FOOD CONTACT LEGISLATION AND MIGRATION

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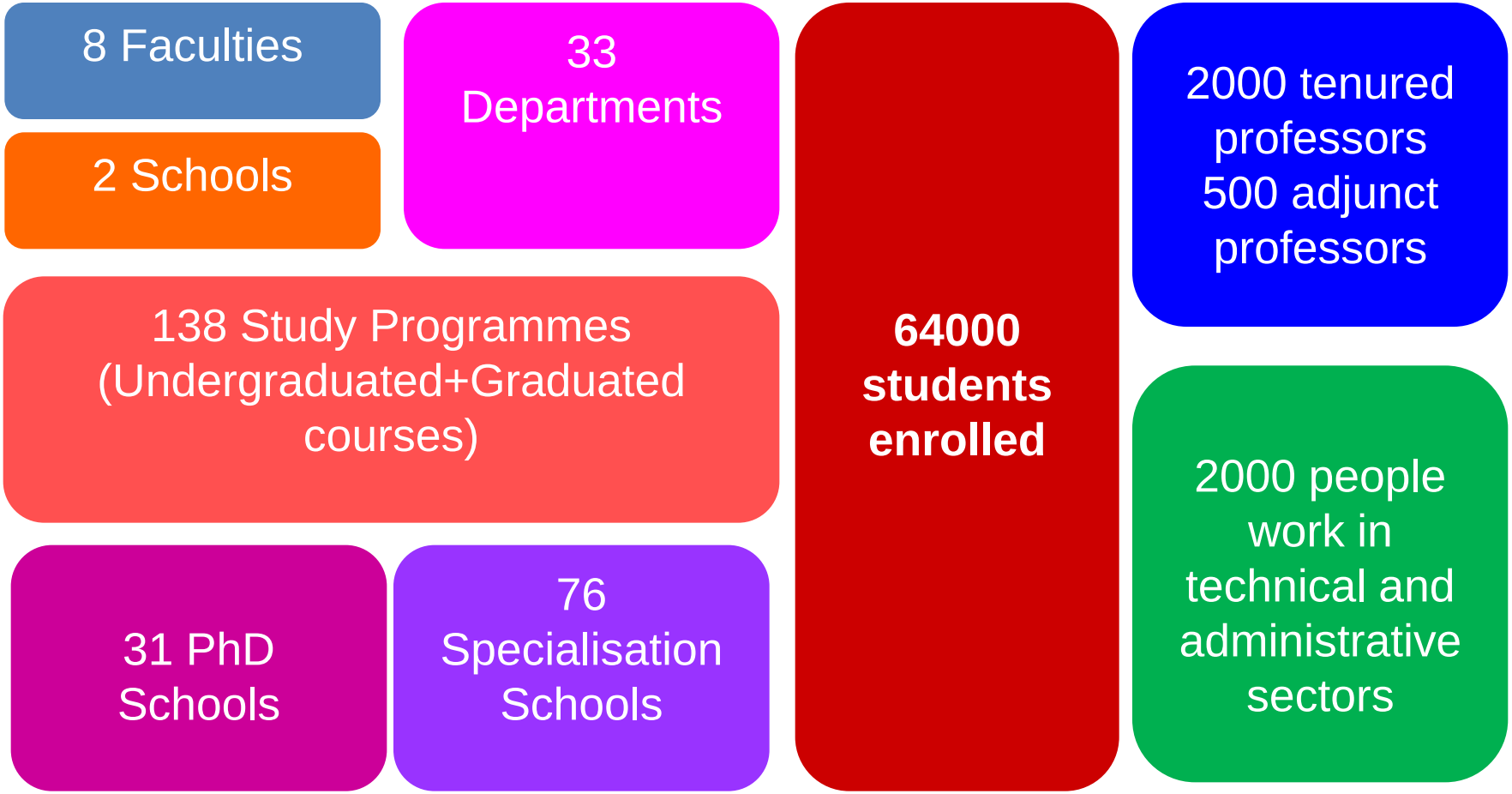
TUT ActInPak Summer school - Active and intelligent packaging solutions (June 12-16, 2017, Tampere, Finland)

The Department of Food, Environmental and Nutritional Sciences, Università degli Studi di Milano

PackLAB
UNIMI Food Packaging Laboratory

University of Milan: facts and figures



The Department of Food, Environmental and Nutritional Sciences

5 Divisions belong to the Department:

PackLAB
UNIMI Food Packaging Laboratory

- Food Microbiology and Bioprocesses
- Agro-Environmental Systems
- Food Technology
- Chemical and Biochemical Sciences
- Human Nutrition

DEFENS
DEPARTMENT OF FOOD, ENVIRONMENTAL AND NUTRITIONAL SCIENCES

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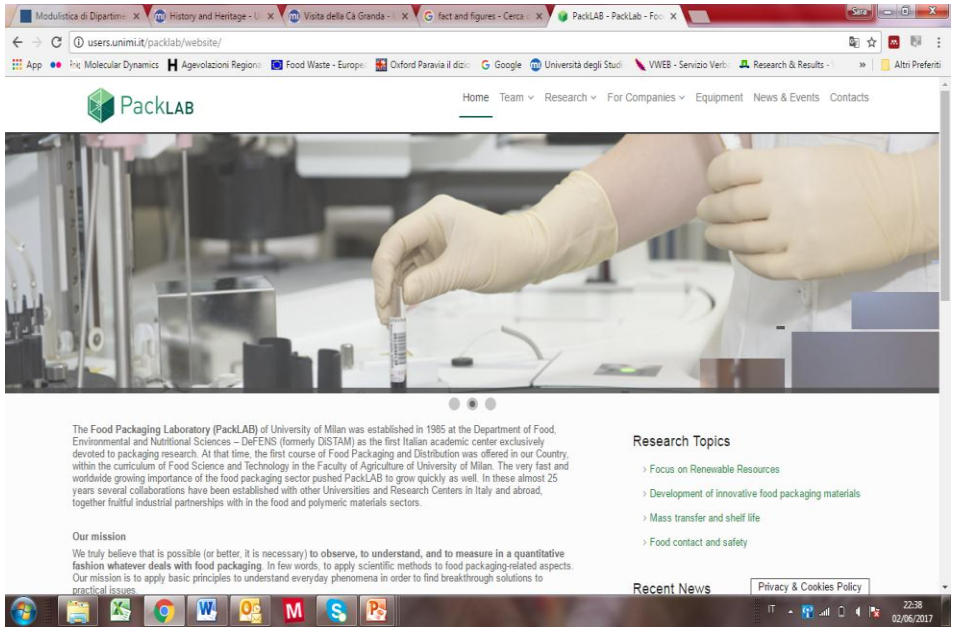
Food Technology Division

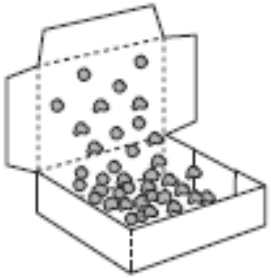
PackLAB
UNIMI Food Packaging Laboratory

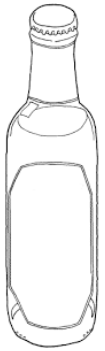
An Operative Unit devoted to food packaging (the PackLab) has been established in our University since 1985.

PackLab is the only unit in the University of Milan engaged in research, teaching and testing in the Food Packaging field.

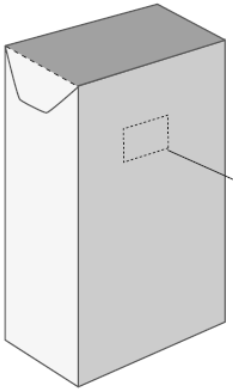


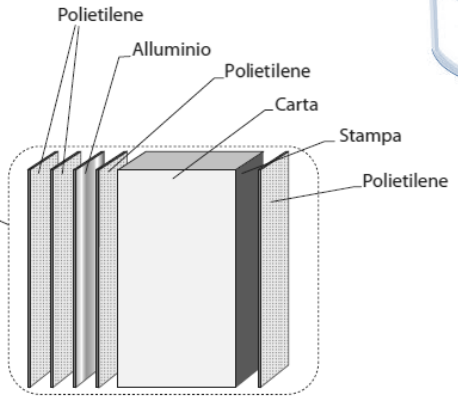
Food Contact Materials, FCM

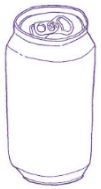


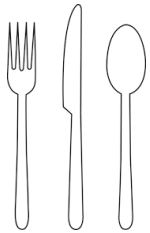


FCM









GLASS
PLASTICS
PAPER&BOARD
SILICON
RUBBERS
CERAMICS
ALUMINUM
STEEL
CORK
ADHESIVES
INKS
ACTIVE PACKAGING
INTELLIGENT PACKAGING
MULTI-MATERIALS
……

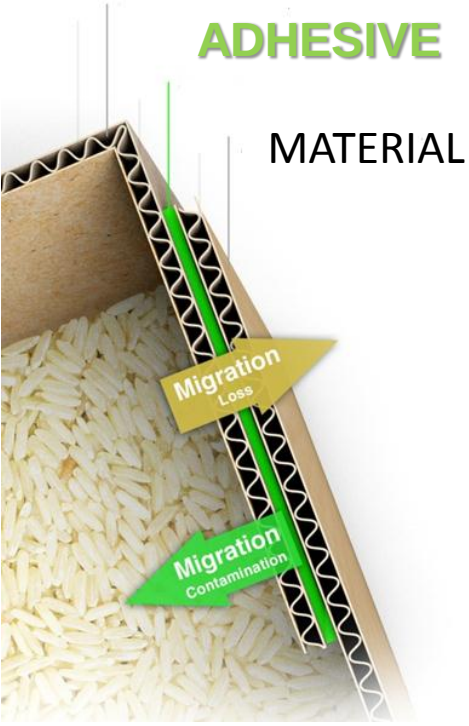
SAFETY of FCM

Food Contact Materials

MIGRATION

MATERIAL 1

Transfer of substances from the PACKAGE to the FOOD



A RISK for the CONSUMER

Food Contact Materials

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they **do not transfer** their constituents to food in **quantities** which could:

(a) endanger human health; or

(b) bring about an unacceptable change in the composition of the food; or

(c) bring about a deterioration in the organoleptic characteristics thereof.

