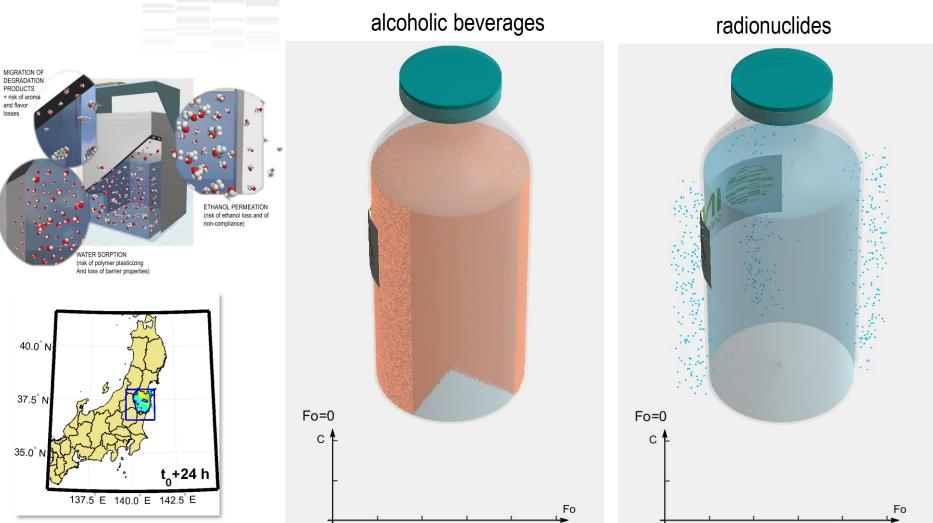




1>>> INTRODUCTION/ MASS TRANSFER PHENOMENA AS OBJECT OF STUDY

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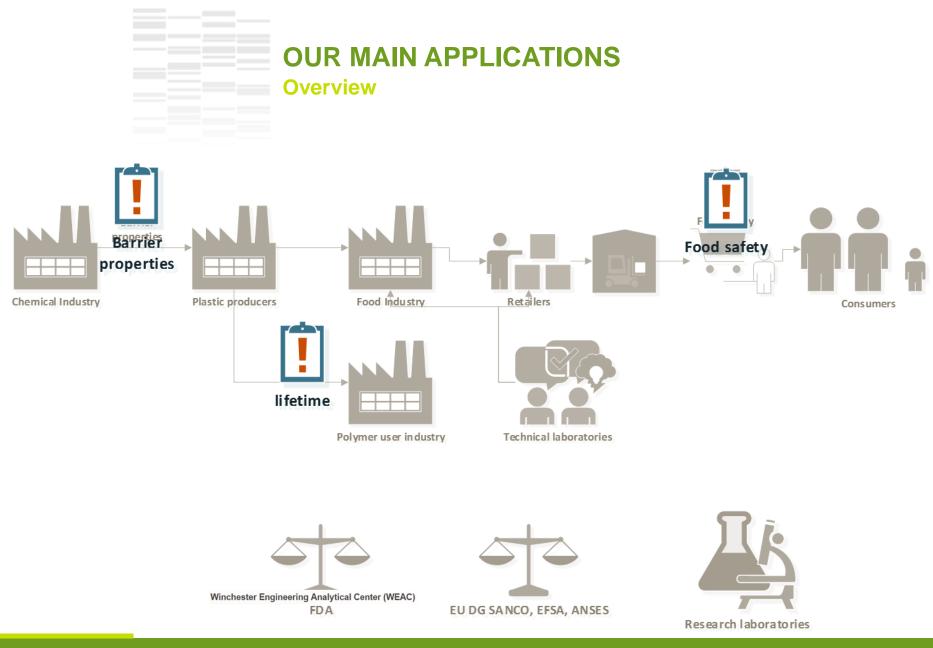
PERMEATION OFFOOD CONTENTS PERMEATION FROM ENVIRONMENT



Fukushima-Daichi; March 12th, 201

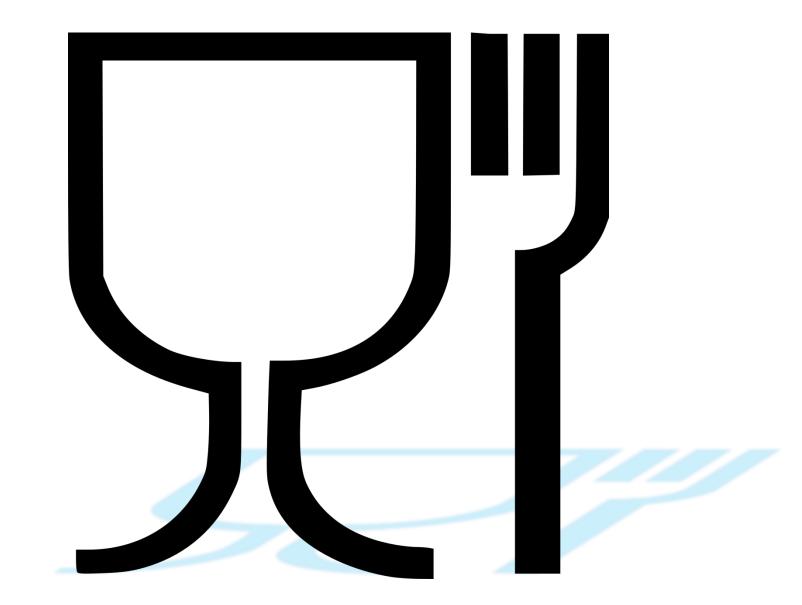


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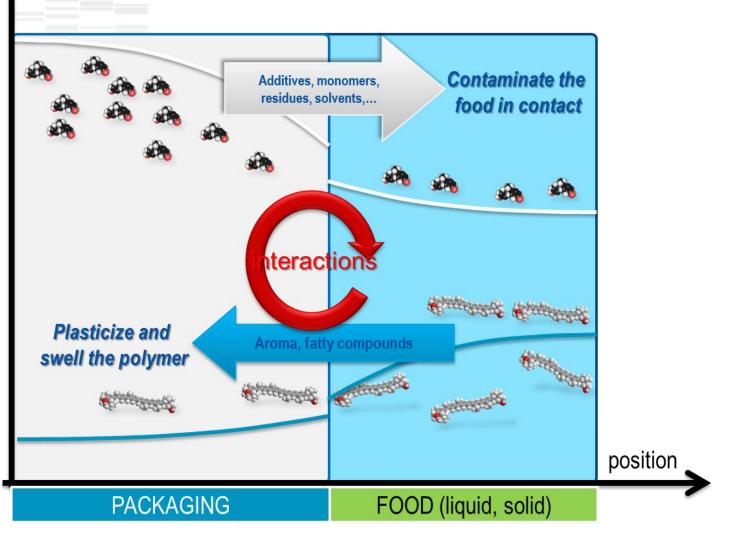


REGULATION 10/2011/EC



What is migration ?









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

THERMOPLASTICS, ELASTOMERS



Classification of polymers

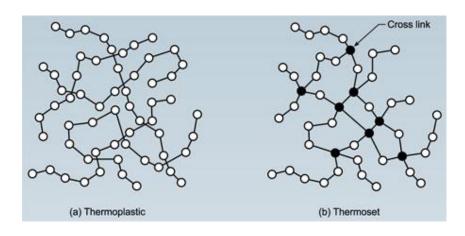
Thermoplastics : A thermoplastic, or thermosoftening plastic, is a polymer that melts, and returns to a solid state upon cooling.

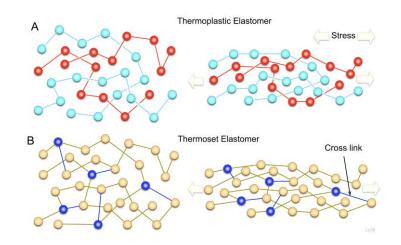
Examples : PE, PP, PS, PVC ...

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

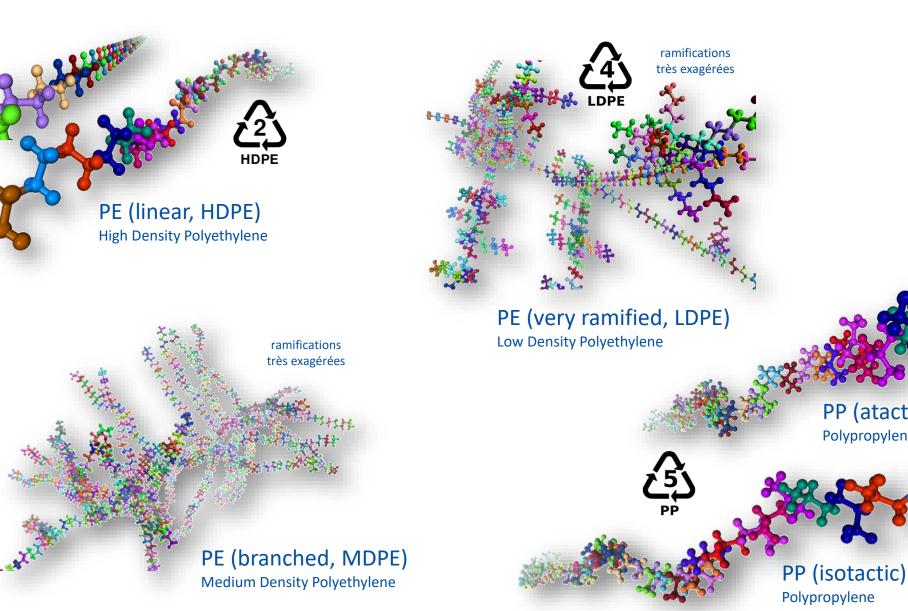
Examples : Phenolic, epoxydes ...

Elastomers : An elastomer is a polymer with viscoelasticity (colloquially "elasticity") *Exemples* : Silicones, natural rubber ...





Polyolefins : PE – PP



PP (atactic) Polypropylene

POLYOLEFINS

8	10	. 1		100	
86	R . 1	e 2	- 24	1.00	

Vapour barrier

(Low density polyethylene)

- 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

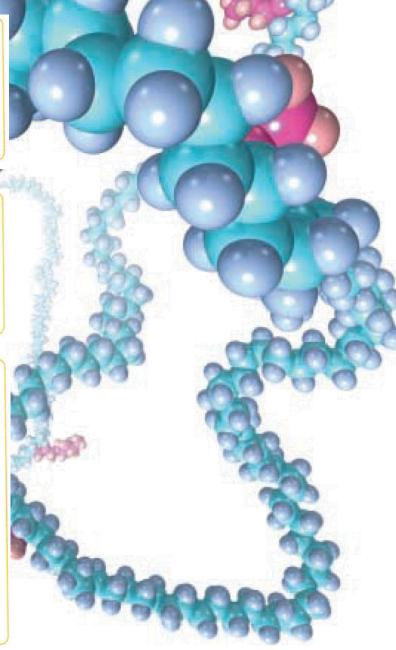
(High Density Polyethylene)

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

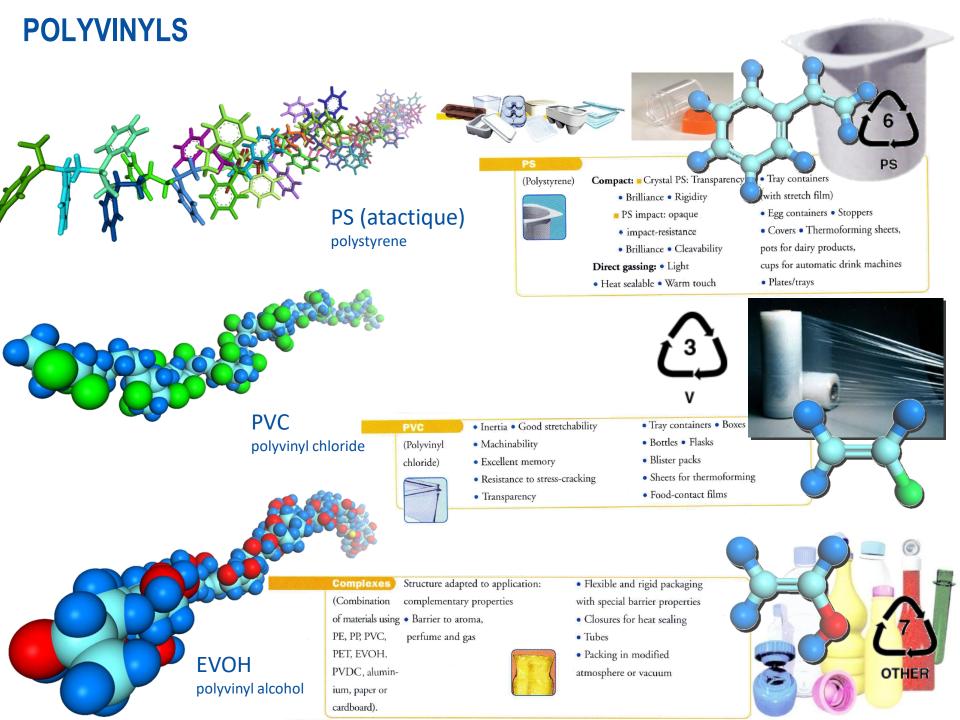
- Large drums
- Screw or clip tops
- Bottles
- Crates and cases Covers
- Films for postal dispatch
- Flasks Drums and reusable
- containers Pots Tubes

- 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
 - Clarified PP
 - OPP (oriented PP)
 - EPP (expanded polypropylene:
 - resistance to repeated impact)

- Alveolate material Tray containers
- Screw and clip tops
- Reusable crates and cases Covers
- Thermoforming sheets
- Transparent films and bags
- Bottles
- Reheatable plates Pots
- Tubs Tubes
- Flasks
- Films
- Reusable wrapping



VoGrafy



PET

- (Polyethylene terephthalate)
- Gas barrier
- (C)PET (crystallised):

(A)PET (amorphous):

• Shiny • Impact resistant

• Resistant to internal pressure

• Resistant to stress-cracking

- same properties as (A)PET
- but not transparent
- Temperature resistant to 220° C
- PETG (glycol): amorphous, same properties as (A)PET

- Tray containers Boxes Bottles
- Transparent Perfume compatible • Lids
 - Thermoforming sheets
 - Films Flasks Pots
 - Oven trays (220°C)
 - Blister packs Bottles
 - Films Flasks Pots

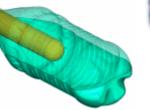
• Tray containers • Lids • Thermoforming sheets