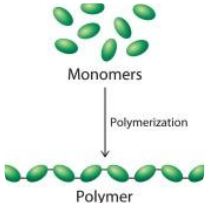
Art.3 Reg. EC 1935/2004

- MIGRATABLE SUBSTANCES
- MECHANISMS of MIGRATION
- WHAT THE LEGISLATION SAYS
- HOW to MEASURE MIGRATION
- WHAT ABOUT ACTIVE PACKAGING

FCM

MIGRATABLE SUBSTANCES

INTENTIONALLY ADDED SUBSTANCE - IAS



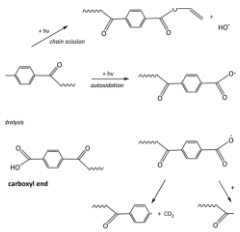
Monomers and catalysts, aids to polymerization (in PLASTICS)

Additives and coadjuvants (antioxidants, lubrificants, dyes, fillers, etc)

Inks, adhesives, etc.

MIGRATABLE SUBSTANCES

NON INTENTIONALLY ADDED SUBSTANCES- NIAS

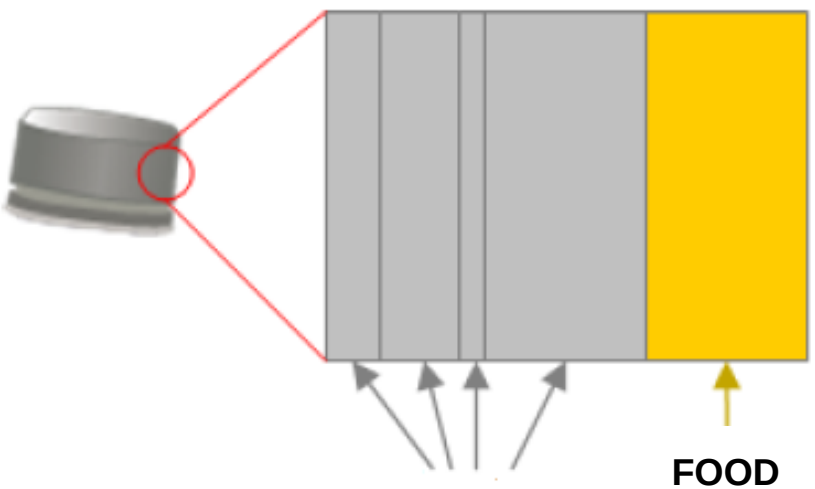


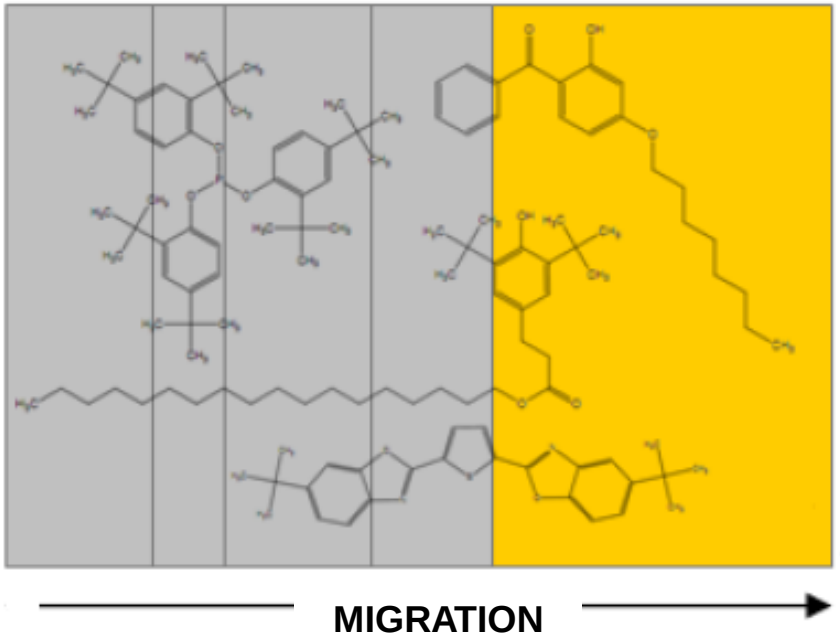
Reactions and degradation products

Impurities of the raw materials

Contaminants

IAS e NIAS are always present in the FCM and they can POTENTIALLY MIGRATE into FOODS

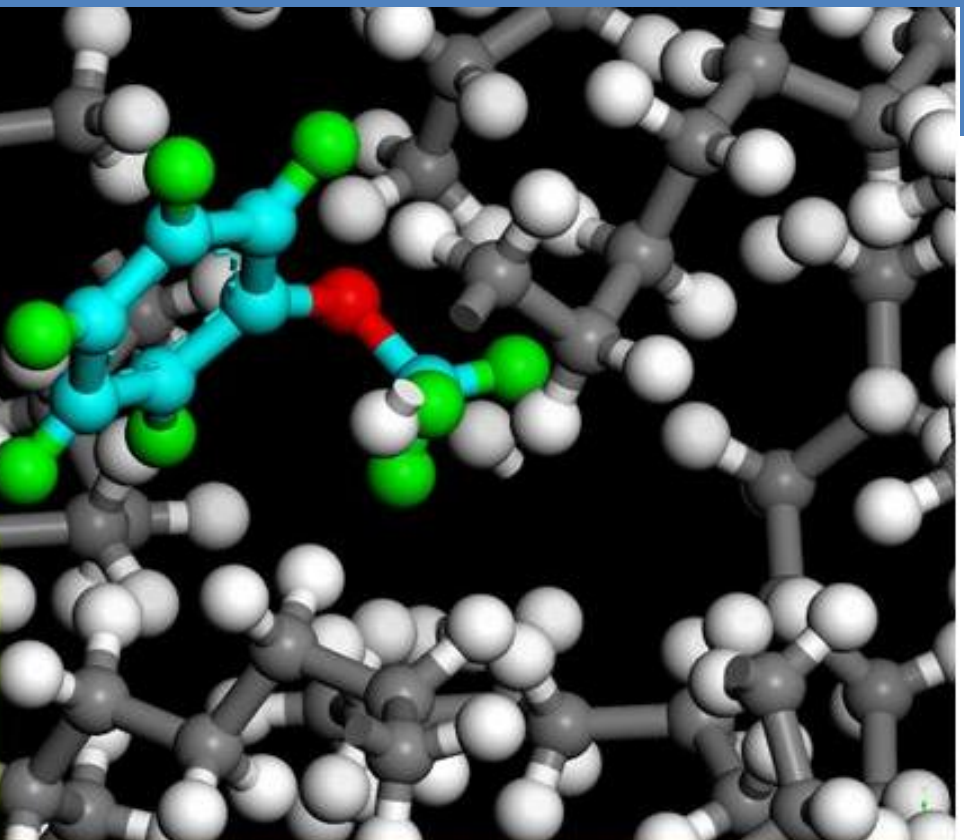




Why IAS e NIAS can migrate?

The MEDIUM i.e. synthetic and natural polymers

- Heterogeneous media, with «large» free volume
- Thermal motion of chain segments
- .....