• Gas barrier

• UV barrier

PET/PEN

copolymer

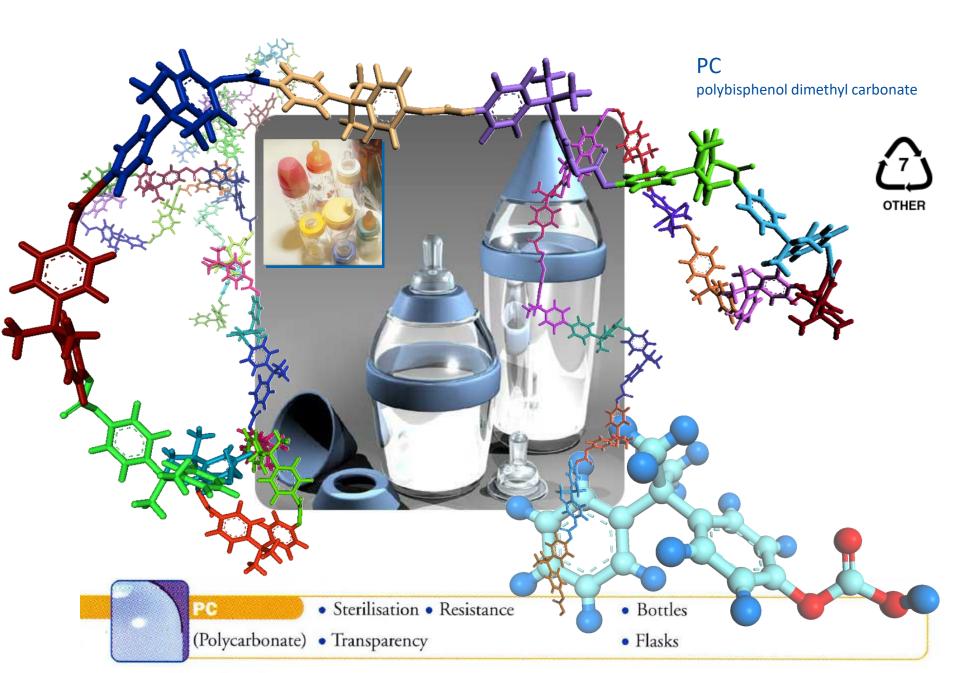


PET Polyethylene terepthalate

 Bottles • Flasks

PETE

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 ++++++



+++ to +++++

+++++

+++++

+ to +++

+++

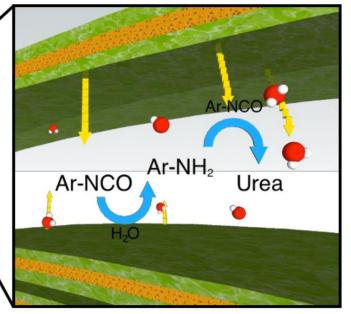
+ to +++

Varnish

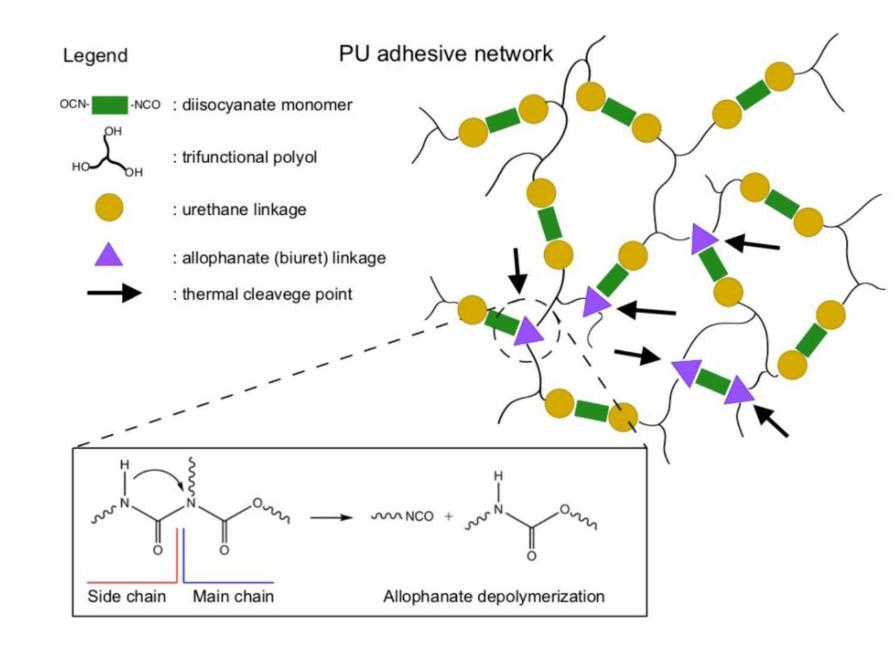
Ink

Polymeric Layer Polymeric Layer Polymeric Layer

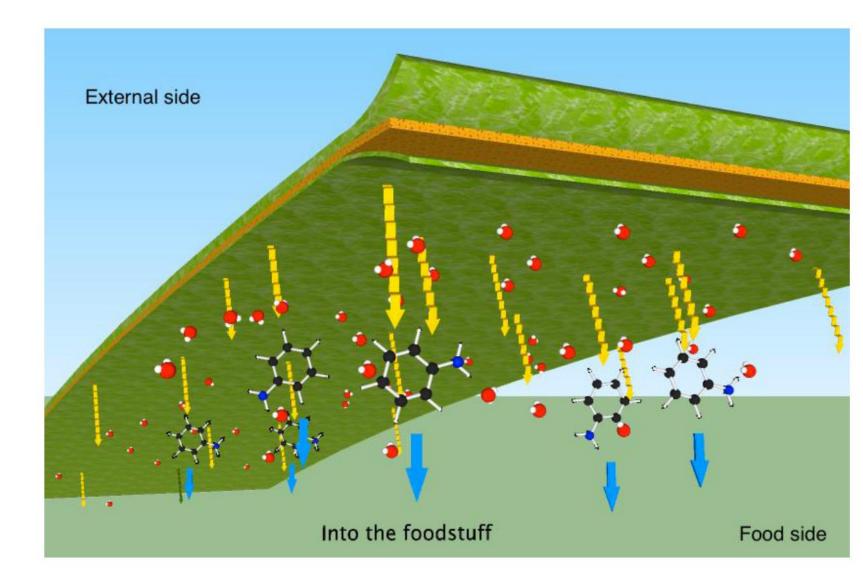


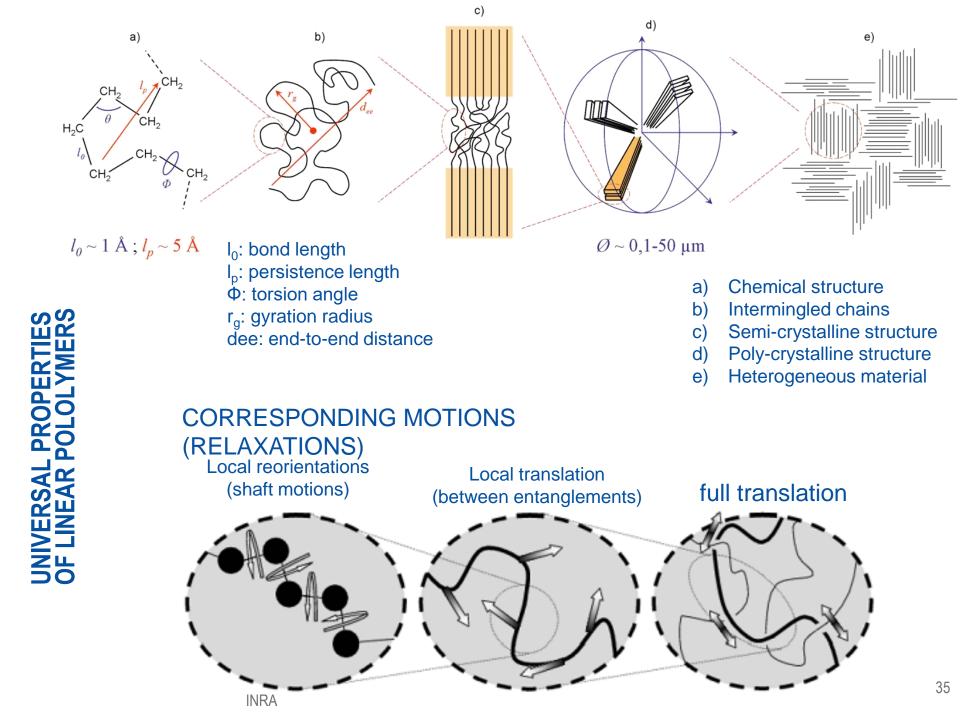


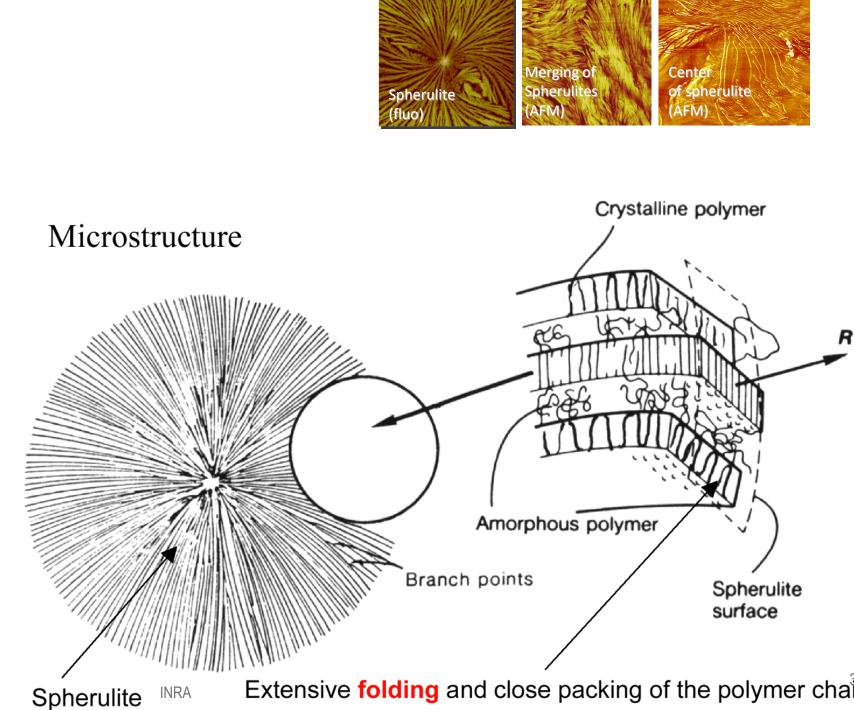
Laminates







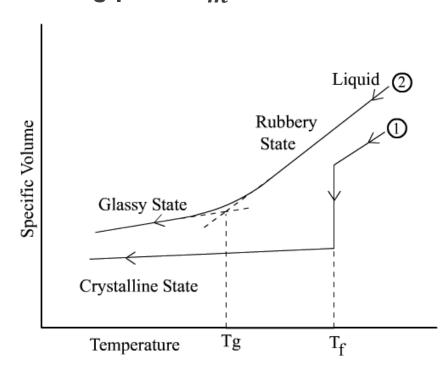




Extensive folding and close packing of the polymer chain INRA

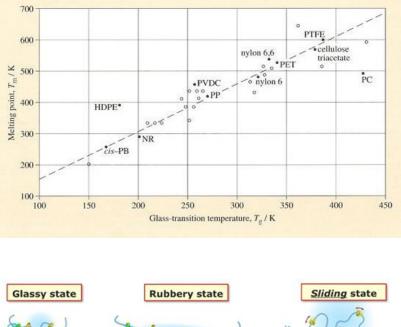
Critical temperatures for polymers

Glass transition temp. T_g Melting point T_m

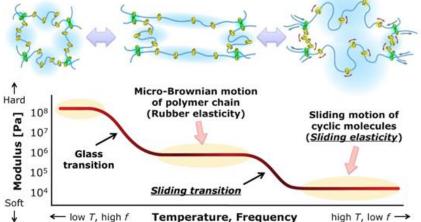


$$T_{g} = T_{g\infty} - \frac{K}{\left\langle M_{n} \right\rangle}$$

INRA



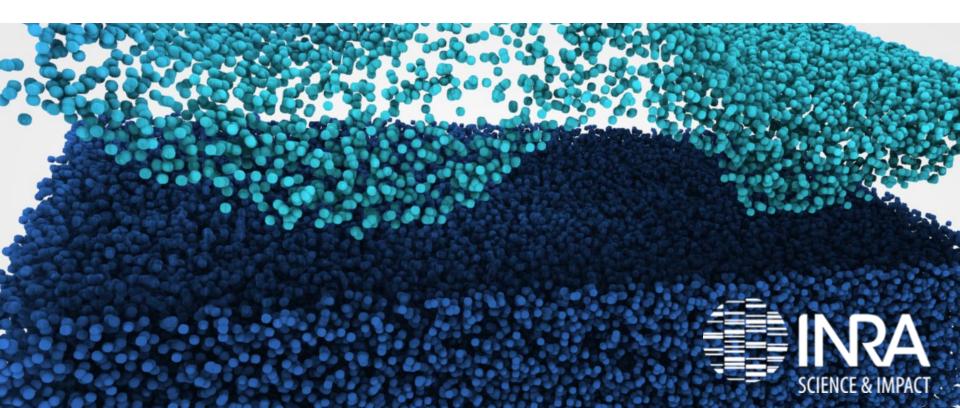
 $T_g \approx \frac{2}{3}T_m$



TOWAR	RDS BIODEGRADABLE POLYMERS	polymer	Tg (°C)	Tm (°C)
e.g.	· · · · · ·	PE	-120	60
		PCL	-60	60
	La	PBSA	-45	114
		PEA	-30	112
	Long Of Marine	PBAT	-30	110
	TTTTTTTTTTT	PHBV ₁₅	+5	145
	$\left(\begin{array}{c} & & \\ & $	PHB	+10	175
polarity	$ \begin{array}{c} & & \\ & & $	PLA	+58	+152
		EVOH	+60	+190
	~lop-lop-lop-	PET	+90	+270
		Proteins		
		Starch	>200	Degradation before
		Hemicelluloses	@0% RH	melting
	$HO \longrightarrow OH \longrightarrow$	Cellulose		

ADDITIVES

THERMOPLASTICS, ELASTOMERS



FOOD APPLICATIONS

French Fries

Innevative Solutions for Packaging

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NON FOOD APPLICATIONS

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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(<i>n</i> -octyl)tin <i>S</i> , <i>S</i> '-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-n-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, phthalo- cyanine blue	0.1–5 (Various polymers)

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

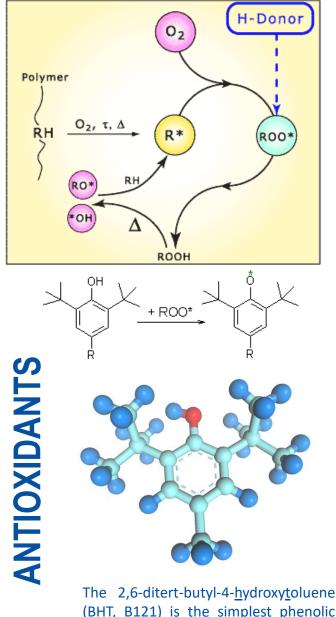
Source: Compiled from FDA (1987) and British Plastics Federation (1980).

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	Х	Х	Х	x	x	x	Х		Х
Shock agent	X	Х	Х	x	x	x	х		
Initiator			D	D		D			
Catalyst	D	D			D		D		D
Lubricant	Х	Х	Х	X	X			X	
Plasticizer	А		А	А		А			
Charges	А	Α	А	Α	Α	А	А	А	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),

	nom	CAS Formule M (g∙mo[¹)	Structure 3D	nom	CAS Formule M (g∙mo[¹)	Structure 3D
	2,6-Di(tert- butyl)hydroxytoluène (BHT)	128-37-0 C15 H24 O 220.35		Acide 3-(1,1- diméthyléthyl)-4- hydroxy-5-méthyl- Benzènepropanoïque (Irganox 245)	36443-68-2 C34 H50 O8 586.76	and the second s
	Monoacrylate de 2,2'- Méthylenebis(4-méthyl- 6-tert-butylphénol) Irganox (3052)	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- diméthyléthyl)-phénol (Irganox 1330)	1709-70-2 C54 H78 O3 775.20	
	2-méthyl-4,6- bis[(octylthio)méthyl]- phénol (Irganox 1520)	110553-27- 0 C25 H44 O S2 424.75	and the second second	Isocyanurate de s- Triazine- 2,4,6(1H,3H,5H)-trione, 1,3,5-tris(3,5-di-tert- butyl-4-hydroxybenzyl)- (8CI); 1,3,5-Tri(3,5-di- tert-butyl-4- hydroxybenzyle) (Irganox 3114)	27676-62-6 C48 H69 N3 O6 784.08	
	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 430.71	2 3 1 4 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Benzène propanoate de 3,5-bis(1,1- diméthyléthyl)-4- hydroxy-, 1,1'-[2,2- bis[[3-[3,5-bis(1,1- diméthyléthyl)-4- hydroxyphényl]-1- oxopropoxy]méthyl]- 1,3-propanediyle] (Irganox 1010)	6683-19-8 C73 H108 O12 1177.63	
	1,1-Bis(3,5-di-tert-butyl- 2- hydroxyphényl)éthane (Isonox 129)	35958-30-6 C30 H46 O2 438.68		bis[2,4-bis(1,1- diméthyléthyl)-6- méthylphényl] éthyl ester (Irgafos 38)	145650-60-8 C32 H51 O3 P 514.72	a the second sec
	2,6-Di-tert-butyl-4- (octadécanoxycarbonylé thyl)phénol (Irganox 1076)	2082-79-3 C35 H62 O3 530.86		2,4,8,10-Tetraoxa-3,9- diphosphaspiro[5.5]un décane, 3,9-bis[2,4- bis(1,1- diméthyléthyl)phénoxy]- (Ultranox 626,640)	26741-53-7 C33 H50 O6 P2 604.69	
e C / t	Propionate de 3, 3'- thiobis-, didodécyle (Irganox 800)	123-28-4 C30 H58 O4 S 544	and the second sec	Diphosphite de Bis(2,6- di-tert-butyl-4- méthylphényl)pentaéry thritol (Mark PEP 36)	80693-00-1 C35 H54 O6 P2 632.75	×
)	3,5-bis-(1, 1- diméthyléthyl)-4- hydroxynenzène propionate d'hydrazine (Irganox 1024)	32687-78-8 C34 H52 N2 O4 552.79		1,1',1''- Phosphite de 2,4-bis(1,1- diméthyléthyl)-Phénol (Irgafos 168)	31570-04-4 C42 H63 O3 P 646.92	



(BHT, B12<u>1</u>) is the simplest phenolic antioxidant. It yields a stable phenoxy radical i) by mesomery, ii) steric effect due to large tert-butyl, and iii) captodative effect.

nom	CAS Formule M (g∙moΓ¹)	Structure 3D	nom	CAS Formule M (g∙mo[¹)	Structure 3D
Acide 4 <i>H</i> -1- Benzopyran-2- carboxylique	248595-13- 3 C18 H20 O5	s and the	Adipate de Di(2- éthylhexyle (DEHA)	103-23-1 C22H42O4	
	316.35 6160-78-7			370.57 77-90-7	
4- Methylumbelliferyl- beta-D-	C16H18O8	Startes-	Citrate de tributyl-	C20 H34 O8	
galactopyranoside	338.31		acétyle	402.88	
2-	117-81-7				
diéthylhexyl)phtalat e (DEHP)	C24H38O4 390.56				
	TRALLIANS RUPTORS	The second secon	CUNG FIL no disposable		

Conra	d et al	. (2004	4)	
			A	
0	0.25	0.5	25 1.0	

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

Carbon black
PM 42080

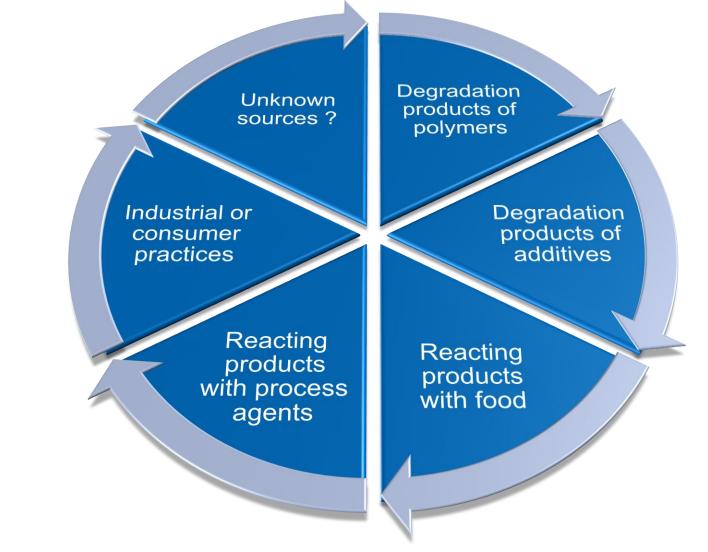
Benzo[a]pyrene, carcinogenic impurity (< 0,25 mg/kg C)

specifications for the HAP

ANTIUV

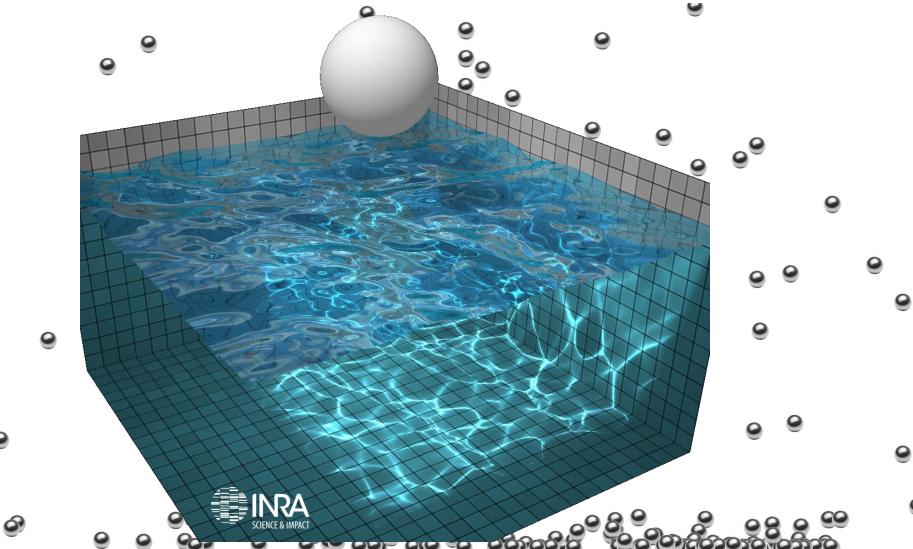


	nom	CAS Formule M (g∙mol ¹)	Structure 3D	nom	CAS Formule M (g∙moΓ¹)	Structure 3D
-	2-Hydroxy-4- methoxybenzophénone (Chimassorb 90)	131-57-7 C14 H12 O3 228.24		Acide 3,5-bis(1,1- diméthyléthyl)-4-hydroxy- benzoïque (Cyasorb 2908)	67845- 93-6 C31 H54 O3 474.76	K. S.
-	1-(2-Hydroxyéthyl)- 2,2,6,6-tetraméthyl-4- 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	×
ack	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	-20-2-	Didécanoate de 1,10- bis(1,2,2,6,6-pentaméthyl-4- piperidinyle) (Tinuvin 292)	41556- 26-7 C30 H56 N2 O4 508.78	No. of the other
\bigcirc	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	With the the	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	Strategier
	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	WHILE AND			



MIGRATION ISSUES

PAST CRISES, DIFFUSION-SOLUBILIZATION, REGULATION















Is it safe? How to assess it? How to grant it?

51

OPEN

http://ec.europa.eu/food/food/rapidalert/index_en.htm



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HEALTH AND CONSUMERS European Food Commission EUROPA > European Commission > DG Health and Consumers > Overview > Food and Feed Safety General Food Law Animal Nutrition Labelling & Nutrition Biotechnology Novel Food Chemical Safety Biological Safety Official controls Food waste Food improvement agents Print Rapid Alert System for Food and Feed (RASFF) - Introduction Home | Transmission of information | Members of the Network | Notifications | Publications | RASFF portal database Resources Press Releases Health & Consumer Voice Newsletter Publications **Rapid Alert System for Food and Feed** What's New?

- Rapid Alert System for Food and Feed (R
 Press release on 2012 RASFF annual rep
- Questions and answers on 2012 RASFF

Welcome to the RASFF porta

The Rapid Alert System for Food and Feed (R exchange information about measures take information helps Member States to act mor feed.

- Read more about the legal basis of RASF
- Who are the members of RASFF?
- 🔊 🔍 🔍 🔍 🔍 🔍 🔍 🔍

The effectiveness of RASFF is ensured by kee Commission, <u>EFSA</u>, <u>EFTA</u> surveillance authorit structured way by means of templates.