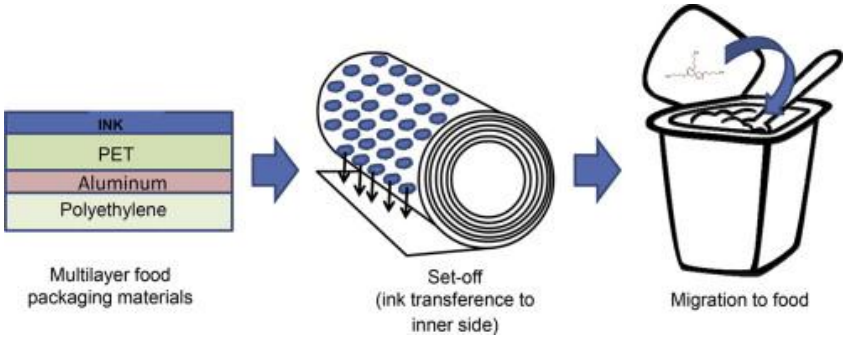


IAS and NIAS

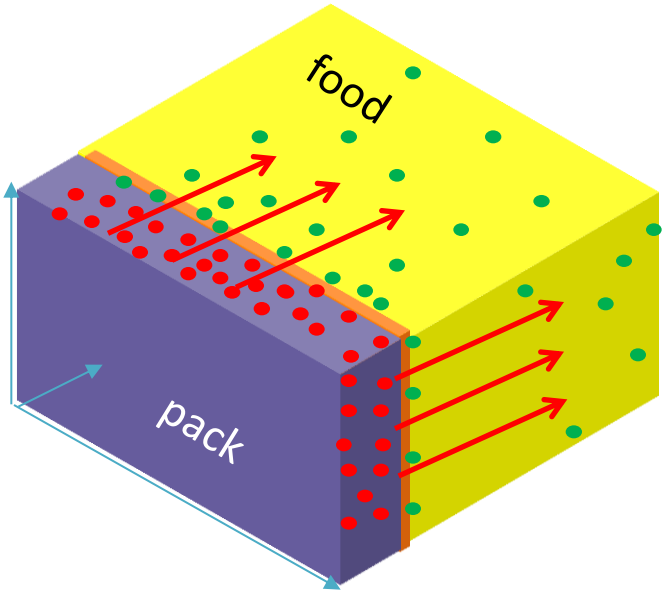
- Free molecules, not covalently bonded
- Molecules of «small» dimensions with respect to the media (molecular mass lower than1000 Da)
- Chemical nature different from the media

MIGRATION PHENOMENON

MIGRATION is defined as «*the mass transfer from an external source into food by sub-microscopic processes*»



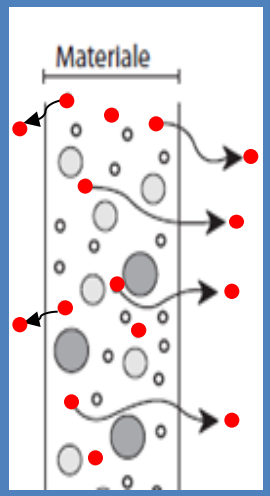
(Picture from Aznar et al., 2015)



PHENOMENAL DESCRIPTION of MIGRATION

MIGRATION through the GAS PHASE

ENVIRONMENT



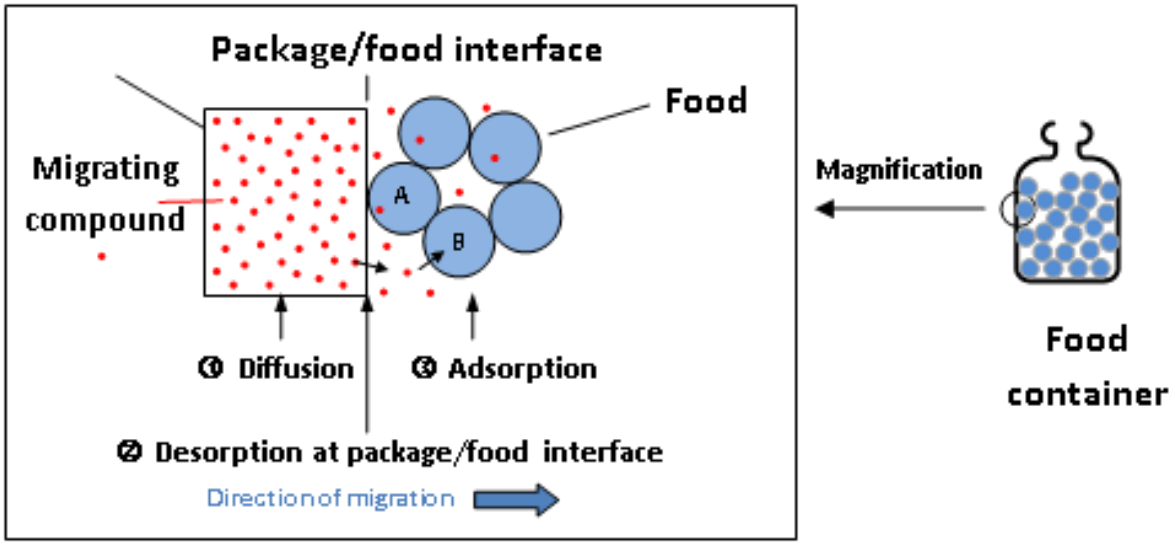
FOOD

- VOLATILE MIGRANT

MECHANISM

1.Diffusion
2.Desorption at the interface
3.Adsorption onto the food

Volatile substances, with high vapor tension, can migrate without enter in direct contact with the food. They can also be dispersed in the environment



Lee, DS. et al. 2008

Plastics, paper….

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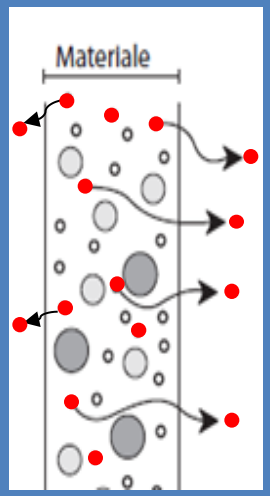

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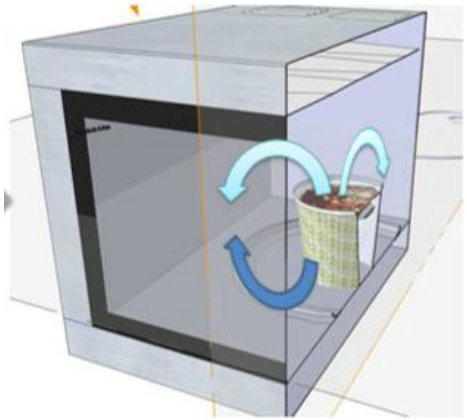
- ❑ RATE of DIFFUSION into the MATERIAL
- ❑ MIGRANT CHEMICAL AFFINITY with the FOOD
- ❑ TEMPERATURE



PHENOMENAL DESCRIPTION of MIGRATION

NON volatile MIGRANTS diffuse into the **FOOD**
only after a **DIRECT CONTACT**

A The migrant has a **high diffusion coefficient** in the material and is readily dissolved into the contacting food phase

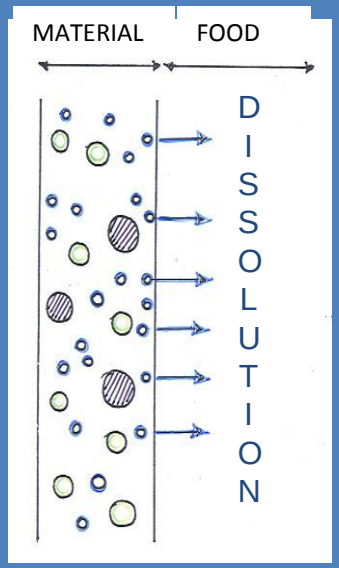
B The migrant is of **low diffusion** in the material at the initial contact with food. It attains high diffusion coefficient only after some food components has been adsorbed and diffused into the film (SWELLING): **dual-mode interaction**

FOOD-CONTACT

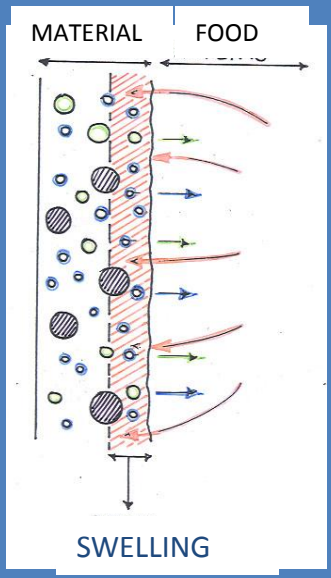
- Nature and composition of the material, migrant and the food
- Contact surface
- Time of contact
- Temperature of contact
- Turbolences

Sostanze poco diffusive Sostanze diffusive Componente alimento

A



B

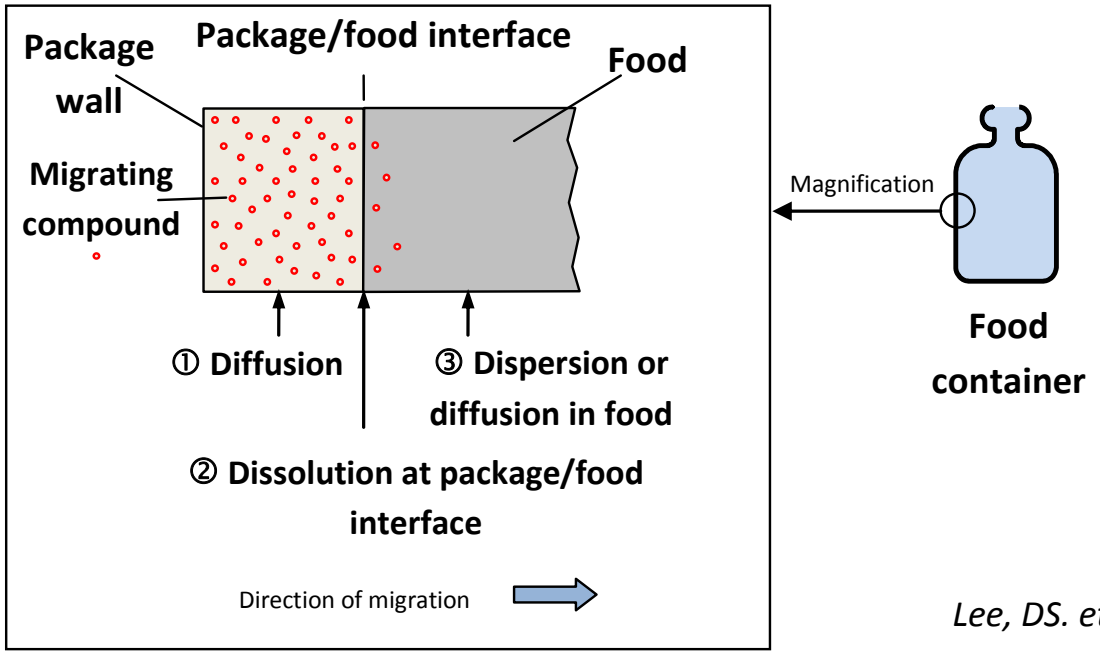


PHENOMENAL DESCRIPTION of MIGRATION

NON volatile MIGRANTS diffuse into the FOOD only after a DIRECT CONTACT

① **Diffusion of migrant in package wall toward package/food interface.**

Frequently this is the slowest or rate-determining step of migration. In a **dual interactive mode**, concurrent penetration of solvent or food ingredient may change the package wall structure to swollen state increasing the mobility of migrant.



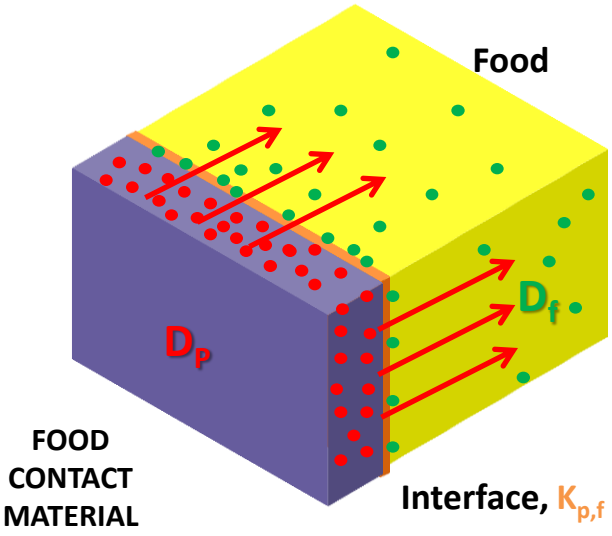
② **Dissolution of migrant at package/food interface**.

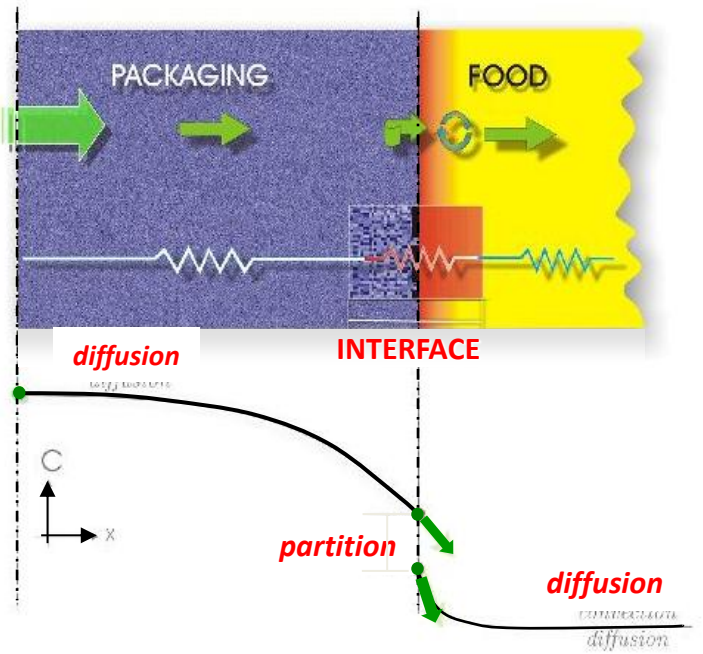
The dissolution depends on the affinity of migrant to the package phase and food phase.

③ **Dispersion or diffusion of migrant into food**.

The migrant will then disperse into liquid foods or diffuse into solid foods.

Lee, DS. et al. 2008. Food Packaging Science and Technology





- Additive in film Cp, ($mg/kg_{polymer}$)
- Additive in food Cf (mg/kg_{food})

Dp=coefficient of diffusion of the additive in the polymer ($m^2\ s^{-1}$)

Df= coefficient of diffusion of the additive ($m^2\ s^{-1}$)

Kp,f= coefficiente di ripartizione dell'additivo tra polimero e alimento (Cp∞/Cf ∞)

- $$J = -D_p \frac{dC}{dx}$$

Fick's I law

J= diffusion flux ($mg\ m^{-2}\ s^{-2}$)

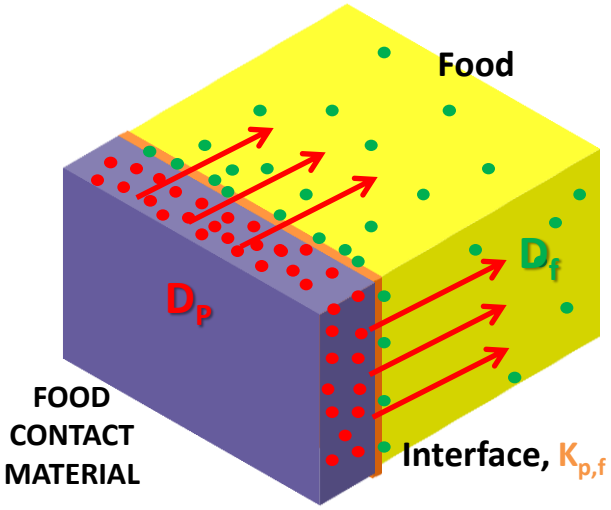
Dp=coefficient of diffusion of the additive in the polymer ($m^2\ s^{-1}$)

C= migrant concentration ($mg\ m^{-3}$)

x= distance in the packaging layer

$$\frac{\partial C_{x,t}}{\partial t} = Dp\frac{\partial\ C}{\partial x^2}$$

Fick's II law:
Monodirectional diffusion in a non-steady state:
The flux changes in the space and the concentration profile during time



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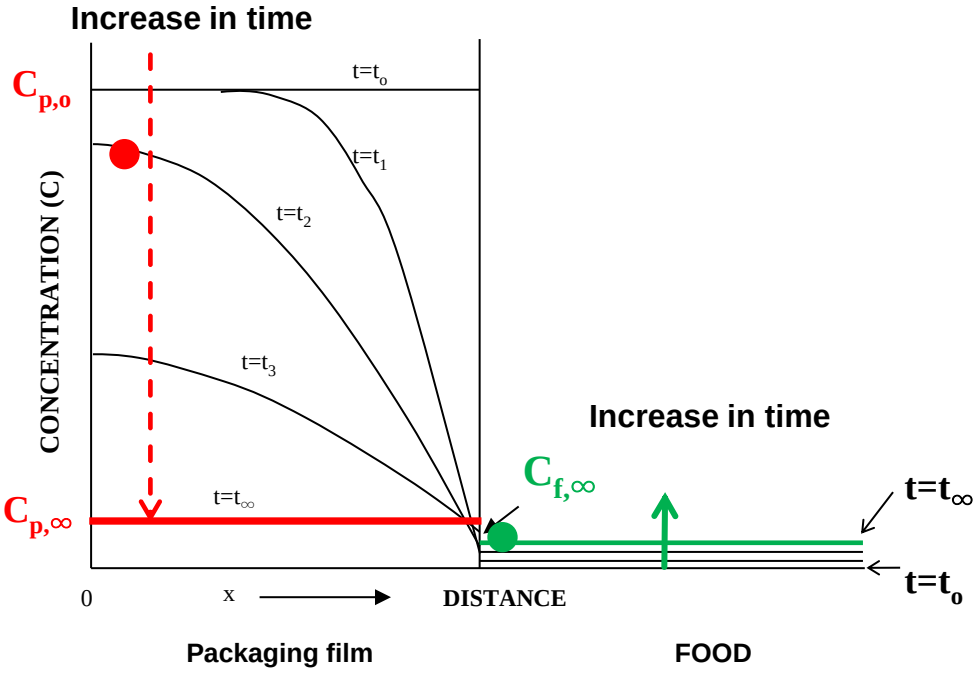
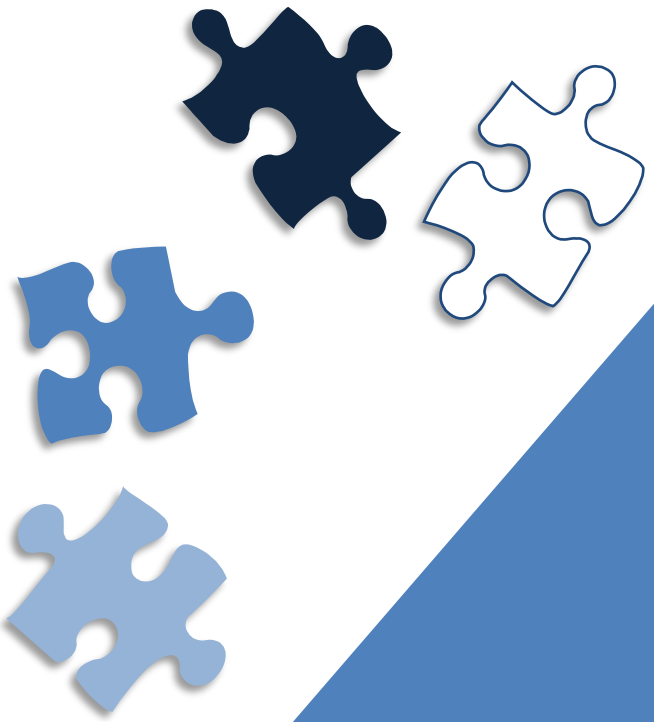


The extent of migration depends on several variables :

- Nature and composition of both the material and the substances
- Nature and composition of the food
- Contact surface
- Time of contact
- Temperature of contact

….