RASFF Portal

<u>ar</u> (ai criceria - I	Subject This	DAMITHONE	Ргоанст туре	e tood contact	materiar nazaru category migrauon		🚔 🔼	<
				<< Fi	irst <<	<< Previous 100 << $ m Notifications \ 1 \ to \ 9 \ of 9 ightarrow >> Next 100 >>$	>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>>		
	Classification	Date of case	Last change	Reference	Country	Subject	Product Category	Туре	
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	FCM	Ĩ
2.	information for follow-up	21/01/2011	14/03/2011	2011.0088	DE	plastic mugs from Greece	food contact materials	FCM	0
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	FCM	9
	- formation	21/12/2010	10/00/001			migration of 2-methyl-4-(methylthio)-2-morpholinopropiophenone (simulant of 10% ethanol: 86 un/ko - noh) of ethyl-4-			(
4.	information	21/12/2010	10/03/201			Notification detail - 20	11.0316		
5.	information	18/03/2010	10/03/201	migrati		nethyl-4'-(methylthio)-2-morpholinopropiophenone, yl thioxanthone (DETX) (sum 685 µg/kg - ppb) from			C
6.	alert	31/07/2009	10/03/201		Reference : 2011.0316 Notification date : 10/03/2011 Last update : 16/03/2011				0
7.	information	11/04/2006	02/02/200			ion type: food contact material - information for attention - official on taken: withdrawal from the market			C
8.	alert	17/01/2006	02/02/200			ion from : Germany (DE)			C
9.	alert	17/01/2006	02/02/200			n status: distribution restricted to notifying country	DACE	5 C	C
				F		Product : printing ink on drinking cups category : food contact materials	Rapid Alert System for Food	d and Feed	

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



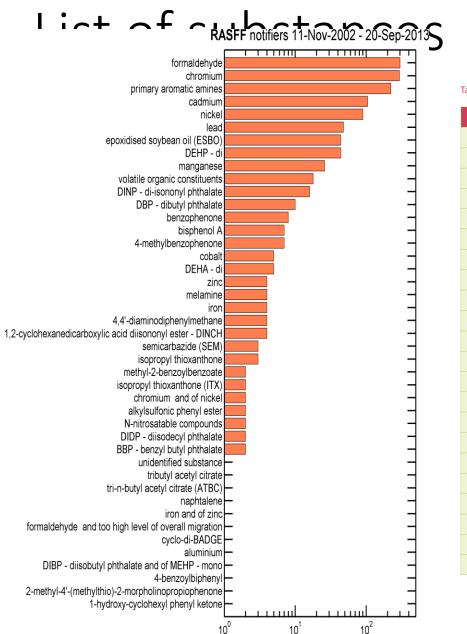
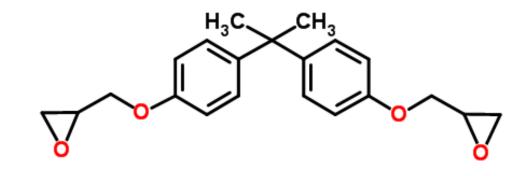
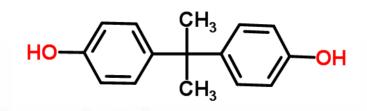


Table 6 - Migration of substances (except heavy metals) from food contact material

	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

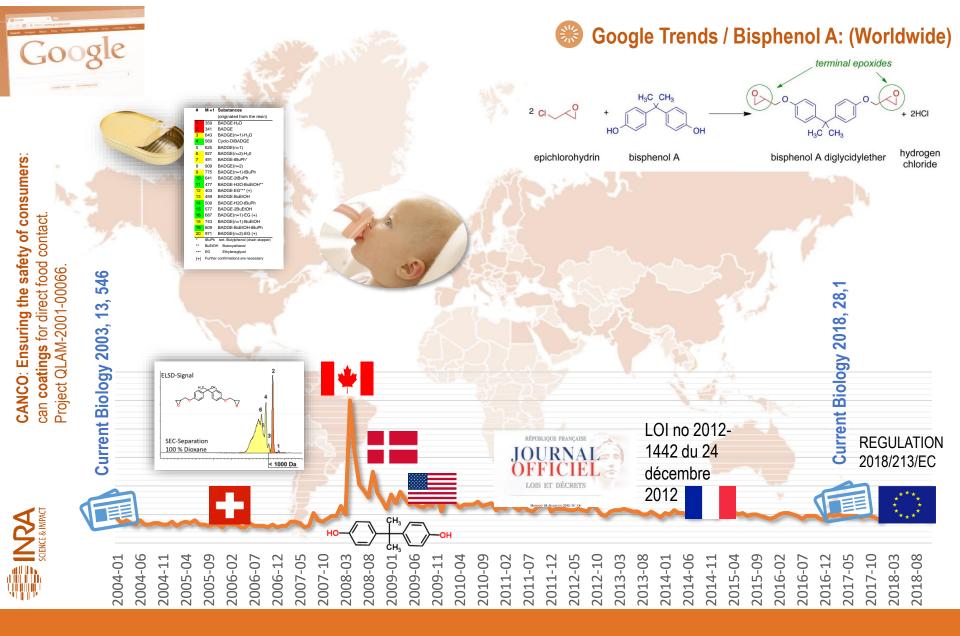
2011 figures





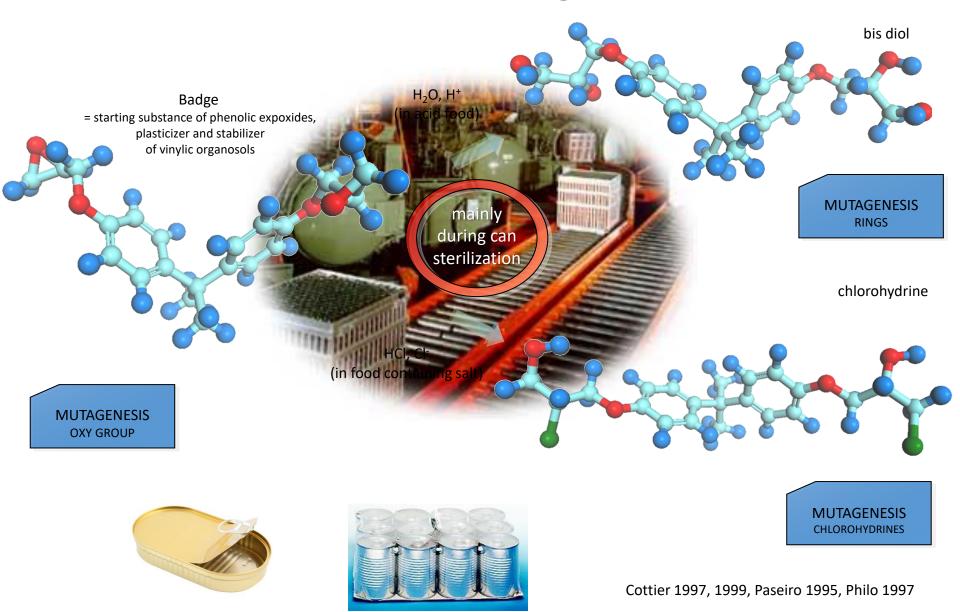
BISPHENOLS

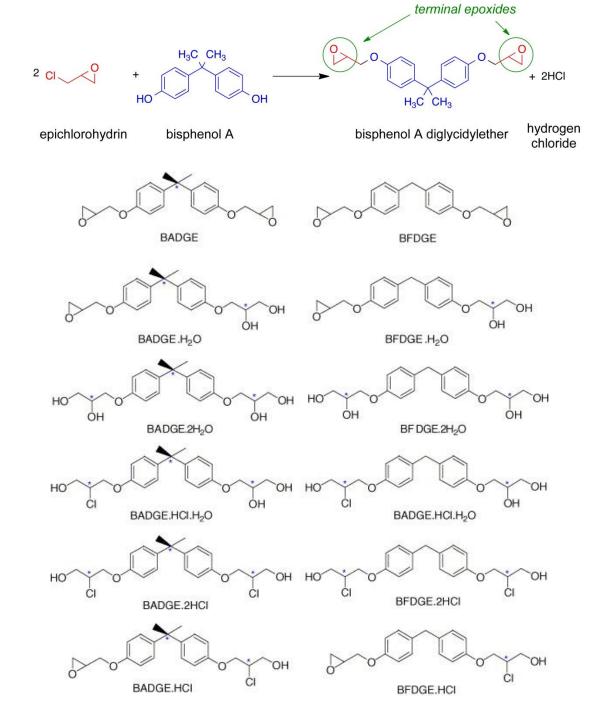






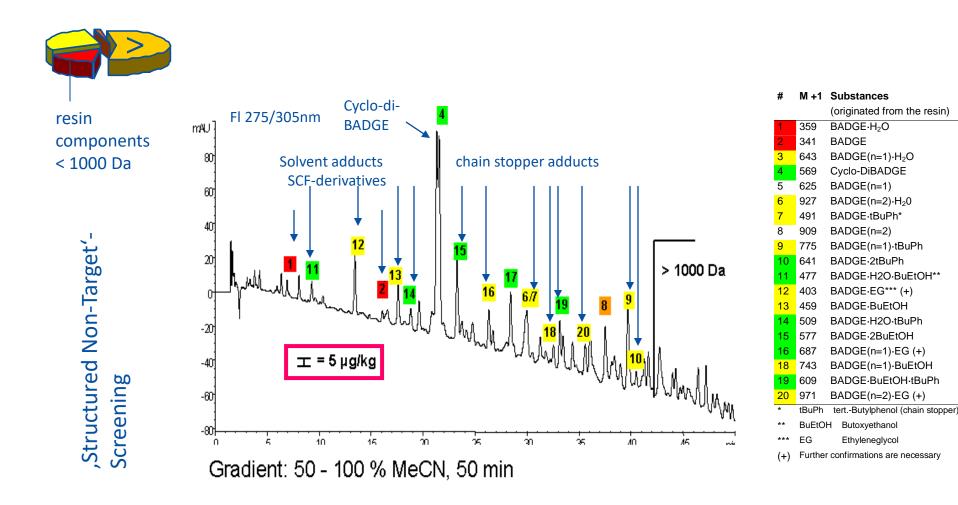
EPOXIDE=reactive migrants





SCREENING OF MIGRANTS FROM CAN COATINGS <1000 Da SAMPLE: STANDARD EPOXY-COATING, MECN-EXTRACT

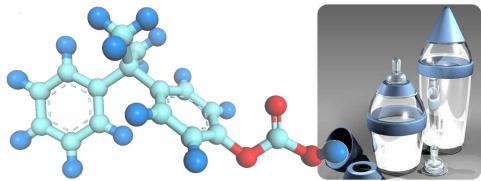




Bisphenol A Exposure Causes Meiotic Aneuploidy in the Female Mouse

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.

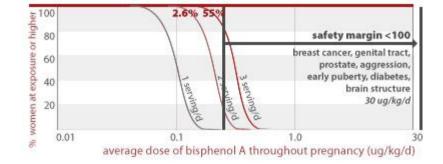
Results: A sudden, spontaneous increase in meiotic disturbances, including aneuploidy, in studies of oocytes from control female mice in our laboratory coincided with the accidental exposure of our animals to an environmental source of bisphenol A (BPA). BPA is an estrogenic compound widely used in the 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.

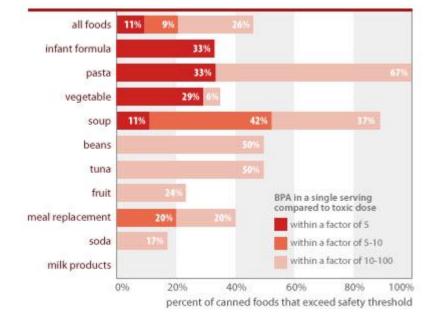


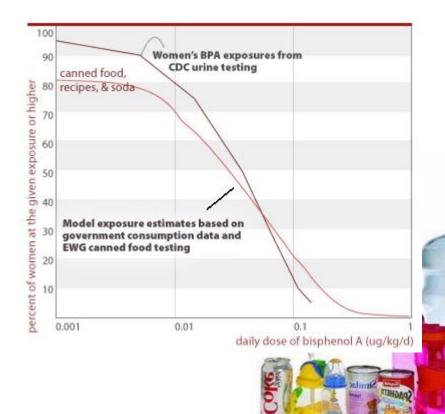
Conclusions: Both the initial inadvertent exposure and subsequent experimental studies suggest that BPA is a potent meiotic aneugen. Specifically, in the female mouse, short-term, low-dose exposure during the final stages of oocyte growth is sufficient to elicit detectable meiotic effects. These results 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







Source: Chemical analyses of 97 canned foods by Southern Testing and Research Division of Microbac Laboratories, Inc., North Carolina

Google Trends – 2003-present



Termes associés 🛛 💿	Les plus fr	En progre
bpa bisphenol a	100	
bpa	95	
bisphenol a bottles	60	
bisphenol a plastic	55	
bisphenol a biberon	55	
biberon bisphenol	50	
sans bisphenol a	50	
biberon sans bisphenol	40	
bisphenol a free	35	
bisphenol a baby	35	-

Epilogue



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 dernier.

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 groupe B

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



Mercredi 26 décembre 2012 / N° 300

LOI 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.



L 41/6	EN	Official Journal of the European Union	14.2.2018
		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			
		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.

UPDATE 2018

Current Biology

Replacement Bisphenols Adversely Affect Mouse Gametogenesis with Consequences for Subsequent Generations

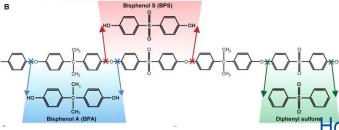
Highlights

- 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





Authors

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

Correspondence

pathunt@wsu.edu

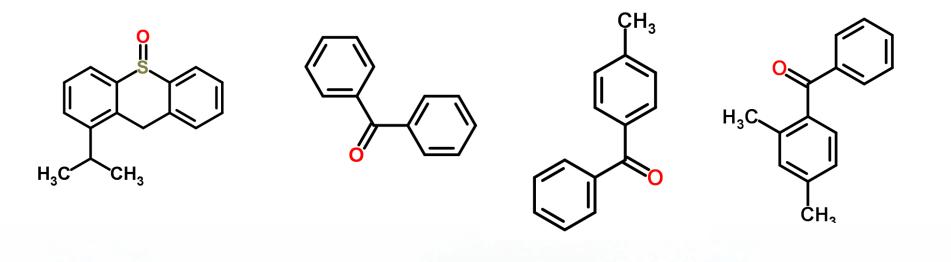
In Brief

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.

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

SUMMARY

20 years ago, accidental bisphenol A (BPA) exposure 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 suggest BPA effects extend across species (e.g., [18-30]; reviewed in [31-33]). Widespread use has resulted in ubiquitous environmental contamination and human BPA exposure. Consumer concern resulted in "BPA-free" products produced using structurally 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 germline 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 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.



PHOTOINITIATORS



Food and Feed borne crises throughout the food chain





destroy consumer's confidence in food

But what about food packaging





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

AlertNet

♠

REUTERS FOUNDATION (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. "It is incredible that such defenceless beings as babies should face such serious risks in a product as widely used as milk"



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.

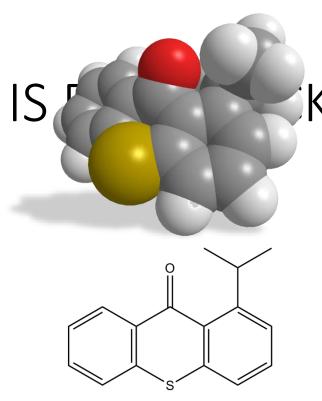
O'Hayer said Tetra Pak removed the printing technology in question in October to prevent any printing compound, even if not dangerous, from seeping into a product.

"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.

AlertNet news is provided by REUTERS



isopropyl thioxanthone

photoinitiator used in UV, curing resins, inks, coatings and adhesives M=241 g·mol⁻¹











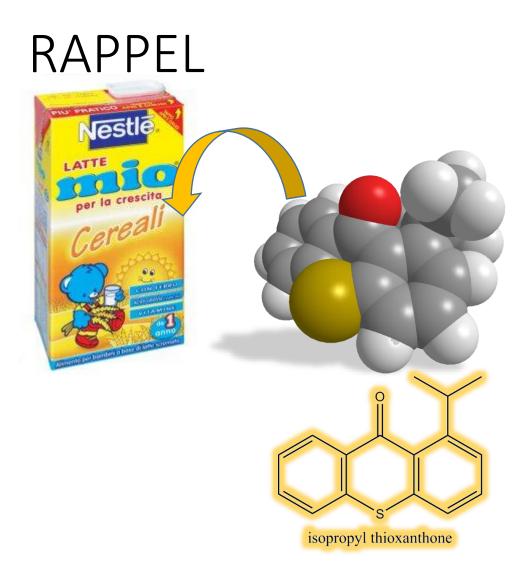
December 15, 2005

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.







Italian police seize contaminated Nestle baby milk 22 Nov 2005 16:45:09 GMT Source: Reuters



PREVIOUS | NEXT >

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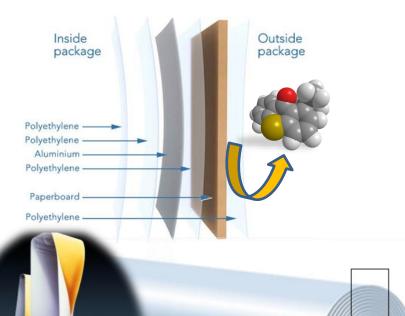
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Modeling would have been able to predict ITX values in food \sim

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

Migrant		2-ITX
Homologous migrant [†]		not available
Polymer		LDPE ^{††}
PARAMETER	notation (unit)	
Thickness	<i>l</i> _P (μm)	50
Volume dilution ratio	L _{F/P} (-)	360
Biot mass number	Bi (-)	10 ³
Contact Time	t (days)	90
Temperature	(°C)	4
Likely initial concentration ^a	$\overline{C}_{i,P}^{0}$ a (mg·kg-1)	100 ± 10
Conservative initial concentration ^b	$\left(C^{0}_{i,P}\right)^{+}$ b (mg·kg ⁻¹)	300
Likely diffusion coefficient ^o	$\overline{D}_{i,P}$ ° (m ² .s ⁻¹)	8.4·10 ⁻¹⁶ [7.6·10 ⁻¹⁶ 9.2·10 ⁻¹⁶]
Conservative diffusion coefficient ^d	$D^{+}_{i,P}$ d (m ² .S ⁻¹)	3.9.10-14
Likely partition coefficient ^e	$\overline{K}_{i,F/P}$ (-)	1.4·10 ⁻⁹ [3.7·10 ⁻¹⁰ 5.1·10 ⁻⁹]
Conservative partition coefficient	$K^{\scriptscriptstyle +}_{i,F/P}$ (-)	10 ³

Last

change

Reference

2005.631

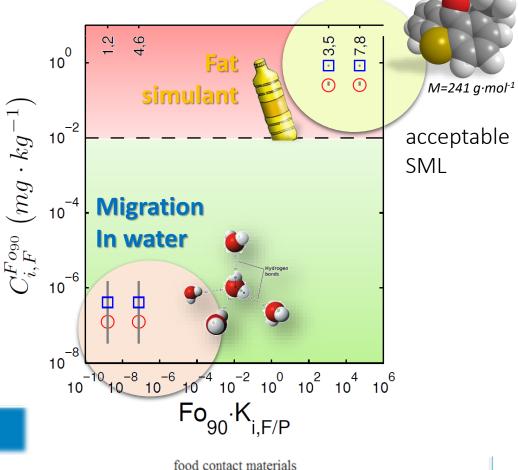
Country

ITALY

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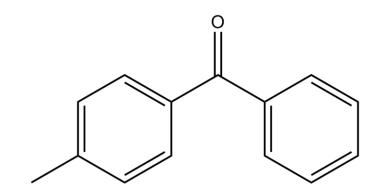
case 6. 08/09/2005

RASFF Portal



migration of isopropyl thioxanthone (250 μ g/l) from packaging of milk for babies from Spain

IS FOOD PACKAG



4-methyl benzophenone

LE VEILLEUR@

Quelques fois on ne voit pas tout..

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.