The rules act on these factors:

- checking the COMPOSITION of the FCM

Toxicologcal evaluation = hazard reduction
(ex. List of additives…)

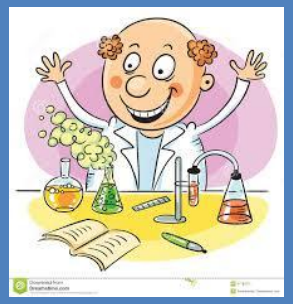
- restricting the PERMITTED USES

Migration monitoring= exposure reduction
(ex. LMS)

WHAT LEGISLATION SAYS ABOUT MIGRATION

Which are the fundamentals?

……..Why is the legislation so important also for a scientist?



...the European legislation

For ALL the FCM

EC Regulation 1935/2004

It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs).

EC Regulation 2023/2006

The GOOD MANUFACTURING PRACTICES ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation

specific EU measures

- **Regenereted Cellulose Film** — Directive 2007/42/EC
- **Ceramics** — Directive 84/500/EEC; I amendment 2005/31/EC
- **PLASTIC MATERIALS**
  - **Consolidated version of Regulation (EU) No 10/2011 and amendments**
  - **Regulation (EU) 2016/1416** - amending and correcting Regulation (EU) No 10/2011 for the specifics of these amendments.
  - **Regulation (EC) No 282/2008** on recycled plastic materials and articles intended to come into contact with foods
- **Synthetic rubbers** — Directive 93/11/EEC nitrosammine
- **Active and intelligent** — EC Regulation 450/2009

NATIONAL RULES

Paper and Board | Glass | Cork | Stainless Steels-Metals | Tissues | Adhesives | Resins ion exchange | Inks and dyes | Silicons | Coatings | Wax

Food Contact Materials

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(a) endanger human health; or

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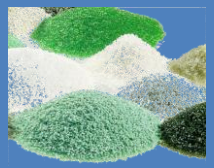
Art.3 Reg. EC 1935/2004

Art.3 Reg. EC 1935/2004

PLASTIC MATERIALS

Reg 10/2011

Reg 1416/2016



FCM

Reg EU 10/2011- Reg 1416/2016

4 criteria
(all must be met!!)

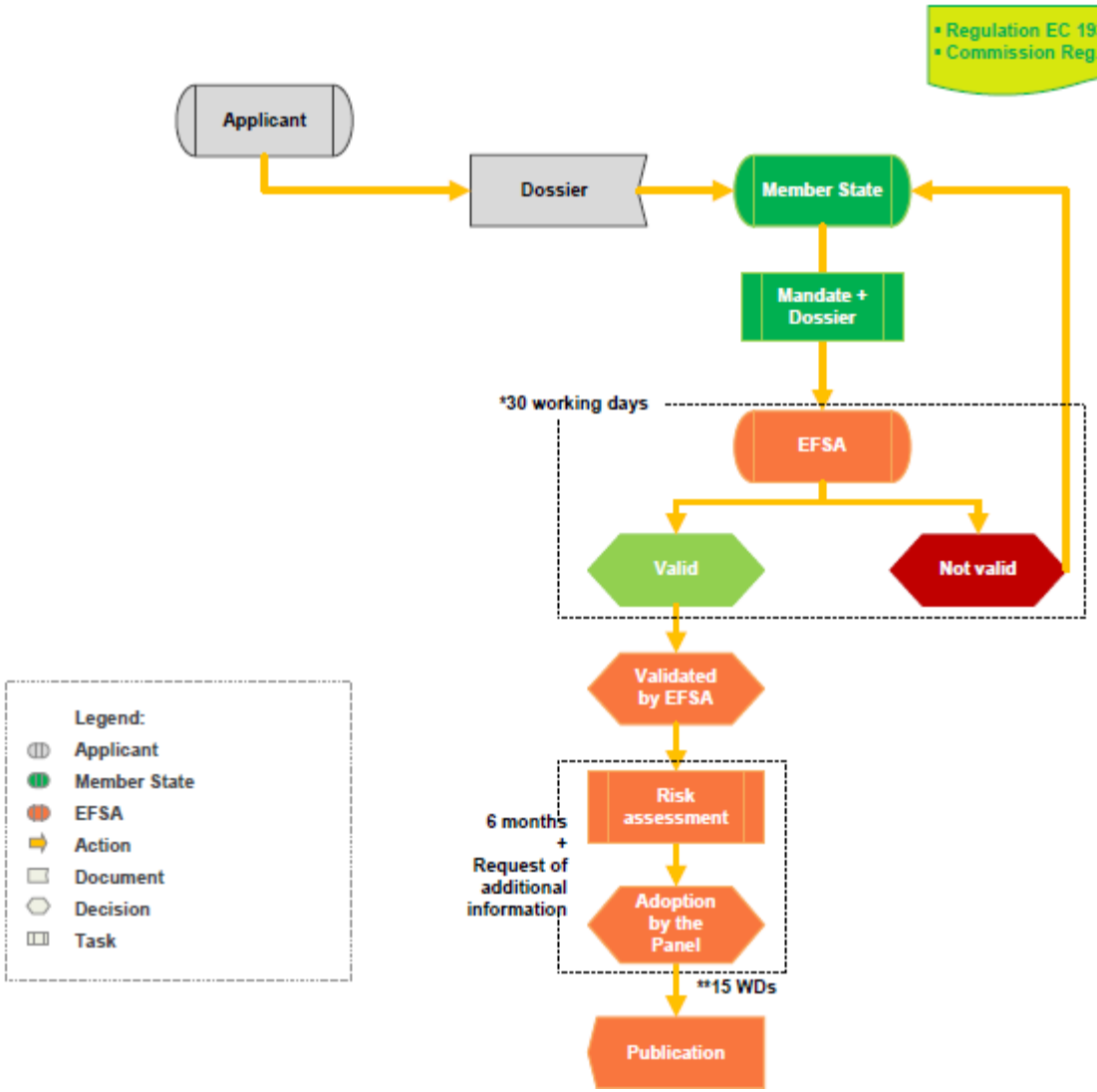
(a) monomers or other starting substances;
(b) additives excluding colorants;
(c) polymer production aids excluding solvents;
(d) macromolecules obtained from microbial fermentation.

NIAS

Only the substances included in the **Union list of authorized substances** (Annex I+ amendments) may be **intentionally used** in the manufacture of plastic layers in plastic materials and articles.

……with restrictions…….

Application helpdesk ..authorization for new substances



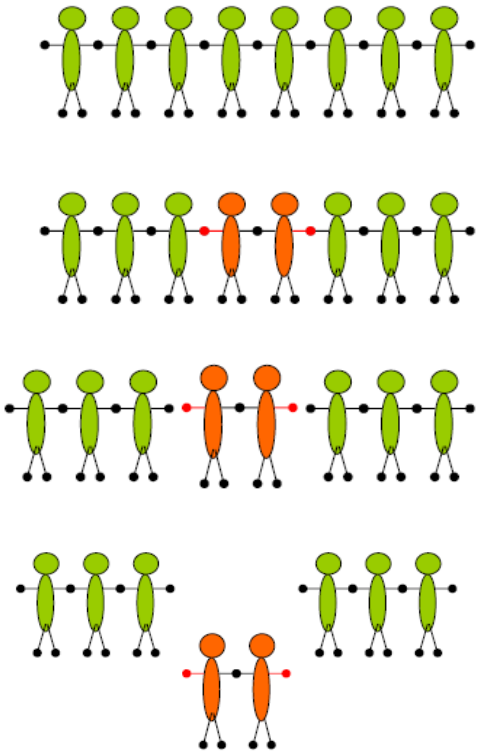
The application procedure is described in Regulation EC 1935/2004.

The **technical dossier** of an application submitted under Regulation EC 1935/2004 must be compiled according to EFSA's guidance.

Applications should be submitted to the national competent authority of a Member State, which will transmit your application to EFSA

MIGRATION

NIAS (i.e. degradation products)



Active polymer (absorbing system)

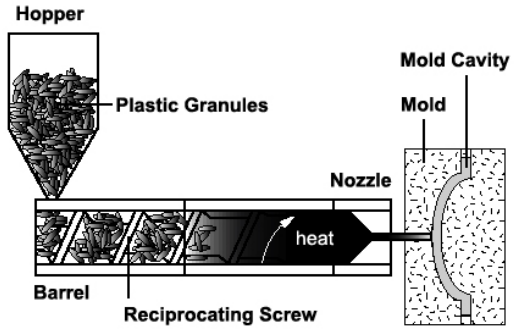
The polymer **reacts** with residual O2 present in the package

The degradation products of the polymer can **migrate into food**

The degradation products of the polymer can **migrate into food**

CCM Conference, Bonn 3 June 2008

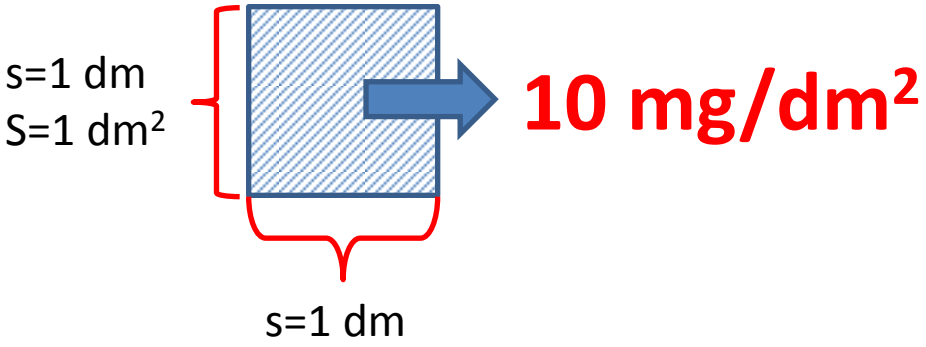
THE NEED FOR A RISK ASSESSEMENT AS REQUESTED BY REGULATION



In principle, non-intentionally added substances will have to comply with the general safety requirements of Article 3 of the Framework Regulation and are subject to risk assessment

Reg EU 10/2011- Reg 1416/2016

OVERALL MIGRATION LIMIT:

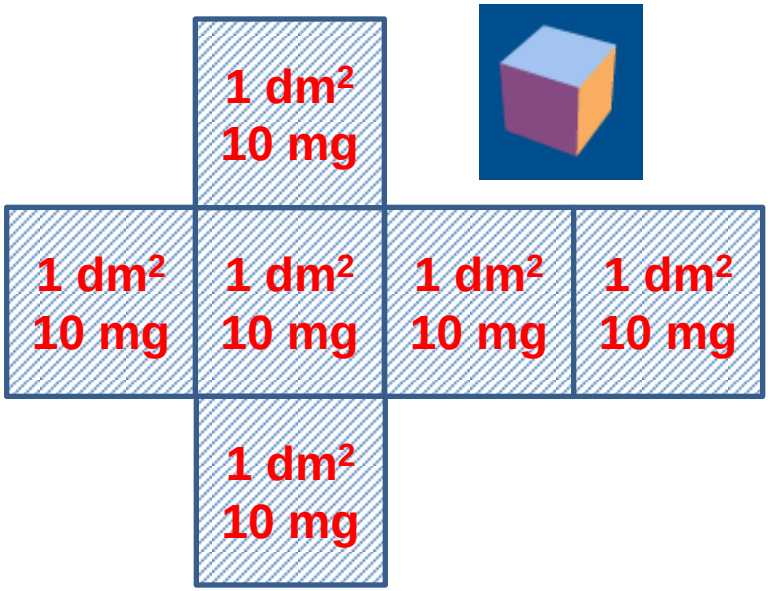


10 mg/dm²

OVERALL MIGRATION

Maximum amount of non-volatile substances that can be released by a packaging material into foods or simulants

Reg EU 10/2011- Reg 1416/2016



Food contact surface area is **6 dm2 per kg food**

Migration of 60 mg from 6 dm^2
INTO
1 dm^3 of FOOD VOLUME=
1kg of FOOD MASS
(assuming the food density equal to 1)

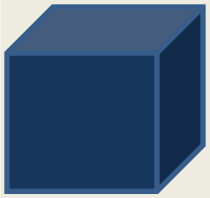
60 mg/kg $_{food}$

OVERALL MIGRATION LIMIT:

10 mg/dm^2=
60 mg/kg $_{food}$

(for packaging dedicated to INFANT FOODS)

Art.3 Reg. EC 1935/2004

	Side (dm)	Cube Surface (dm^2)	Cube Volume (dm^3)	S/V
	1	6	1	6
	10	600	1000	0.6
	0.5	1.5	0.125	12

OVERALL MIGRATION LIMIT:

10 mg/dm^2= 60 mg/kg food

(for packaging dedicated to INFANT FOODS)

For **small packaging** where the surface to volume ratio is higher the resulting migration into food is higher

For **infants and small children** which have a **higher consumption of food per kilogram bodyweight** than adults and do not yet have a diversified nutrition, special provisions should be set in order to limit the intake of substances migrating from food contact materials

Reg EU 10/2011- Reg 1416/2016

SPECIFIC MIGRATION LIMITS:

FOR PLASTICS
Union list Reg EU 10/2011 + amendments
Reg EU 1416/2016

mg/kg food

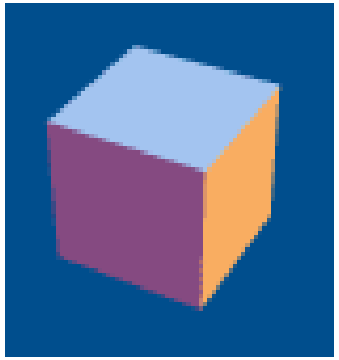
SPECIFIC MIGRATION

maximum permitted amount of **a given substance** released from a material or article into food or food simulants

SPECIFIC MIGRATION

The SML is based on the safety evaluation of the substances by EFSA taking into account information on the toxicity and the migration behaviour of the substance provided by the applicant.

For setting the SML, it is conventionally assumed that **1kg** of food containing **the substance** is consumed **daily** by a person with **60 kg bodyweight**. It is assumed that the **1kg of food** is in contact with a plastic food contact material **releasing the substance at the SML**.
It is further assumed that the **food contact surface area** is **6 dm2 per kg food**.



Reg EU 10/2011- Reg 1416/2016

Additives

Solvents from printing inks

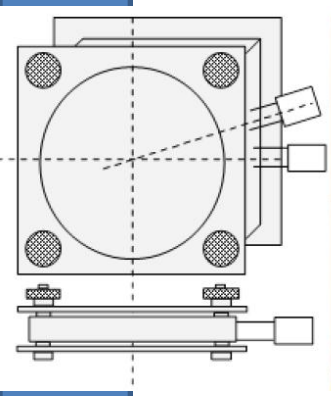
Solvents from adhesives

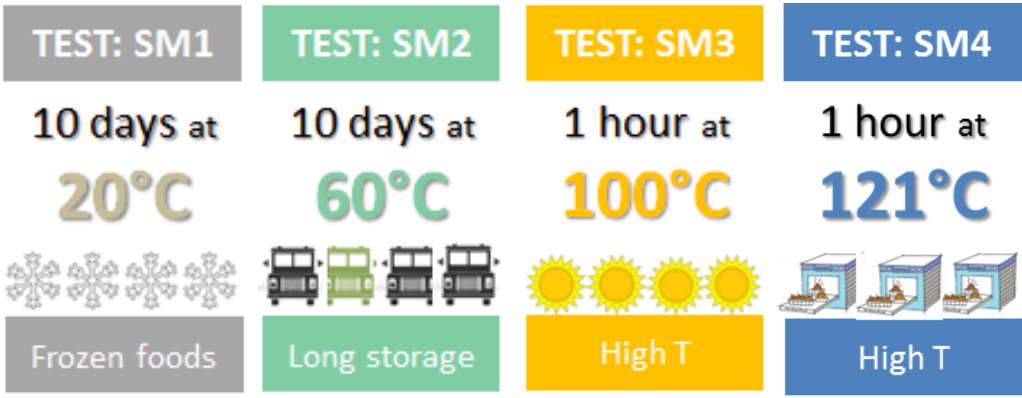
NIAS…….

Evaluation of eventual deterioration in the organoleptic characteristics of foods in contact with packaging materials

HOW TO MEASURE MIGRATION and SENSORIAL INERTNESS?

In order to achieve **comparable results** in the verification of compliance with the migration limits, testing should be performed under standardized test conditions including testing **time**, **temperature** and test medium (**food simulant**) representing **worst foreseeable conditions of use** of the plastic material or article.





OVERALL MIGRATION –SPECIFIC MIGRATION ON PLASTICS

HOW TO MEASURE MIGRATION?

1. TEST MEDIUM: SIMULANTS ……or FOODS

- **Simulant** should represent the **major physico-chemical properties** exhibited by food.
- **Simulant** means a test medium **imitating food**; in its behaviour the food simulant **mimics migration** from food contact materials
- The results of **specific migration testing obtained in food** shall prevail over the results obtained in **food simulant**. The results of specific migration testing obtained in food simulant shall prevail over the results obtained by screening approaches.

OVERALL MIGRATION –SPECIFIC MIGRATION ON PLASTICS

Table 1

List of food simulants

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B
Food simulant	Ab
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E'

Food simulants **A, B and C** are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances

Food simulant **B** shall be used for those foods which have a **pH below 4.5.**

Food **simulant C** shall be used for alcoholic foods with an **alcohol content of up to 20 %** and those foods which contain a **relevant amount of organic ingredients** that render the food **more lipophilic.**

OVERALL MIGRATION –SPECIFIC MIGRATION ON PLASTICS

Food simulant	A
Ethanol 50 % (v/v)	Food simulant D1
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E'

Food simulants D1 and D2 are assigned for foods that have a **lipophilic** character and are able to **extract lipophilic substances.**

Food simulant D1 shall be used for **alcoholic foods** with an alcohol content of **above 20 %** and for **oil in water emulsions**.