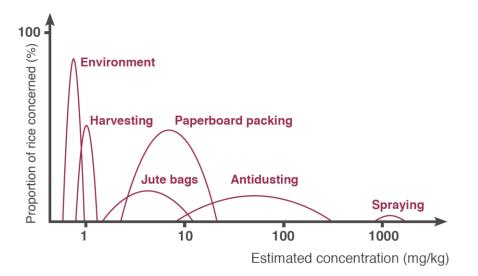
"Nous avons été informés le 6 février par notre maison-mère qu'il fallait retirer de la vente deux références, des muesli au chocolat et des muesli aux fruits. Les marchandises ont été retirées le 9 février", déclare Jérôme Gresland, directeur des achats de Lidl pour la France, confirmant une information du Canard enchaîné. Des sites comme 60 millions de consommateurs ou rappelsproduits.fr permettent aux

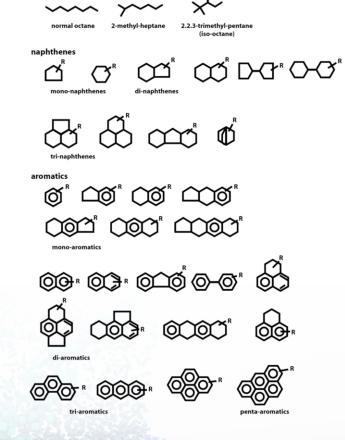
consommateurs s'informer sur les produits – steaks hachés avariés, circuits hydrauliques de voiture défectueux, saucisson contenant des salmonelles – rappelés par les constructeurs et fabricants.

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.







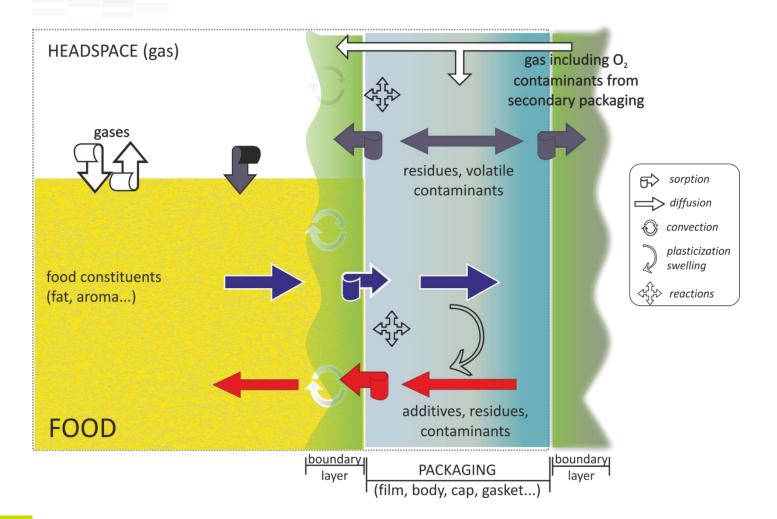
alkanes

MINERAL OILS



Coupled mass transfer

between the food product and the packaging material



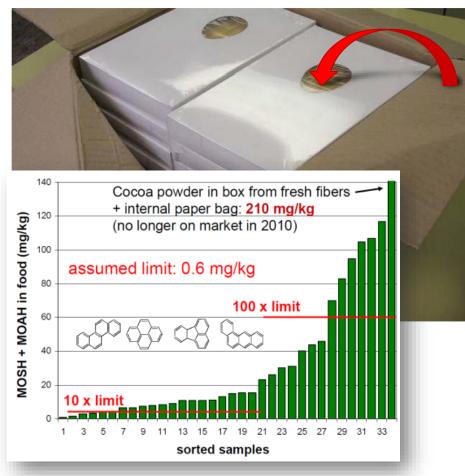


CONTEXT: EXAMPLES NOT COVERED BY SPECIFIC MEASURES: NON-SPECIFICALLY REGULATED MATERIALS, DRY AND AQUEOUS FOOD FALSELY CONSIDERED SAFE

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

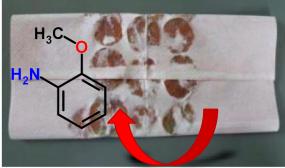
(Biedermann et al., 2011; Packaging Technol & Sci 2011, 24, 281-290)



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)







FOOD WATCH – October 2015

SOURCES DE CONTAMINATION DES ALIMENTS PAR LES HUILES MINÉRALES

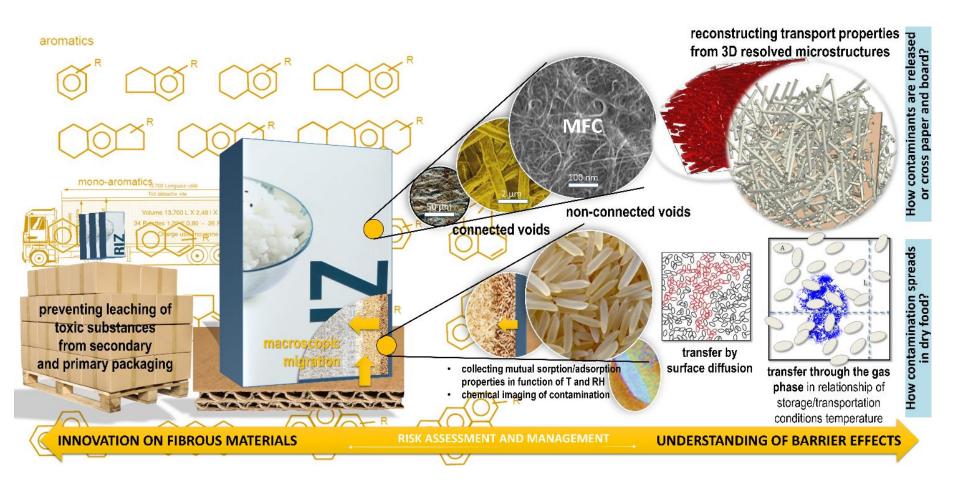




http://www.foodwatch.org/fr/presse/communiques-de-presse/page-detailcommuniques-de-presse/des-hydrocarbures-dans-nos-assiettesfoodwatch-tire-le-signal-dalarme/



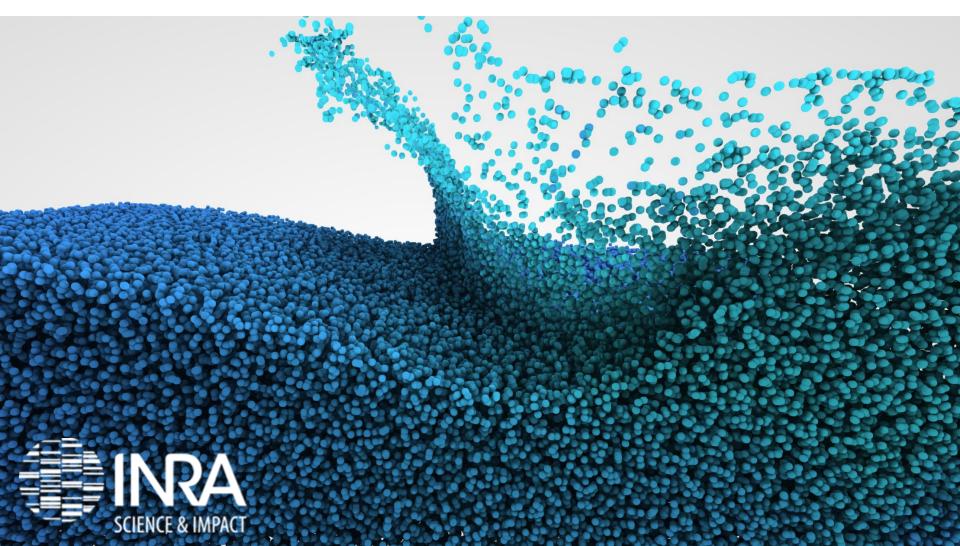
NEW RESEARCH PROJECT FoodSafeBioPack (2021-2024)





TOXICITY

ACUTE TOXICITY vs NEW TRENDS



"Truth in science can be defined as the working hypothesis best suited to open the way to the next better one."—Konrad Lorenz, Austria



theguardian

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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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I C g Article history

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scientists

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pollution resembles

photosynthesis and potentially wreaking

havoc on country's food

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legal action against the

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supply, experts warn

nuclear winter, say

Air pollution now impeding

Health · Cancer

Food & drink industry

Food science · Chemistry



OP/ED 8/20/2013 @ 8:00AM | 13,109 views



main and the second sec

FOLLOW

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

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.

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

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.

A CONFERENCES AND MORE

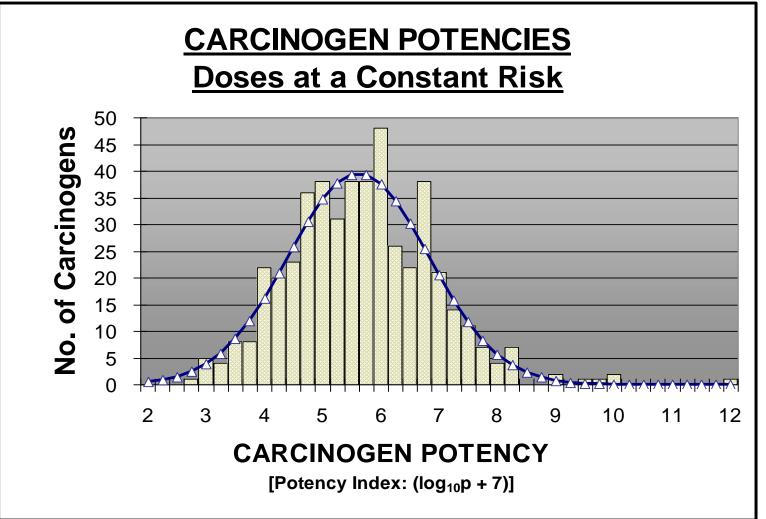




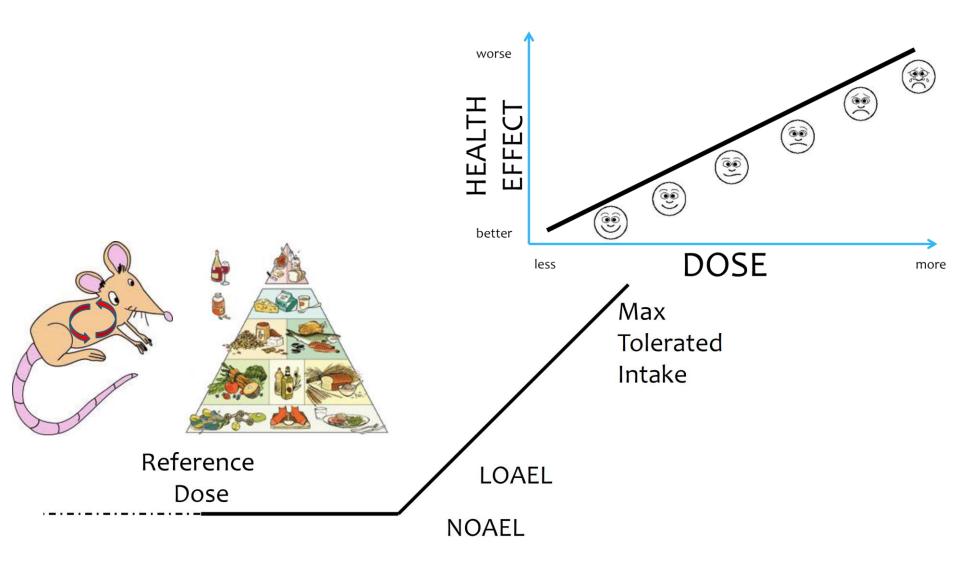
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based on acute toxicology concepts





ACUTE TOXICOLOGY



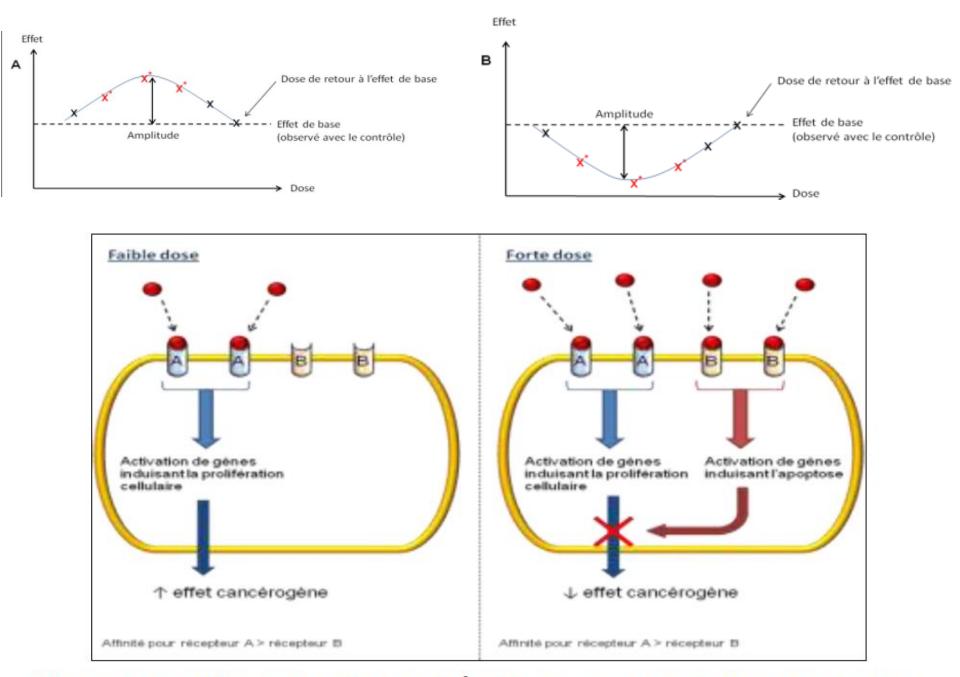
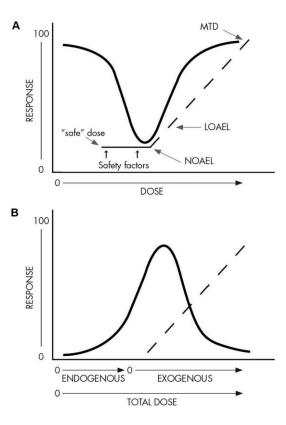


Figure 3 : Equilibre entre effets prolifératifs et pro-apoptotiques selon la dose



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 µg/kg · d (679)	No NOAEL was ever established in toxicological studies (38)	<50 mg/kg ⋅ d (38)	~400 µg/kg · d to rodents and nonhuman primates (4, 253)
DEHP	0.5–25 µg/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.

Endocrine Reviews, 2012, 33(3):378-455

• LOW-DOSE EFFECT SUBSTANCES

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

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Center for Beginerative and Developmental Biology and Department of Biology (LNV), Tifts University, Mediord, Masachustets US: 255: The Endocrine Designation Exchanger (C: A. Paenic, Cachael 84/28; Jaboratory for Intergrative Studies in Amphibian Biology (CI: B.H.), Molecular Tocochogy, Group in Endocrinology, Energy and Resource Group, Maseum of Vertebrate Zoology, and Department of Integrative Biology, University of California, Berkely, California 94/20, Diologian of Estamunal Research and Tearing (U:H.), National Institute of Environmental Health Sciences, National Institutes of Health U.S. Department of Health and Human Service, Research Timingé Park, North Canifornia 27709, Division of Esplerinology and Community Health (D.N.), School of Health (Health, University) of California 27709; Division of Serves, Molecular Polingi Jaboratory (D.N.), School of Health (Health, University) of Manecola, Minreacola, Minreacola, Serves, Molecular Polingi Jaboratory (D.S.), Masachutes General Topolati Center for Cancer Research, Charlestown, Masachusetts 0219; Department of Anatomy and Cellular Biology (AM.S.), Titts University School of Medicine, Boston, Masachusetts 0219; Department of Anatomy and Cellular Biology (AM.S.), Tutts University School of Medicine, Boston, Masachusetts 0219; Department of Research Serves, Research Titta, University of Masachusetts 0219; of Masachusetts 0219; Department of Research (Serves), Tabola, Serves, Serves), School of Medicine, Boston, Masachusetts 0219; Department of Research (Serves), Tabola, Serves), Fabio, Clantestown, et Masachusetts 02103; and Environmental Health Serves, Pable, Clantestown, Masachusetts 02109; Berley, Serves, Bable, Clantestown, et Masachusetts 10003; and Environmental Health Serves, P.M.D., Clantestown, Manett, Masachusetts 10003; and Environmental Health Serves, P.M.D., Clantestown, Masachusetts 2010; Berley, Berley,

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, PPAR γ 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	Incontinida	Estro copia activity	0.025 mg/kg . d
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 Carbendazim	Fungicide Fungicide	Alters aromatase Affects FSH, LH, and testosterone levels; alters spermatogenesis and Sertoli cell morphology	30 mg/kg ∙ d (EPA) 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

Mise au point

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Complications liées à l'exposition n utero au diéthylstilbestrol (DES)

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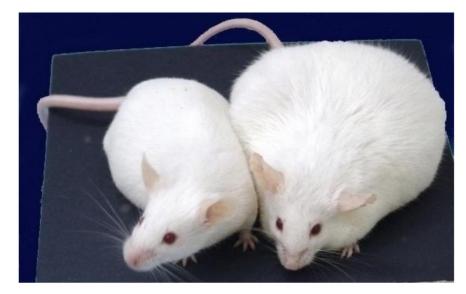
Actualisation 2011

Agence française de sécurité sanitaire des produits de santé

Agence française de sécurité sanitaire des produits de santé

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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.

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.



OF PACKAGING MATERI

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

A Recherche

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

t News in Science News Analysis News Archive Tag library

News in Science

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).

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..

BPA and phthalates do

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

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

Reference = glass bottle water with same water.

ne 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.

peut mimer une horm observé des problème Depuis les années 19 molécules sur d'autres thyroïde qui seraient l batraciens. On se den lipides ne pourrait pas

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



** efsa

European Food Safety Authority

http://www.efsa.europa.eu



CONTAM

Scientific Committee

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



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 microbiology.



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



Panel on Contaminants in the Food Chain Experts in chemistry, exposure assessment, toxicology, epidemiology, and statistics

GMO



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.

92



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



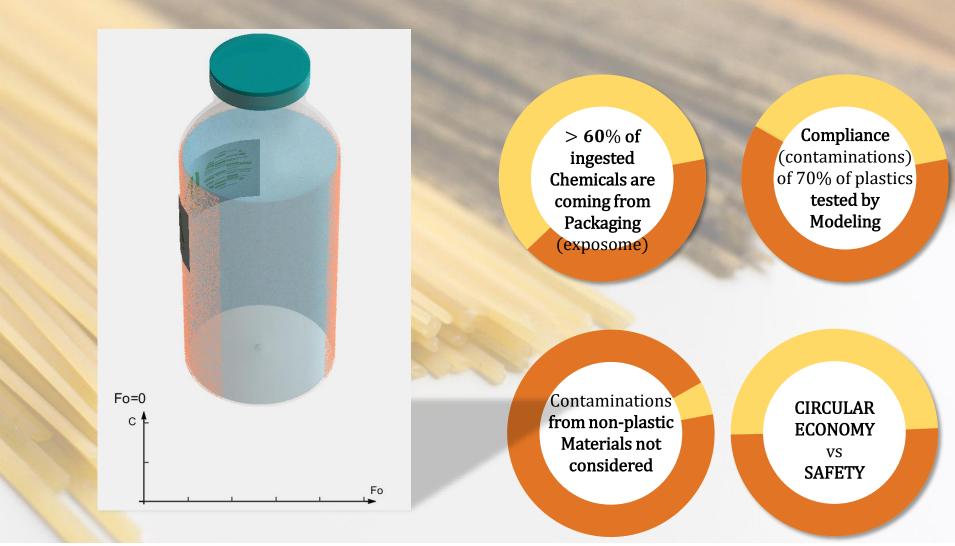
Panel on Plant Protection Products and their Residues Experts in chemistry, toxicology,

CEF



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

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



Food Packaging Forum

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" ANNÉE. - Nº 19

LA CONSERVE ALIMENTAIRE PF

Pulletin mensuel de Vulgarisation Chéorique et Pratique de Fabrication

TOUTE

PARAISSANT LE 15 DE CHAQUE MOIS

Bedige par un groupe de Habricants-Industriels et de Chefs d'Emplois de cette Industrie Ouvn Man sur l et pratique. Proprie ancie la M de la science alimentaire . Nicolas APPERT (1750-1841) École Nationale D'INDUSTRIE ALIMENTAIRE Nicolas Appert COMITÉ DE DIRECTION Bourse du Commerce CHEZ P - Paris le Bulletin Officiel de l'Ecole. NAPOL 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 lonc-

L'enseignement sera tout à la fois théorique

JUILLET 1910

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

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 diplômé, M. RAY-MOND 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

En un mot et suivant l'exemple d'autres pays, une Université nouvelle et bien moderne vient de naitre 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

290

LA CONSERVE ALIMENTAIRE

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

> Pour le Comité de Direction : Aug. CORTHAY.