Food simulant D2 shall be used for foods which **contain free fats at the surface**.

Food simulant E is assigned for testing specific migration into **dry foods**.

OVERALL MIGRATION –SPECIFIC MIGRATION ON PLASTICS

SIMULANT D1

SIMULANT B

SIMULANT C

SIMULANT E

SIMULANT A

SIMULANT D2

Testing in several different food simulants **provides no added** value if it is scientifically evident that **one food simulant always yields the highest migration results for a specific substance or material** and this food simulant can therefore be considered as the **most severe** for such a substance or material.

Annex III in 10/2011 and derogation in 1416/2016 can help us in the right choice (for materials that are not yet in contact with foods)

OVERALL MIGRATION –SPECIFIC MIGRATION ON PLASTICS

Column 1: reference number of the food category

Column 2: contains a description of the foods covered by the food category

Column 3: contains sub-columns for each of the food simulants

(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
	B. cloudy drinks: juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate		X(*)		X		
01.02	Alcoholic beverages of an alcoholic strength of between 6 %vol and 20 %.			X			
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors				X		

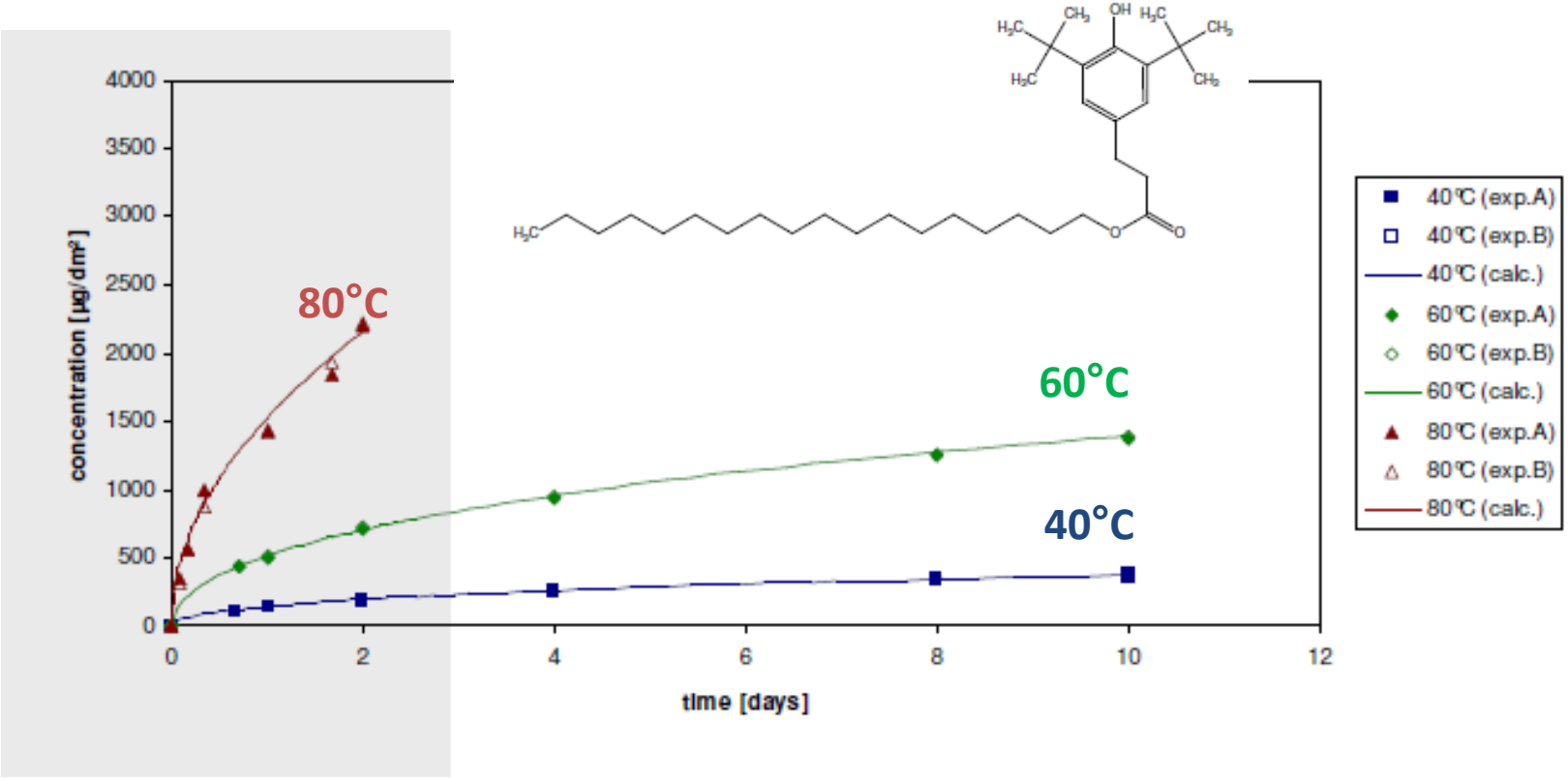
for the whole Table see Reg 10/2011 and Reg 1416/2016)

OVERALL MIGRATION –SPECIFIC MIGRATION ON PLASTICS

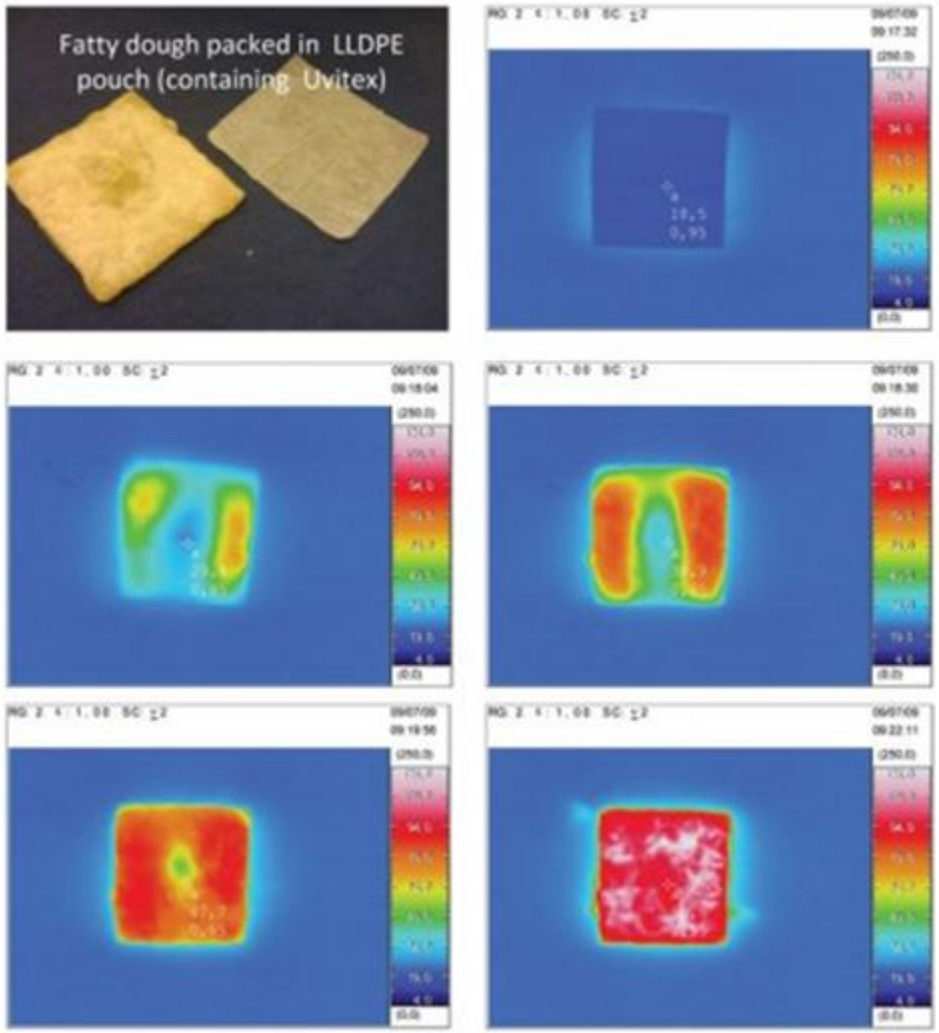
2. WHICH CONDITIONS of TIME and TEMPERATURE?