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



tionnement.

Le règlement de 1908: « ...aucune substance alimentaire ne doit contenir de produit nuisible, produit chimiques... »

.095 19/09/2023

YOUR ROLE				
ROUTINE ASSESSMENT				Risk Tradeoff
			Risk balancing	Conflicts
	role	Scientifc risk assessment	Conflict Evaluative	cognitive, evaluative, normative
	Routine	Conflict: cognitive	Targets:	Targets:DG SANCO, industry stakeholders
	Target: industry	Target: professional associations	European Food Safety Authority	
	Discourse: internal	Discourse: cognitive	Discourse: reflective	Discourse: participatory
	Outcome: simple	Outcome: complex	Outcome: uncertain	Outcome: ambiguous



WHAT IS RISK?

Risk is a function of perception and representation



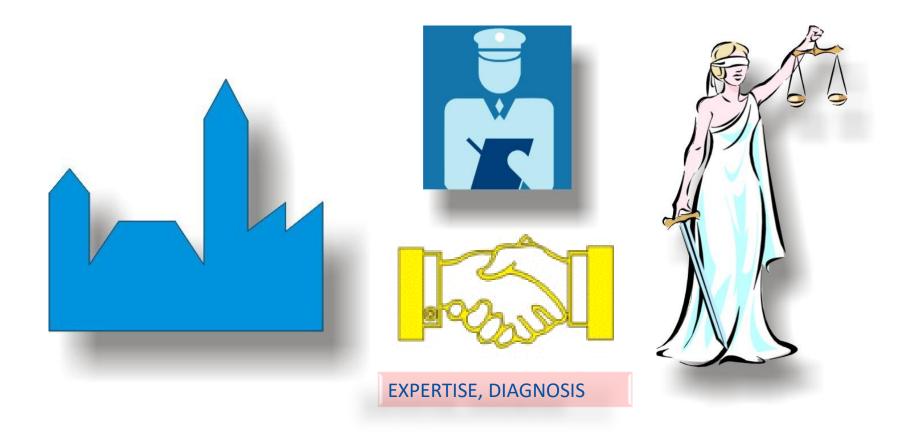








REGULATION=TRANSFER OF RESPONSABILITIES



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



- European professional organisations

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.

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 inert)
 - · 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 premises, and
- · 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. [Expand All]

	[expand m]
Plastic Materials	Ĭ
Active and Intelligent Materials	Ĭ
Recycled Plastic Materials	Ĭ
Ceramics	×.
Regenerated Cellulose Film	*

III. Other Legislation

Legislation on Specific Substances

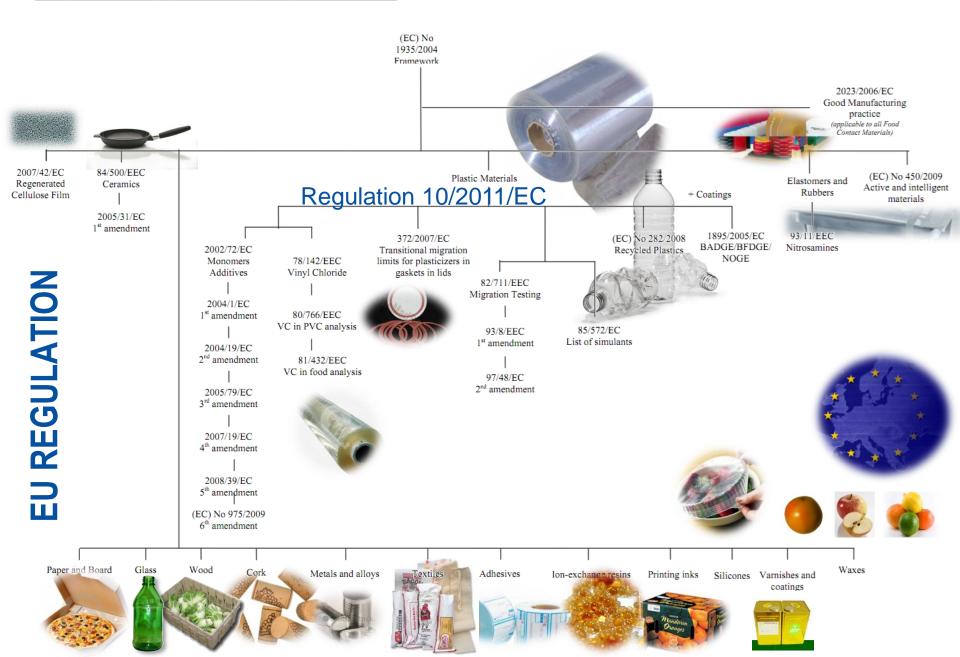
- Regulation 1895/2005/EC restricting use of certain epoxy derivatives in materials and articles intended to come into contact with food
- Directive 93/11/EEC release of N-nitrosamines and N-nitrosatable substances from rubber teats and soothers

- European Reference Laboratory on Food Contact Materials (EURL-FCM)
- European Food Safety Authority

Training

FOOD

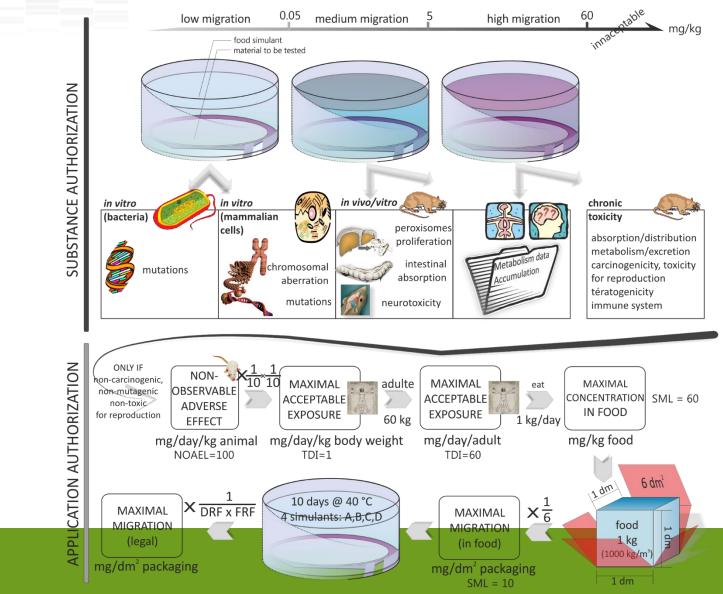
Overview of Community legislation (last update 20/10/2009)



SPECIFIC RULES FOR PLASTICS

COMPLIANCE ISSUES

SCIENCE & IMPAC



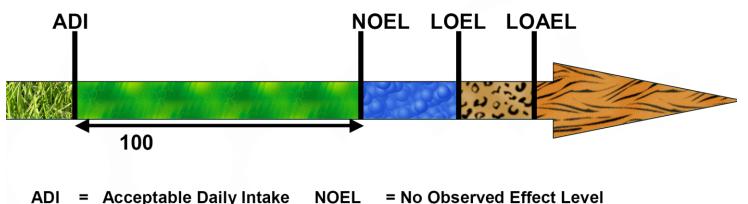
.0101

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)



- SML = Specific Migration Level LOEL = Lowest Observed Effect Level
 - LOAEL = Lowest Observed Adverse Effect Level



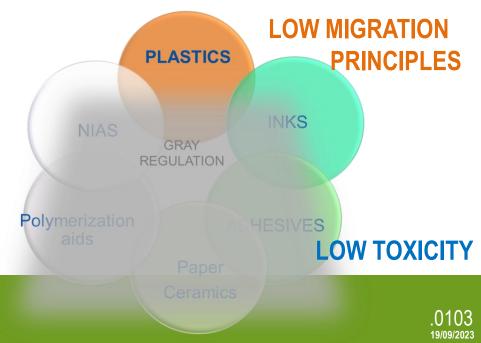
SPECIFIC EU RULES FOR PLASTICS FOR FOOD CONTACT

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



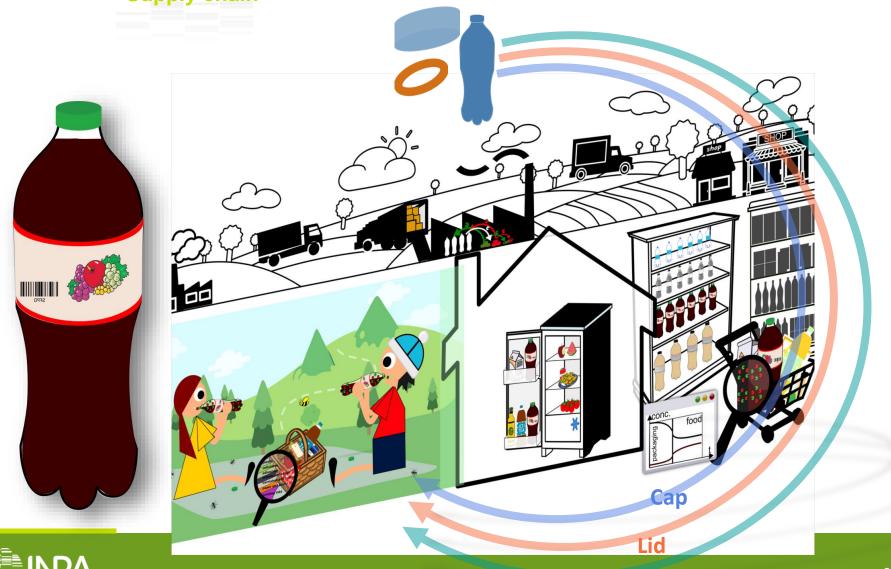




CHAINED STEPS, COMBINED MATERIALS

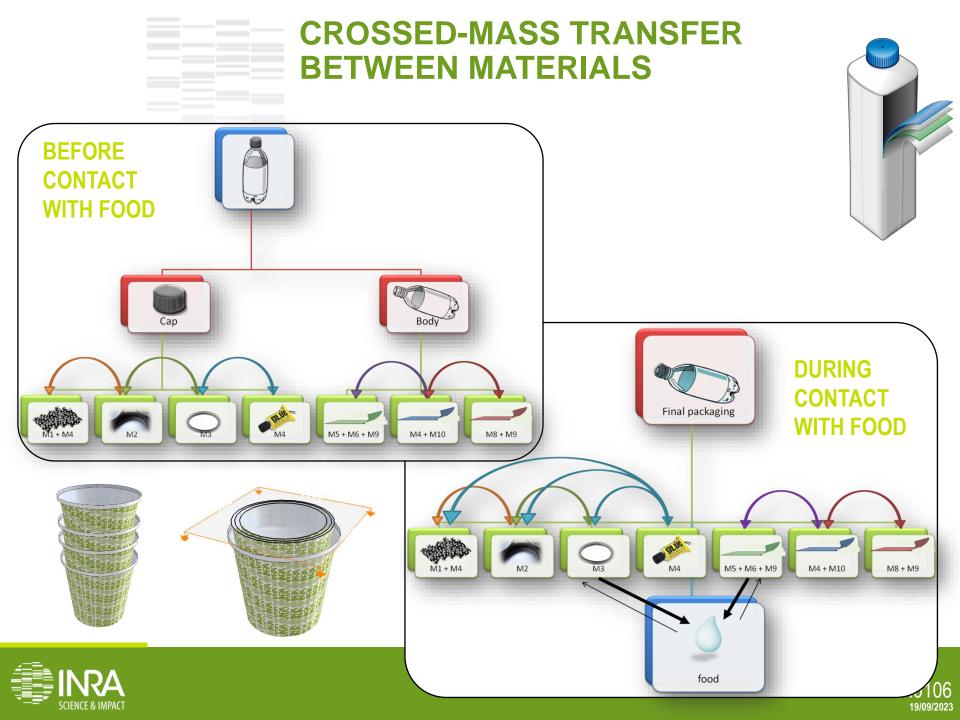
Supply chain

SCIENCE & IMPACT



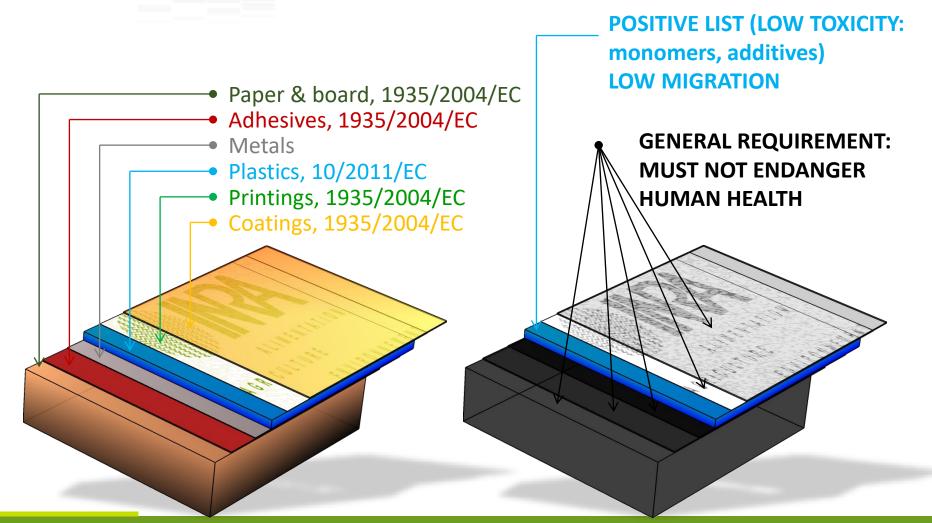
Bottle body





HETEROGENEOUS EU REGULATIONS

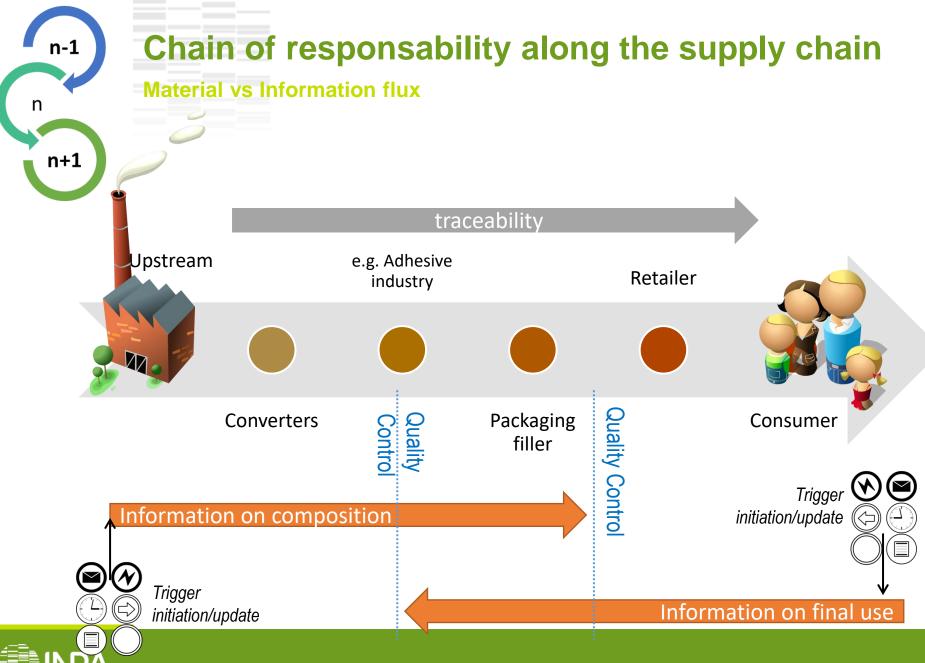
Variable concepts





17 groups of materials listed in Annex 1 of regulation 1935/2004/EC are still not covered by specific measures. They must be produced according to **Good Manufacturing Practices** (Regulation 2023/2006/EC) incl. 3 pillars: quality assurance system, quality control system, documentation.





SCIENCE & IMPACT





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

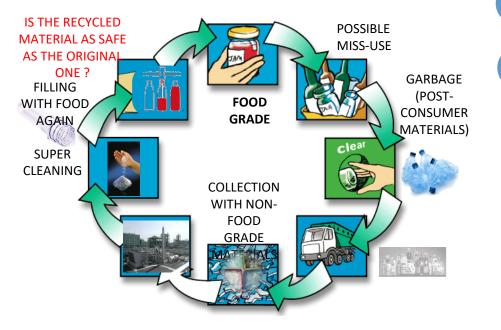
Subsidiarity and proportionality

The need for impact assessments

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

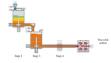
- legislative proposals
- non-legislative initiatives (e.g. financial programmes, recommendations for the negotiations of international agreements)
- implementing and delegated acts

The ordinary legislative procedure COMMISSION Proprovers COUNCIL PARLIAMENT



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 DECLIEATION 202/2000/EC



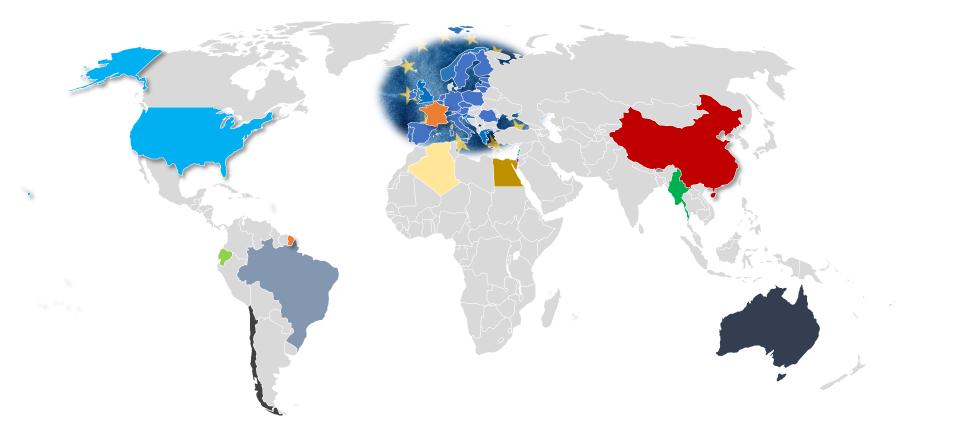
Misuse issues (post-use contaminations) of Polyethylene terephthalate (PET) can be easily handled : glassy polymer, it is mainly contaminated by small contaminants which can be removed by a devolatilization step above T_a Octanal a- Terpinene Terpinolene 1. Filling and use of HDPE milk bottles 2. Recollection 3. Sorting itable for Food Contact? Polyolefins are rubber polymers Recycling which can be easily contaminated Foodgrade HDPE milk bottles by high molecular weight contaminants after use. പ്രുവ്നുനംഗം. යි යි යා ර <u>_____</u>, da, ca, cca, Paper and board contains large amount of residues from printing inks: aromatic (carcinogenic) and aliphatic

්ම-ල' හි

mineral oils can be transferred without contact and lead to cross-contamination between materials J. of Chromatography A. 2013;1293:107-19.

RECYCLED PAPER AND BOARDS IS SOURCE OF RECURING CRISES IN EU





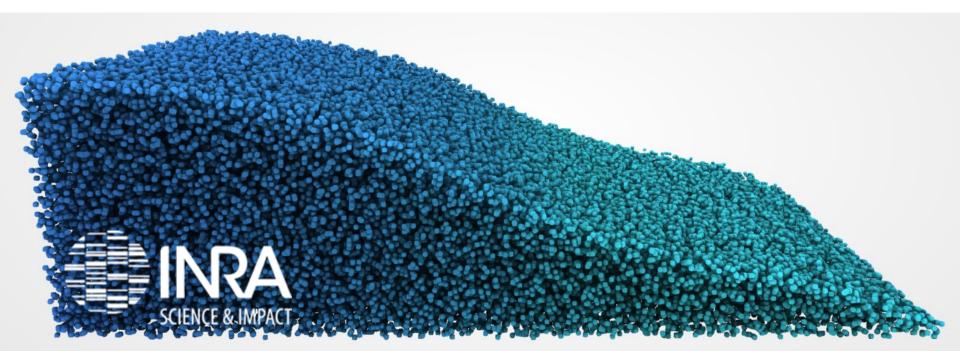
Our approaches developed jointly with EU are a model for several countries and industries (medical devices, biotechnology, cosmetics...



🃸 🗯 🔆 Our impact on practices in other countries

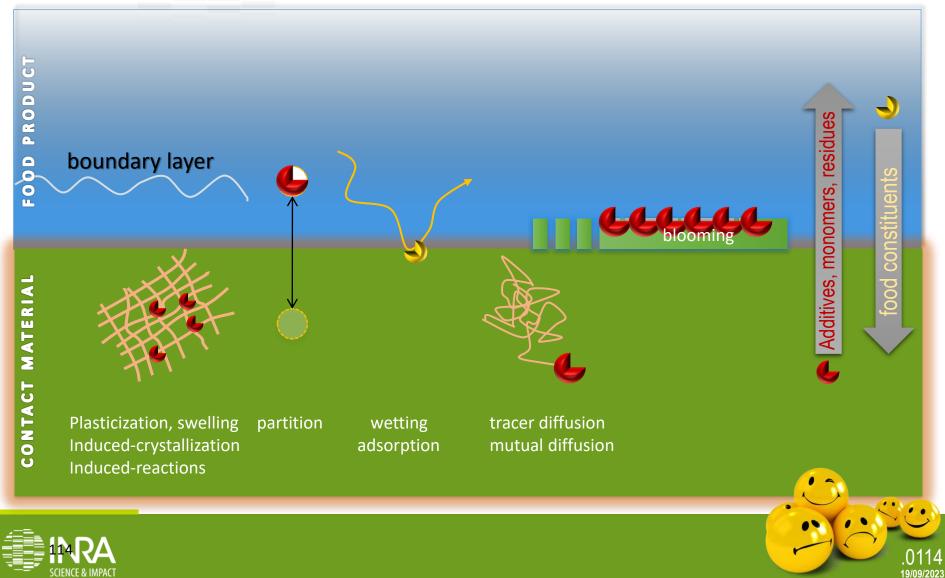
DIFFUSION IN POLYMERS

OVERVIEW, BARRIER PROPERTIES, MIGRATION ISSUES



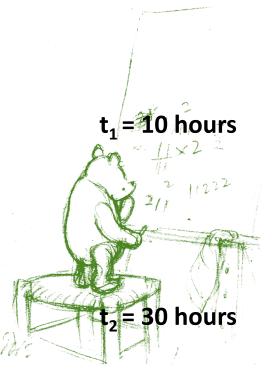


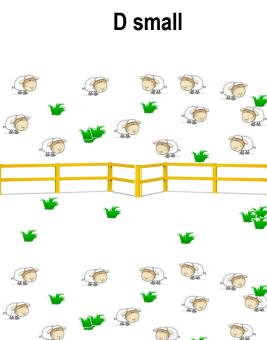
MIGRATION ISSUES CROSSED MASS TRANSFER OF FOOD CONTACT MATERIALS AND FOOD CONSTITUENTS

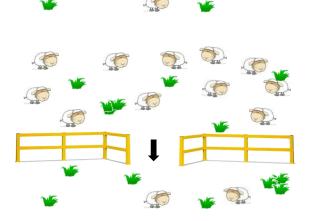




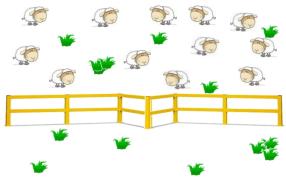
t₀ = 0 hour

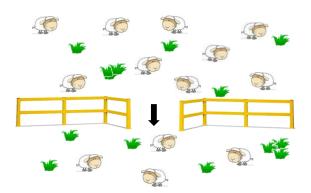


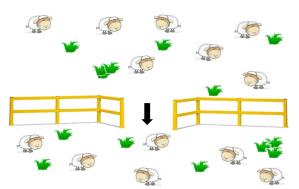








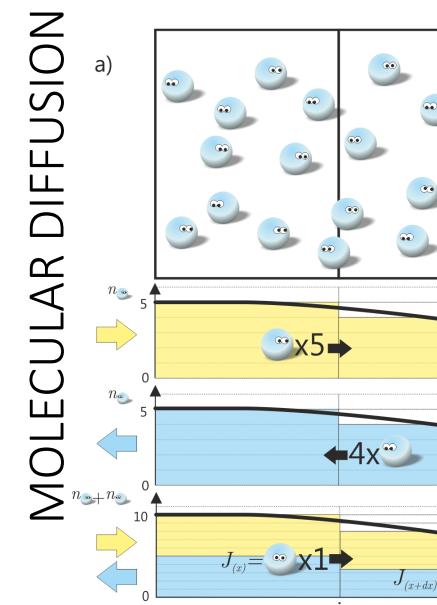






 $\frac{\partial C}{\partial t} = \frac{\partial}{\partial x} \left(D \frac{\partial C}{\partial x} \right)$





 $J_{(x)}$ - $J_{(x+dx)}$ $\frac{d}{dt}$

.

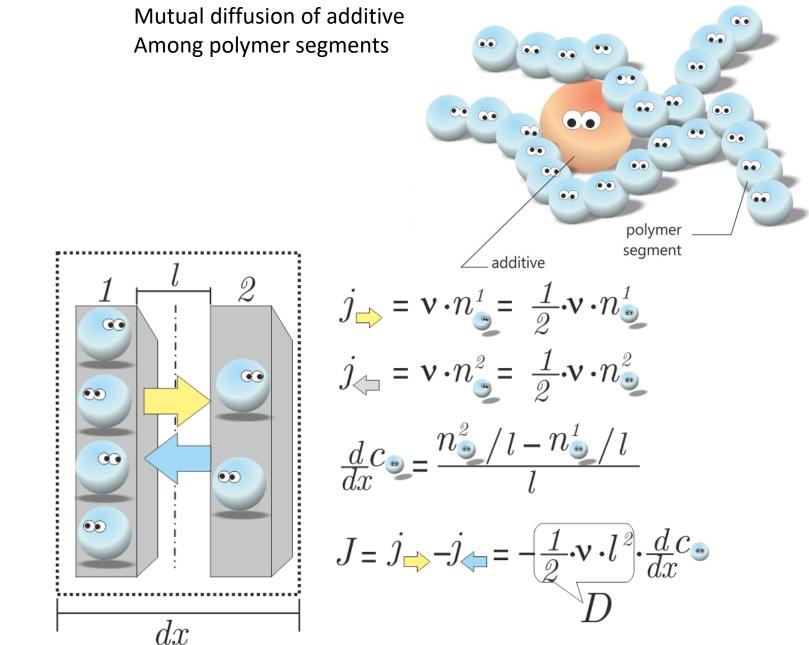
[∞] x4

2x

 \mathbf{i}

Molecules are represented as jumping beads. They have equal probabilities to hop to left and right directions.

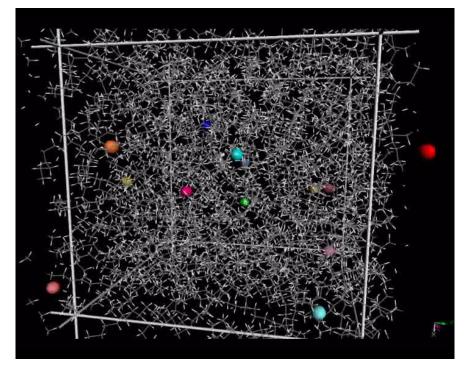
The direction of the next hop at microscopic scale is indicated by the direction towards beads are staring.



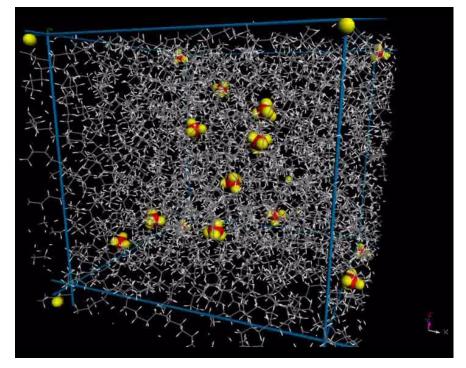
Interpretation of the net flux J (first Fick Law) as the microscopic exchange of molecules at frequency v between states 1 and 2 separated by a distance dx.

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

10 molecules of helium



10 molecules of methane

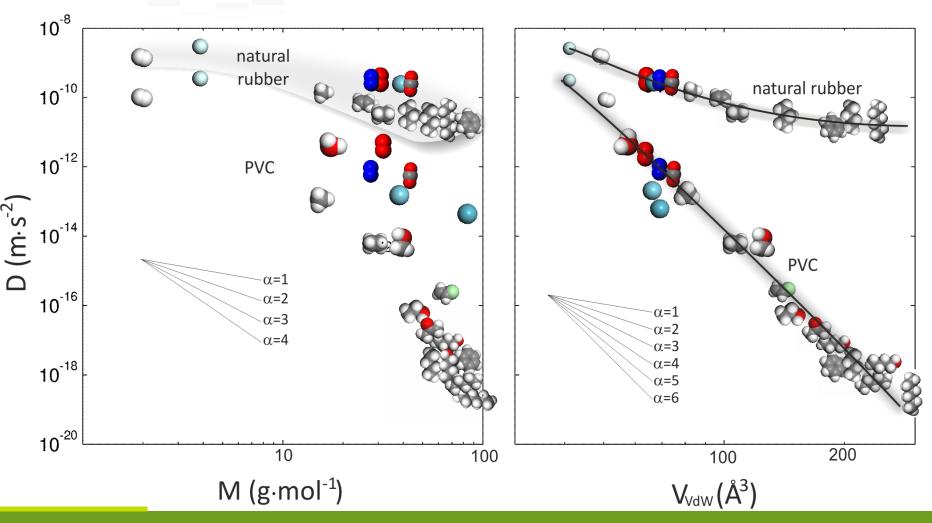




 $\mathbf{D} \approx \frac{1}{6} \frac{\partial}{\partial t} \langle \mathbf{x}_{CM}(t) - \mathbf{x}_{CM}(0) \rangle^2$



SCALING D WITH SOLUTE SIZE STIFF DIFFUSANTS



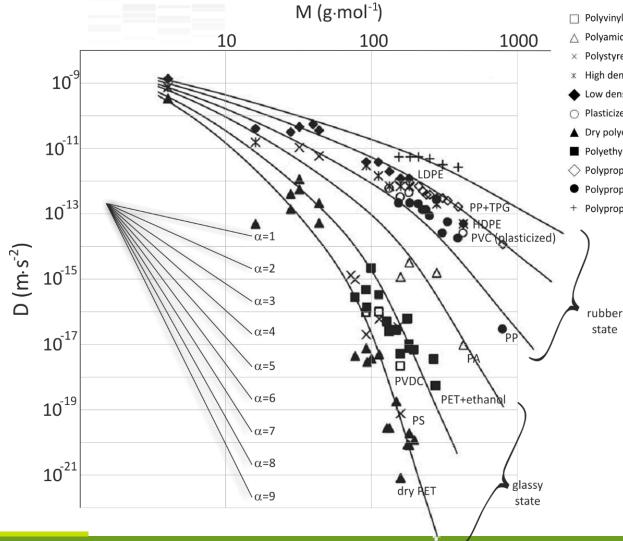


From: A. R. Berens, Pure Appl. Chem., 1981, 53, 365



SCALING EXPONENTS

FOR VARIOUS POLYMERS



- Polyvinylidene chloride (PVDC) at 50% RH
- △ Polyamide (PA)
- × Polystyrene (PS)
- * High density Polyethylene pHDPE)
- Low density polyethylene (LDPE)
- Plasticized polyvinyl chloride (PVC)
- Dry polyethylene terephthalate (PET or PETE)
- Polyethylene terephthalate (PET) in contact with ethanol
- Polypropylene (PP) in contact with glyceryl tripelargonate
- Polypropylene (PP) at 40°C
- + Polypropylene (PP) at 70°C



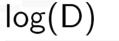
http://www.tandfonline.com/doi/full/10.1080/10408398.2013.849654

Crit. Rev. Food Sci. Nut. 2015 (Fang & Vitrac)

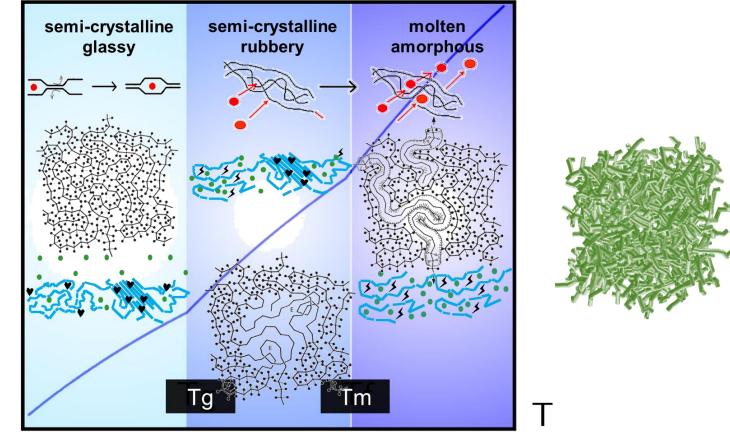


ACTIVATION OF DIFFUSION BY TEMPERATURE













For each temp. range: $D = D_0 \cdot \exp\left(\frac{-Ea}{R \cdot T}\right)$

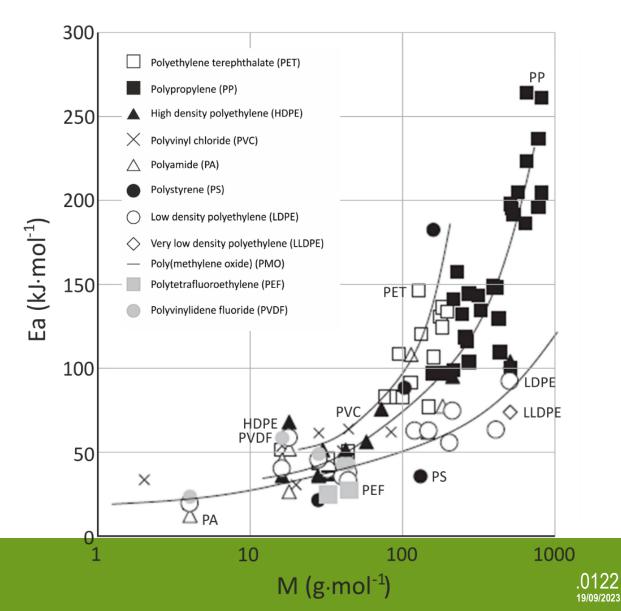


SCALING ACTIVATION ENERGY

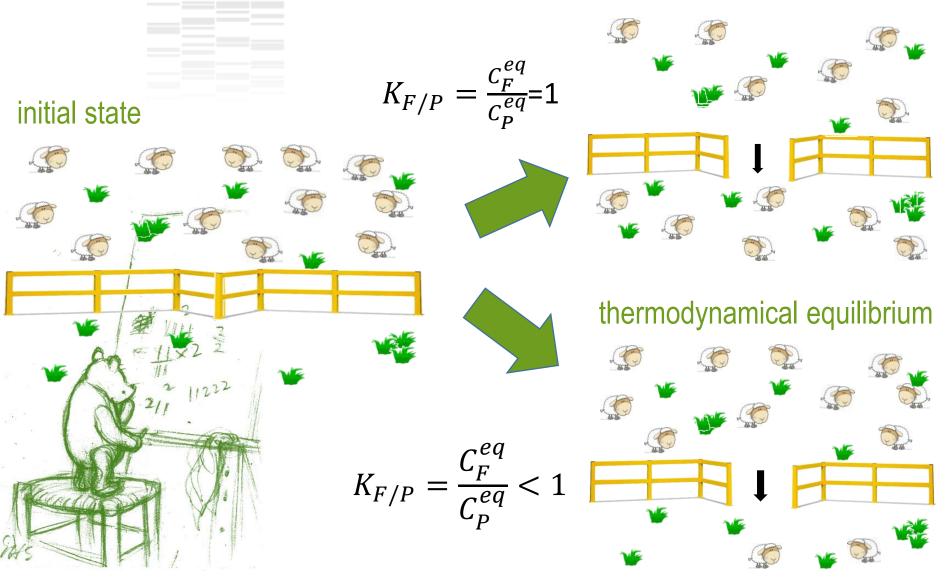
VARIOUS DIFFUSANTS IN VARIOUS POLYMERS

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

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



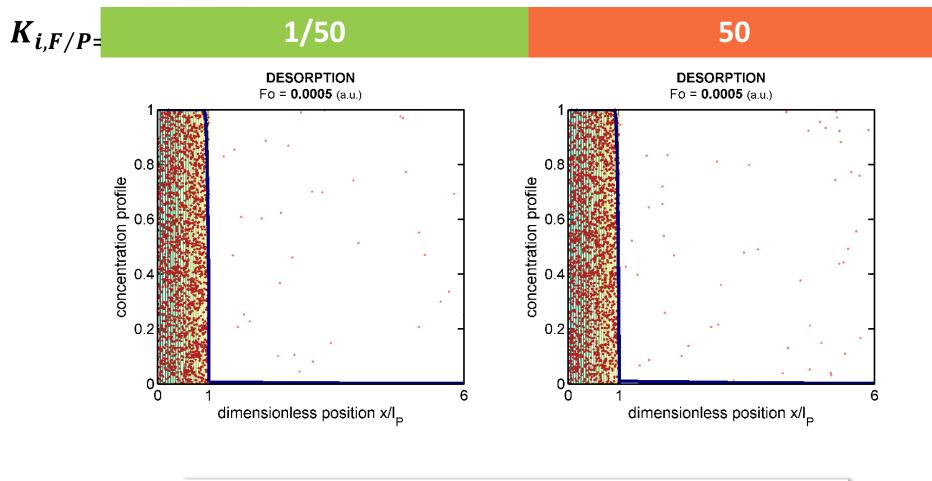
INTUITIVE DEFINITION OF PARTITION COEFFICIENTS





EFFECT OF PARTITION COEFFICIENT ON MIGRATION

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





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



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.

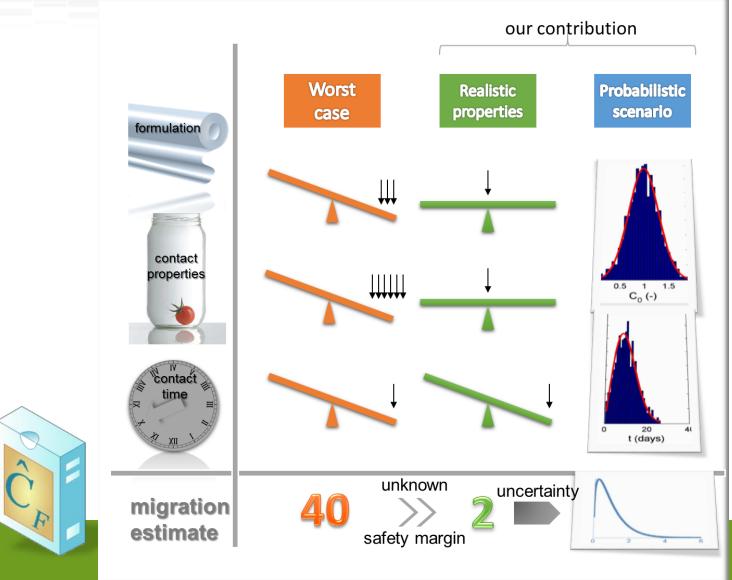
To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed such as to overestimate real migration.





HOW TO OVERESTIMATE MIGRATION

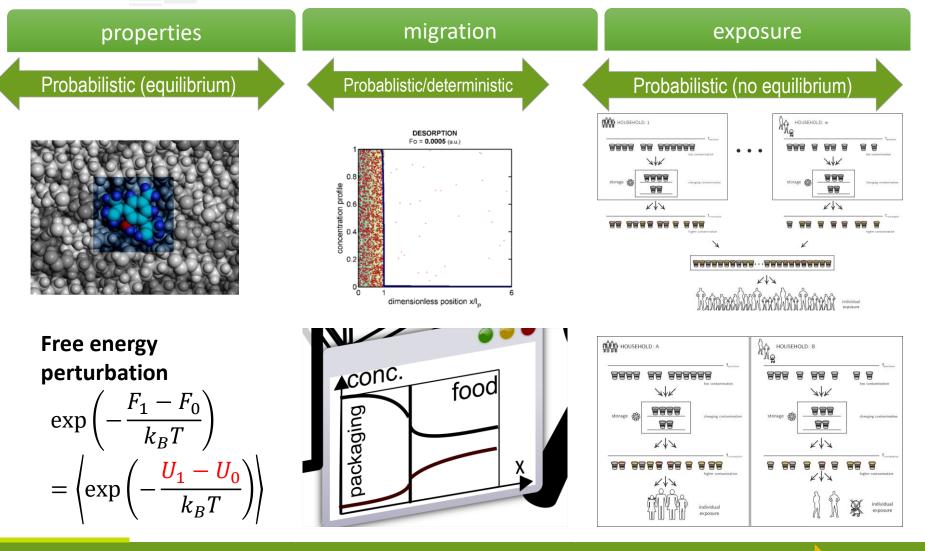
MODELING CAN DEMONSTRATE COMPLIANCE BUT NOT NON-COMPLIANCE



SCIENCE & IMPACT

MIGRATION MODELING

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





SCALE

ALL SOFTWARE ARE BUILT ON SIMILAR ASSUMPTIONS

My Information My user: demouser (change user) My project: common (change project) My database: common2013a.sfpp3.database.xml My Application: Diffusion_1DFV2n (change application) INRA\SFPP3 - 2013-04-18 22:03:53		Archived simulations or templates	
Contact conditions	Layer selec	tor >> 1	Help
 L_FP 100 m³F·m⁻³P import V_F cm³ · A_F cm² · rho_F 1 cm² · k_F 1 import 1000000 import t 6 months import 	I_P 300 µm I_D 1 grm-3 or grcm-3 or grcm-	import import import T	Acetaldehyde Name: Acetaldehyde (Acetic aldehyde;Ethanal;Ethyl aldehyde;CH3CH0;Acetaldehyd;Aldehyde acetique;Aldeide acetica;NCI-C563) CAS: 75-07-0 REF: 10060 InChIKey: IKHGUXGNUITLKF-UHFFFAOYSA-N Formula: C2H40 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 FII Regulation: +Positive List
Save result as:		cceptable thresho pecific migration li	

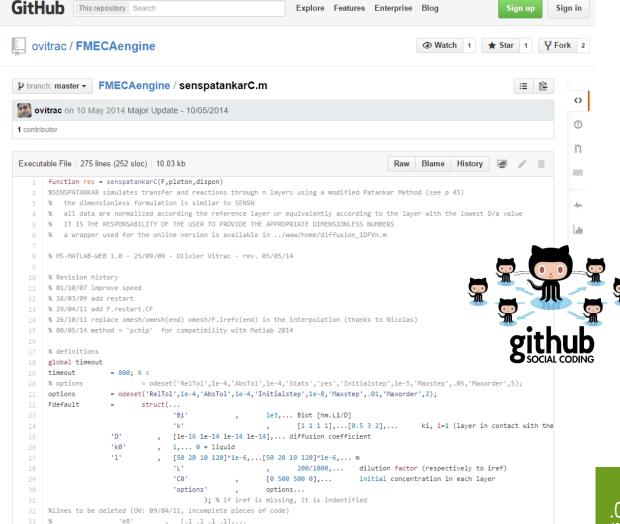
0128 19/09/2023

New trends: OPEN-SOURCE codes

https://github.com/ovitrac/FMECAengine



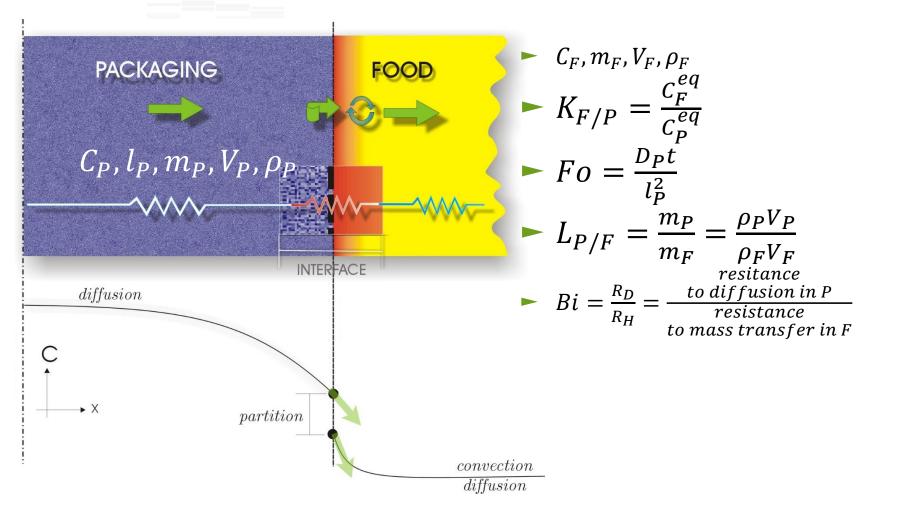
ovitrac / FMECAengin	e	@ Watch
MECA software developed in th ttp://modmol.agroparistech.fr/SI	e framework of the project SafeFoodPack Design PD/	
@ 61 commits	🖗 1 branch 🚯 0 releases	1 contributor
D P branch master - FMEC	CAengine / +	
fix for load_chemspider when it used w	ithout any existing cache	
ovitrac authored 4 days ago		latest commit e33540c651
examples	monolayer example update	4 years ago
production	production examples, pllease change paths to match yours	4 years ago
Dfuller.m	Major Update - 10/05/2014	11 months age
Dhelmroth m	Major Update - 10/05/2014	11 months age
Dimm.m	Major Update - 10/05/2014	11 months age
Dpiringer m	FMECAengine 0.51 (major update) - though not fully tested	5 days age
FMECADfuller m	FMECAengine 0.51 (major update) - though not fully tested	5 days ago
FMECADpiringer m	FMECAerigine 0.51 (major update) - though not fully tested	5 days agr
E FMECAKairP.m	FMECAengine 0.51 (major update) - though not fully tested	5 days ago
FMECAengine_backup_WSLP	FMECAengine 0.51 (major update) - though not fully tested	5 days ago
FMECAgoolymer.m	FMECAengine 0.51 (major update) - though not fully tested	5 days ago
R FMECAkair m	FMECAengine 0.51 (major update) - though not fully tested	5 days ago
FMECApdensity m	FMEGAengine 0.51 (major update) - though not fully tested	5 days ago
FMECAunit m	FMECAengine 0.51 (major update) - though not fully tested	5 days ago
FMECAvp.m	FMECAexgine 0.51 (major update) - though not fully tested	5 days ago
MatchingClosingSymbol m	release v0.45	4 years ago
ModifiedGrainMethod.m	FMECAengine 0.51 (major update) - though not fully tested	5 days ago
R README	first commit	4 years ago
🖹 addax m	additional functions to improve/simplify plots	3 years age
R addzplotpub m	additional functions to improve/simplify plots	3 years ago
B argcheck m	publishing update	3 years ago
argpad m	minor revisions and additions	11 months age
🗈 arganom	Major Update - 10/05/2014	11 months age
autoprofetch m	Major Update - 10/05/2014	11 months age
B autoprojectname.m	Major Update - 10/05/2014	
		11 months age
B bordertext m	Major Update - 10/05/2014 Major Update - 10/05/2014	11 months age
	Major Update - 10/05/2014 release v0.45	11 months age
Duildmarkov.m		4 years agr
bykeywords.m	FMECAengine 0.51 (major update) - though not fully tested	5 days ago
Catstruct.m	release v0.45	4 years ago
Corewer m	minor revisions and additions	11 months age
Celicmp m	release v0.45	4 years ago
CheckCAS m	release v0.45	4 years ago
Checktoolboxinstall m	FMECAengine 0.51 (major update) - though not fully tested	5 days ago





DIMENSIONLESS FORMULATION

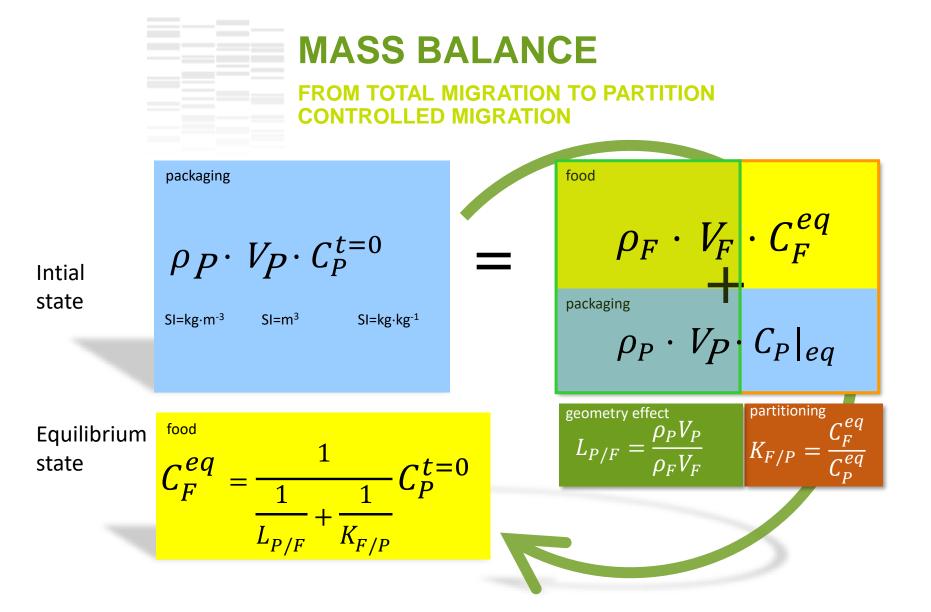
MONOLAYER / DIFFUSION + SORPTION





C =concentration, l =thickness, m =mass, volume, ρ =density K =partition coefficient (relative to mass concentration), L =dilution factor, Fo =Fourier number Ddiffusion coefficient, Bi =mass Biot number, h =surface mass transfer coefficient coefficient

.0130



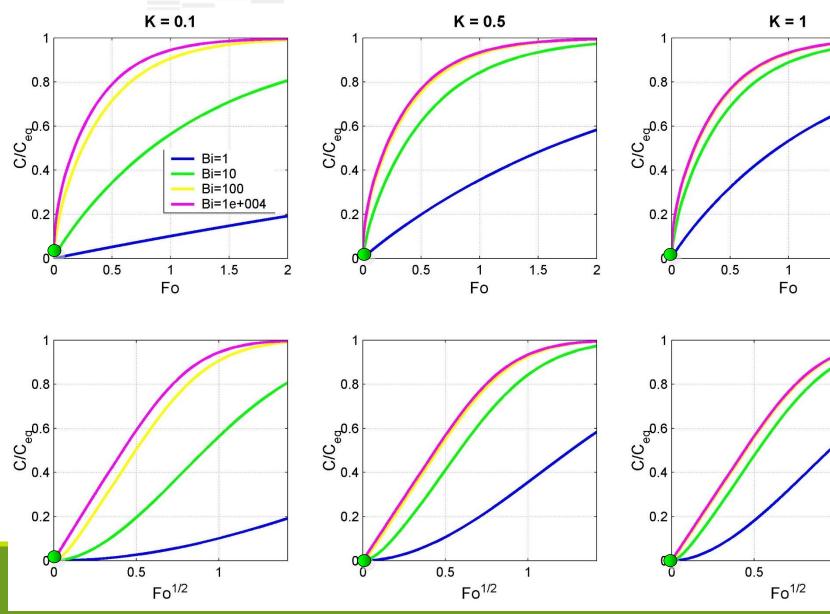
SCIENCE & IMPACT

C =concentration, l =thickness, m =mass, volume, ρ =density K =partition coefficient (relative to mass concentration), L =dilution factor, Fo =Fourier number Ddiffusion coefficient, Bi =mass Biot number, h =surface mass transfer coefficient coefficient

.0131

DIMENSIONLESS MIGRATION KINETICS

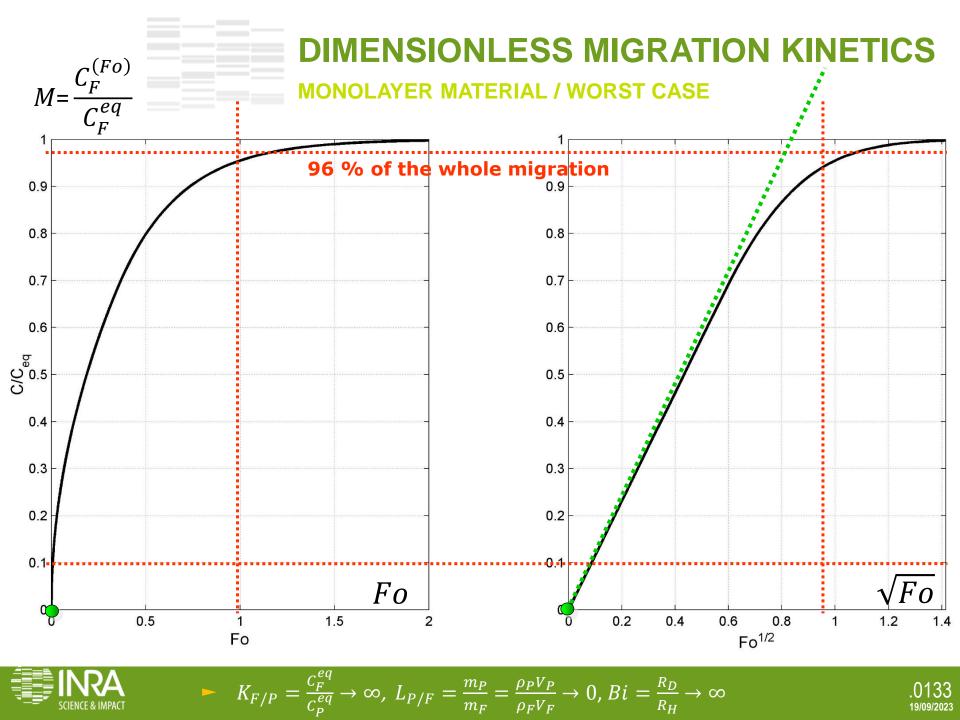
MONOLAYER MATERIAL



1.5

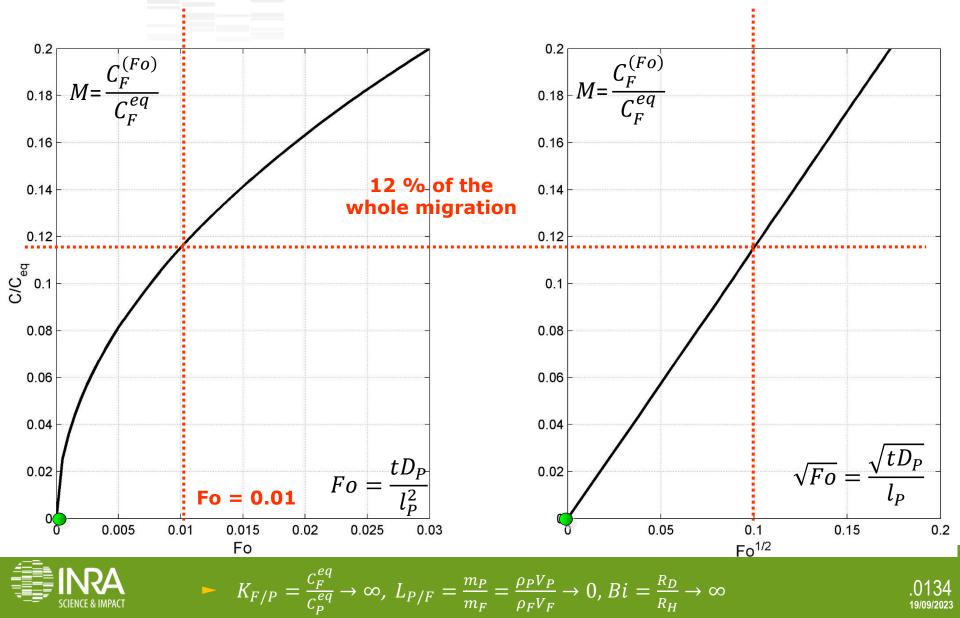
1

2



DIMENSIONLESS MIGRATION KINETICS

MONOLAYER MATERIAL



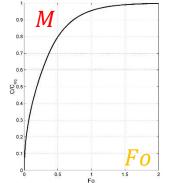


RULES OF THUMB FOR WORST CASE SCENARIOS

MONOLAYER MATERIAL

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

Time to reach a given migration ratio: $t = Fo \frac{l_P^2}{D_P}$ Concentration in food at time t: $C_F(t) = M(Fo) \cdot C_F^{eq} = M(Fo) \cdot \frac{K \cdot L}{K + L} \cdot C_P^{t=0}$

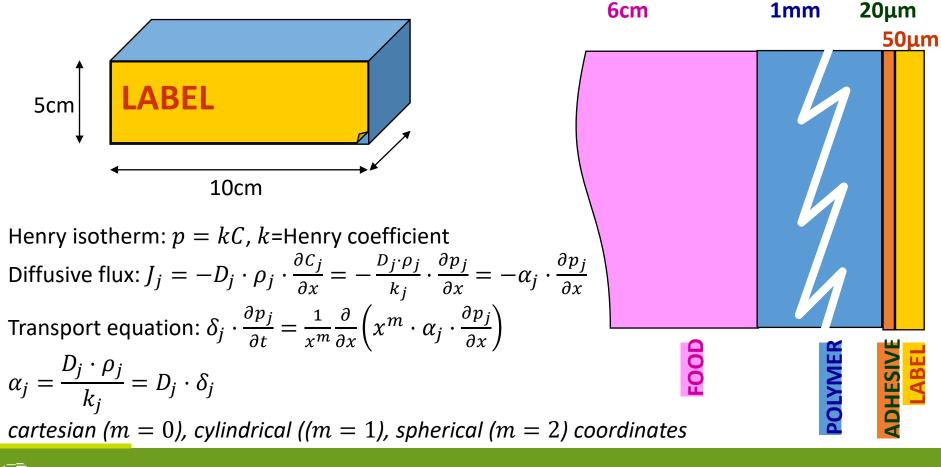




$$K_{F/P} = \frac{C_F^{eq}}{C_P^{eq}} \to \infty, \ L_{P/F} = \frac{m_P}{m_F} = \frac{\rho_P V_P}{\rho_F V_F} \to 0, \ Bi = \frac{R_D}{R_H} \to \infty$$







1

 $\theta = F$

 $\mathcal{2}$

n

.0136

19/09/2023

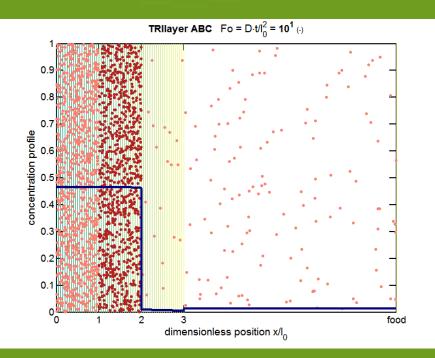




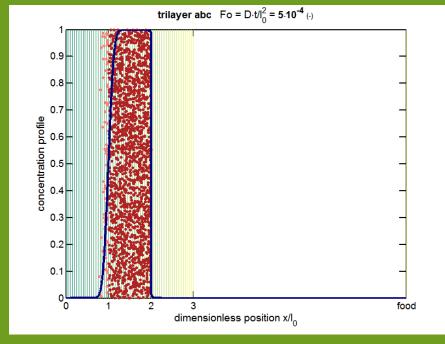
SIMULATION OF MULTILAYER MATERIALS

Functional barrier = barrier to diffusion + sorption

Idem + Iow chemical affinity for the food



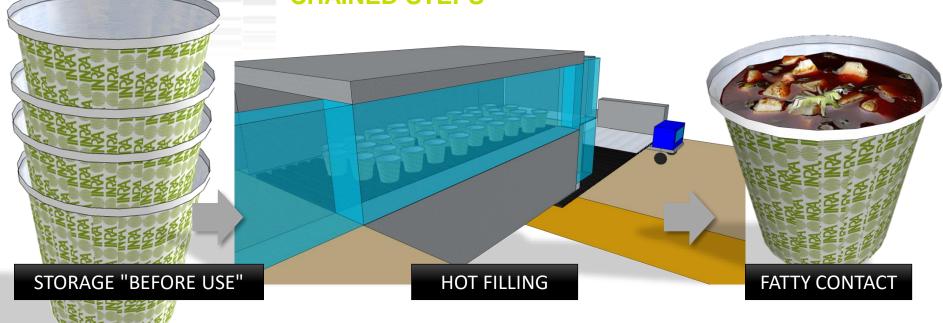
prop	Layer 3	Layer 2	Layer 1	Food
C ₀	0	1	0	0
I/I _o	1	1	1	100
D/D ₀	1	1	0.1	104
k/k _o	1	50	1	1

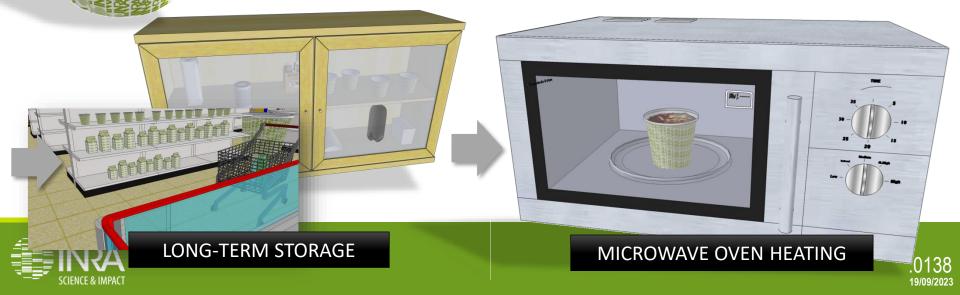


prop	Layer 3	Layer 2	Layer 1	Food
C ₀	0	1	0	0
۱/۱ _۵	1	1	1	100
D/D ₀	1	1	0.1	104
k/k _o	1	50	1	20

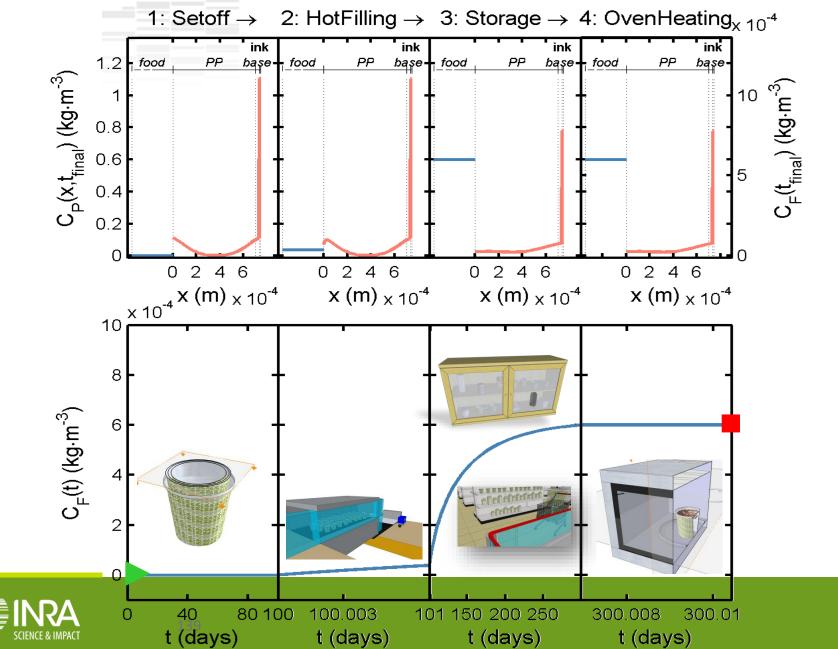


MODELING EXISTS ALSO FOR CHAINED STEPS



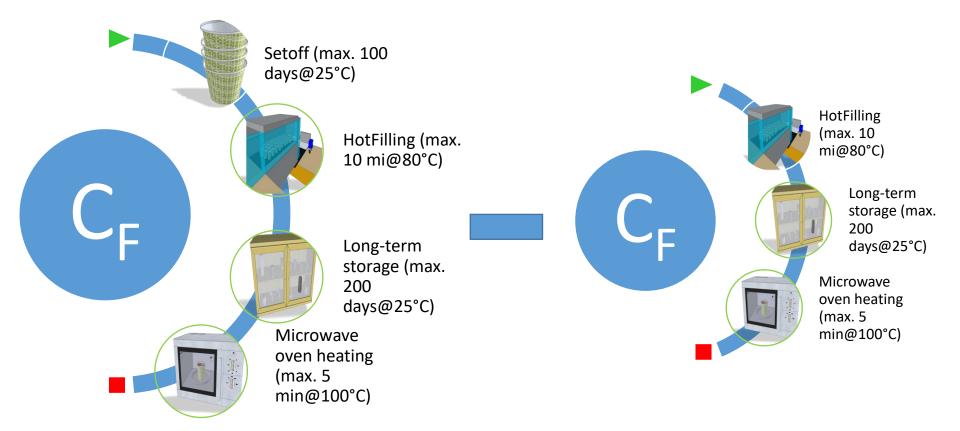


CHAINED STEPS



.0139

ASSESSING THE SEVERITY OF A SINGLE STEP CASE OF "SETOFF" STEP



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

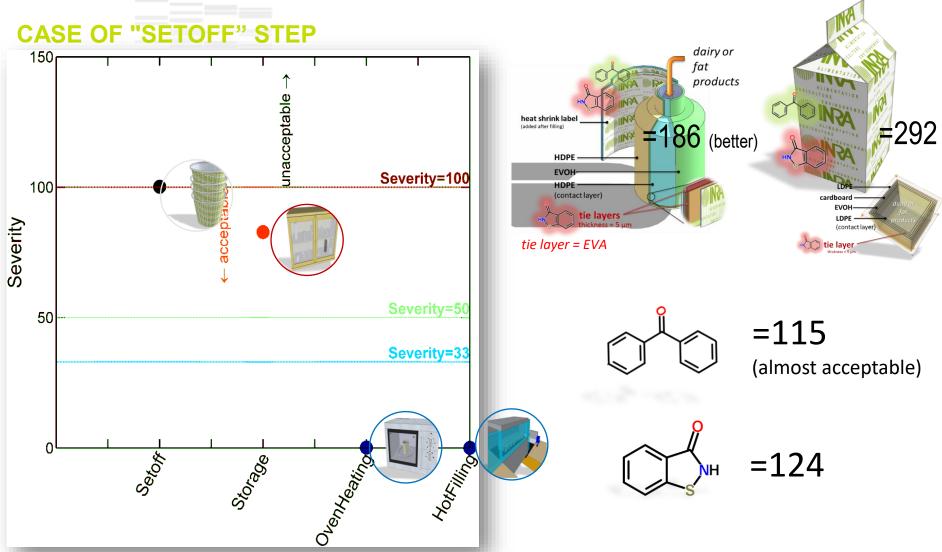


Severity
$$(\hat{C}_F(\text{step }i)) = f | \max | \underbrace{C_{F_M}|_{1 \to 2 \to \dots \to M} - C_{F_M}|_{1 \to 2 \to \dots \to M/i}}_{\text{step ialone}}, C_{F_i}|_i |$$

.0140

comparison with step i removed

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

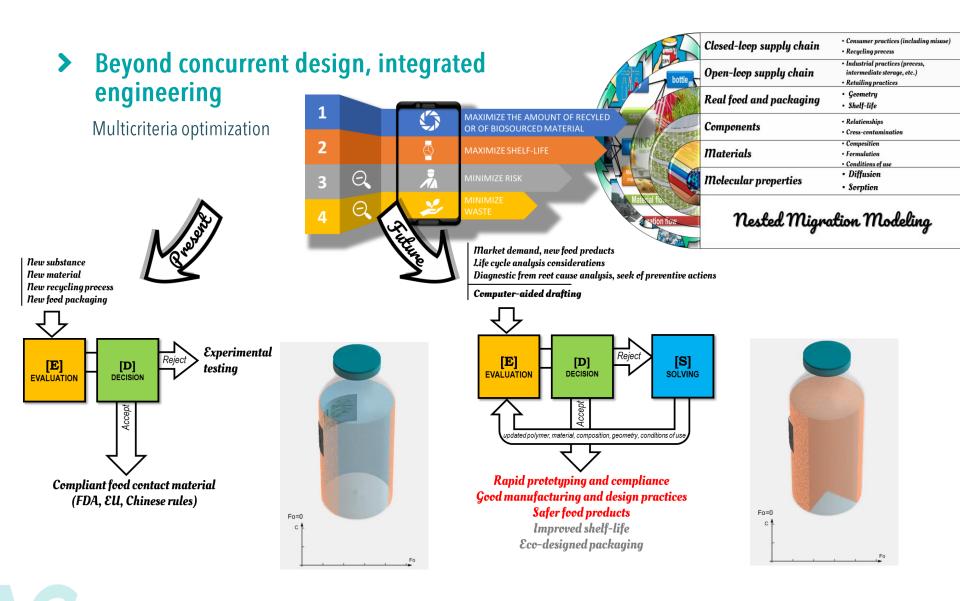




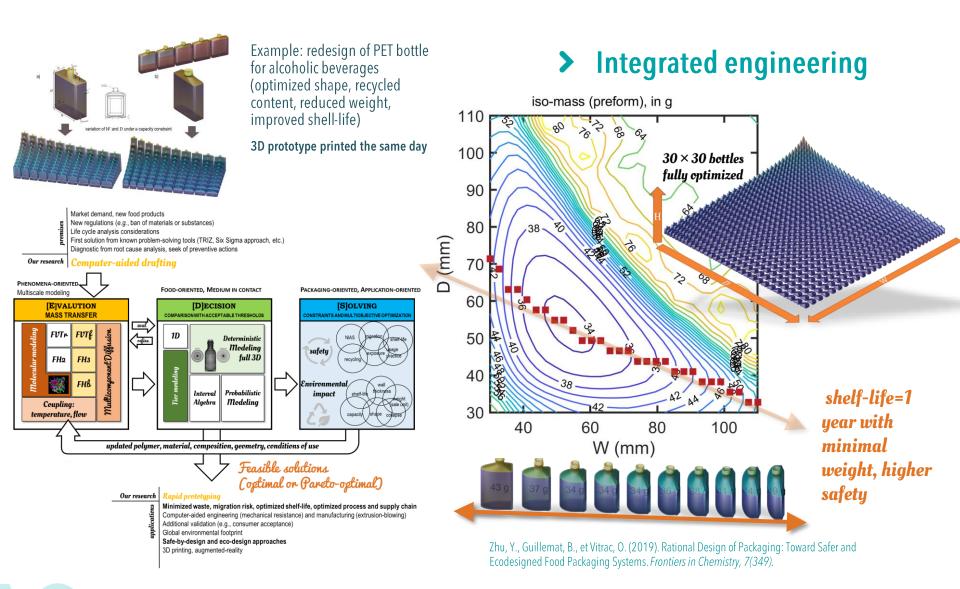
Full methodology described in *AIChE J.* 2013, **59**(4), 1183-1212

.0141

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Conclusions & Perspectives We are sleeping on a volcano... A wind of revolution blows, the storm is on the horizon.

Alexis de Tocqueville (1848, just prior revolutions in Europe).





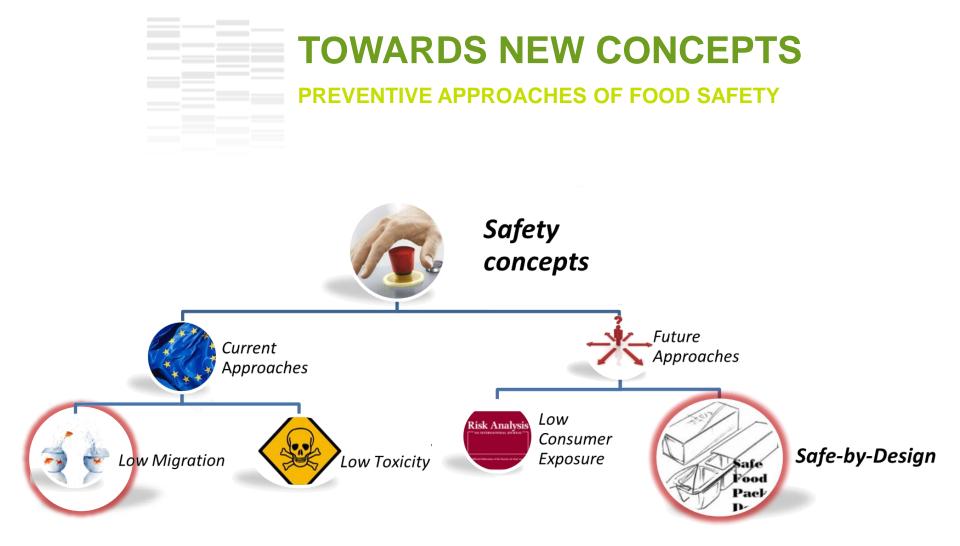
SCIENCE & IMF

leaks (sealants, stoppers)





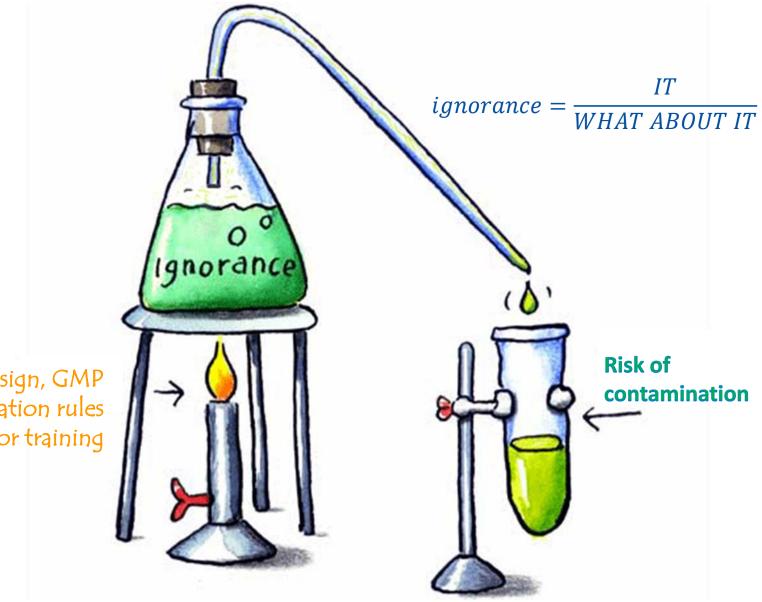






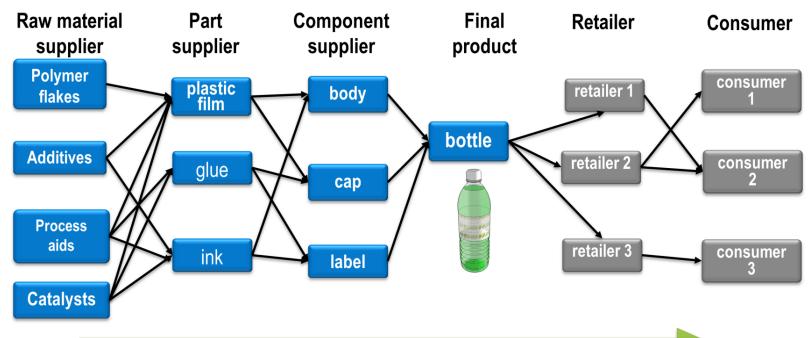


HUMAN RISK



poor design, GMP weak regulation rules poor training





Material flow

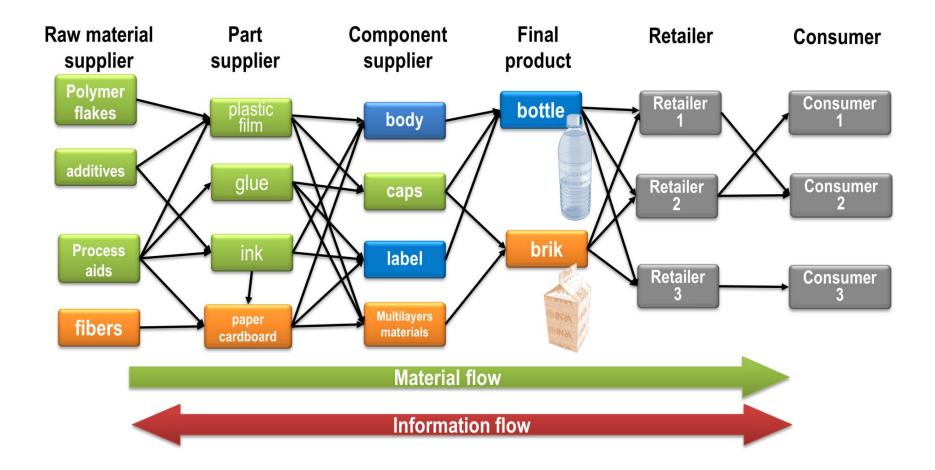
Information flow







DEVELOPING COOPERATION BETWEEN STAKEHOLDERS





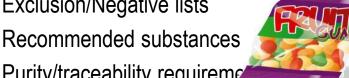


MAIN STEPS TO REVIEW

	FMECA « milk for infa	nts stored in a bri	ck »		
Safe	Formulation	Design	Process	Informations	Mechanisms
Pack Design	Formulation	design	Process	Informations	Described mechanisms
A Contraction of the contraction	 monomers (plastics, adhesives) catalysts antioxidants lubricants biocides (cardboard, ink) mineral oil (cardboard) solvents photoinitiators other residus (NIAS) 	 two components: brick body (4 materials, 5 layers) 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
Collaborative research project SAFEFooDPACK DESIGN	 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 cross- contamination 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: cross- contamination, aging

PRINTING INKS (EUPIA guidelines to be revised)

Exclusion/Negative lists

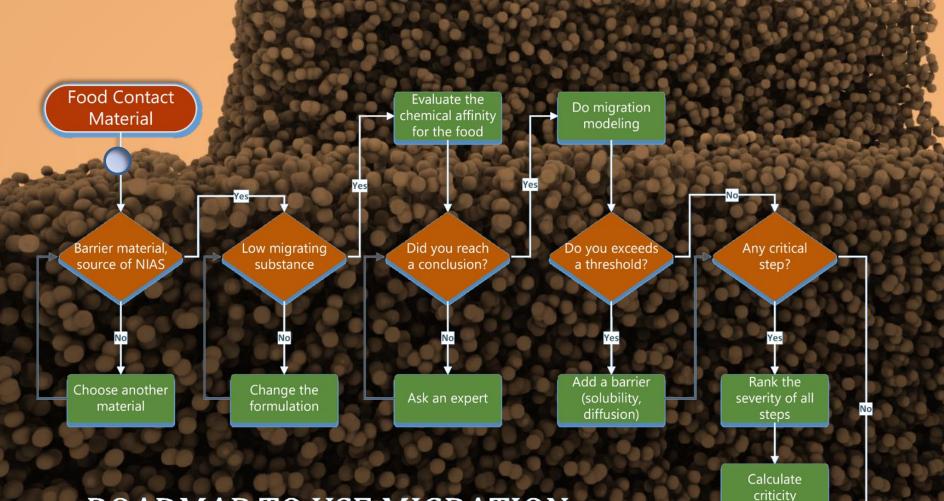


- Purity/traceability requiremd
- Migration (less than 10 ppb for non evaluated substances) and risk assessments
- Inks prepared according to GMP
- No-direct contact with food
- No "visible' Set-off in stacks and reels



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
- List of raw materials and production aids
- No holding/reheating above 90°C
- No microwave uses
- With internal bag



ROADMAP TO USE MIGRATION MODELING FOR SAFER FCM

Go to the market