Time to be selected for testing

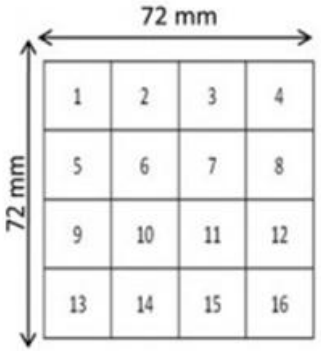
Selection of test temperature

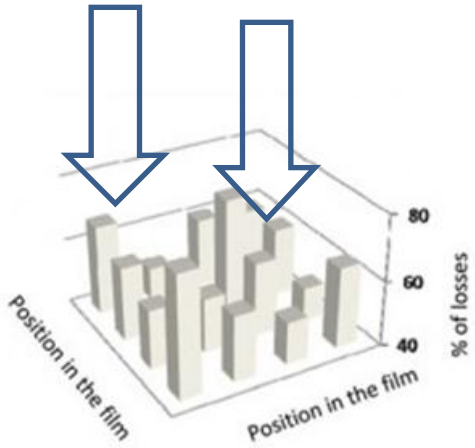


The increase in TEMPERATURE can increase the rate and the amount of migration



Mapping of the surface temperature of LDPE film used to pack fatty dough during ***four minute microwave heating*** *and subsequent predicted migration into food of Uvitex OB initially present in the packaging (Gontard et al., 2010)*





OVERALL MIGRATION

Standardised conditions for testing the overall migration (for the whole Table see Table 3, Reg 1416/2016)

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at contact temperature in [°C] for testing	Intended food contact conditions
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions.
OM2	10 d at 40 °C **10d at 40°C**	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes.
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of t = 120/2^((T-70)/10) minutes, which are not followed by long term room temperature or refrigerated storage.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.

SPECIFIC MIGRATION

Selection of test time (Table 1, Reg 10/2011)

Contact time in worst foreseeable use	Time to be selected for testing
t ≤ 5 min	5 min
5 min < t ≤ 0,5 hour	0,5 hour
0,5 hours < t ≤ 1 hour	1 hour
1 hour < t ≤ 2 hours	2 hours
2 hours < t ≤ 6 hours	6 hours
6 hours < t ≤ 24 hours	24 hours
1 day < t ≤ 3 days	3 days
3 days < t ≤ 30 days	10 days
Above 30 days	See specific conditions

SPECIFIC MIGRATION

Selection of TEMPERATURE (Table 2, Reg 1416/2016)

Worst foreseeable contact temperature	Contact temperature to be selected for testing
T ≤ 5 °C	5 °C
5 °C < T ≤ 20 °C	20 °C

.....

70 °C < T ≤ 100 °C	100 °C or reflux temperature
100 °C < T ≤ 121 °C	121 °C (*)
121 °C < T ≤ 130 °C	130 °C (*)
130 °C < T ≤ 150 °C	150 °C (*)
150 °C < T < 175 °C	175 °C (*)
175 °C < T ≤ 200 °C	200 °C (*)
T > 200 °C	225 °C (*)

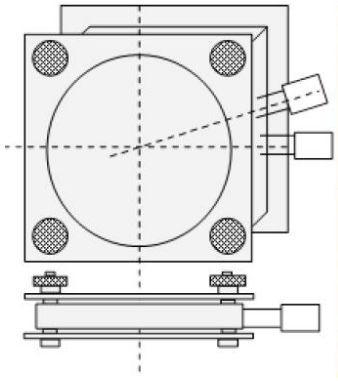
(*) This temperature shall be used only for food simulants D2 and E. For applications heated under pressure, migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100 °C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.'

Standards for FCM Testing

Standard EN 1186 series for overall migration

Standard EN or CEN/TS 13130 for specific migration

OVERALL and SPECIFIC MIGRATION in THE LAB……



– No harmonized standardisation except for gas phase transfer form paper and board (EN 1230)

– German Standard DIN 10955 for sensory testing of FCM

- **is not harmonized**
- is a guide but leaves questions to testing conditions on specific materials open

…THE SAME FOR THE ITALIAN STANDARD UNI 10192:2001

Sensorial inertness IN THE LAB……

- In consequence:

- ❑ uncertainty for testing labs
- ❑ problems may occur in export to other EU member states
- ❑ non co-ordinated working groups on this topic

Compositional requirements

Packaging material INERTNESS

SENSORIAL Inertness

Purity-Safety of the food

If All the 4 criteria meet the Regulation

DECLARATION of COMPLIANCE!!!

WHAT ABOUT ACTIVE PACKAGING????

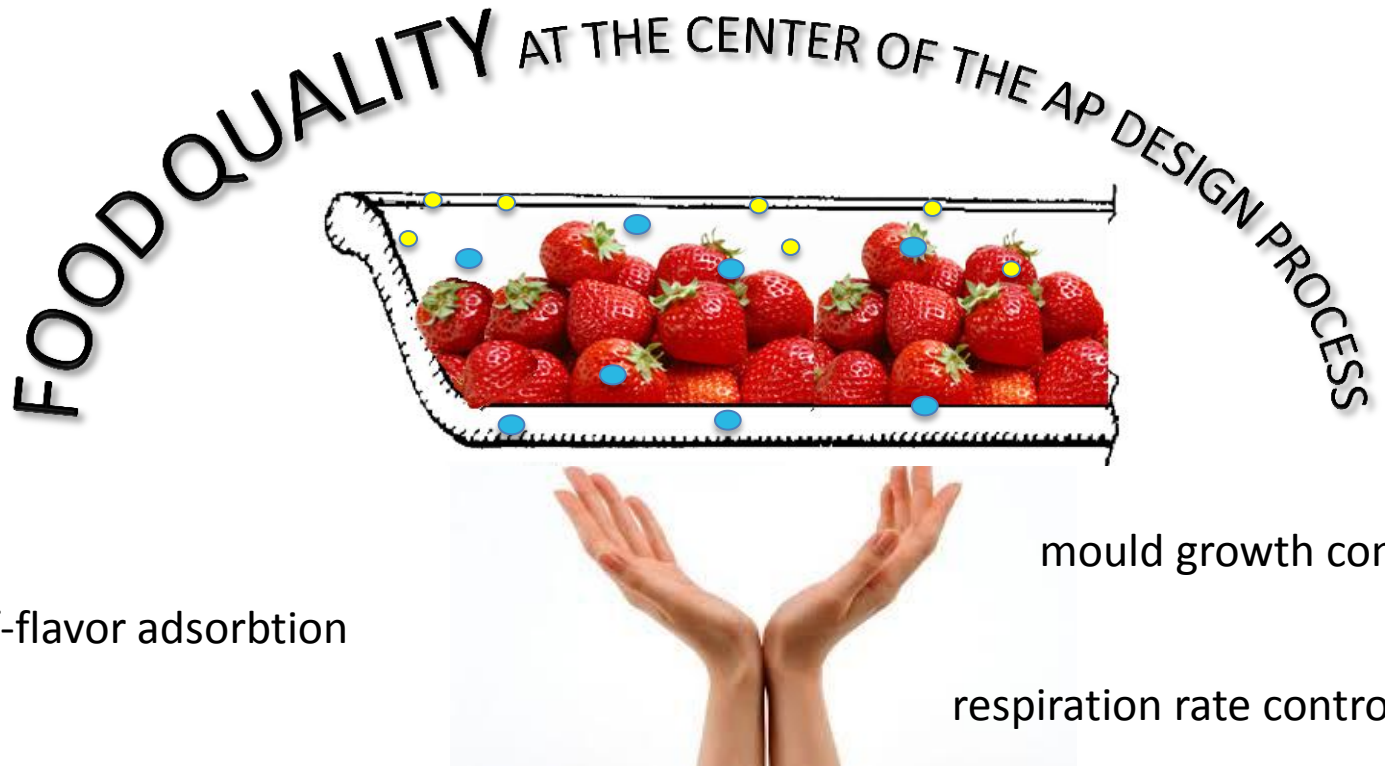
HOW CAN WE CONSIDER THEIR SAFETY AS FCM?

A well-known definition….

- ‘active materials and articles’ means materials and articles that are intended **to extend** the shelf-life or to **maintain** or **improve the condition of packaged food**

- they are designed to **deliberately incorporate** components that **would release or absorb substances into or from the packaged food or the environment surrounding the food**
- (EU Reg. 450/2009)

Food as a target



If the GOAL is the **SHELF LIFE EXTENTION**, an ACTIVE SOLUTION SHOULD ACT REDUCING THE RATE OF THE **MAIN FOOD DECAY EVENT**

..BUT it is not enough

Safety first!!!

ACTIVE PACKAGING SOLUTIONS ARE CONSIDERED AS FOOD CONTACT MATERIALS….thus…

THEY SHALL ONLY BE AUTHORIZED IF IT IS DEMONSTRATED THEY DO NOT PRESENT RISKS TO HUMAN HEALTH (article 8, Reg 1935/2004)

...the European legislation

For ALL the FCM

EC Regulation 1935/2004

It sets out the general principles of safety and inertness for all Food Contact Materials (FCMs).

EC Regulation 2023/2006

The GOOD MANUFACTURING PRACTICES ensures that the manufacturing process is well controlled so that the specifications for FCMs remain in conformity with the legislation

specific EU measures

Regenereted Cellulose Film

Directive 2007/42/EC

Ceramics

Directive 84/500/EEC

I amendment 2005/31/EC

PLASTIC MATERIALS

Consolidated version of Regulation (EU) No 10/2011 and amendments

Regulation (EU) 2016/1416 - amending and correcting Regulation (EU) No 10/2011 for the specifics of these amendments.

Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods

Syn tic ru ers

Di tive 93/ EEC nitros mine

Active and intelligent

EC Regulation 450/2009

Paper and Board | **Glass** | Cork | Stainless Steels-Metals | **Tissues** | **Adhesives** | **Resins ion exchange** | **Inks and dyes** | **Silicons** | **Coatings** | **Wax**

NATIONAL RULES

..Safety first…

L 338/4 EN Official Journal of the European Union 13.11.2004

REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

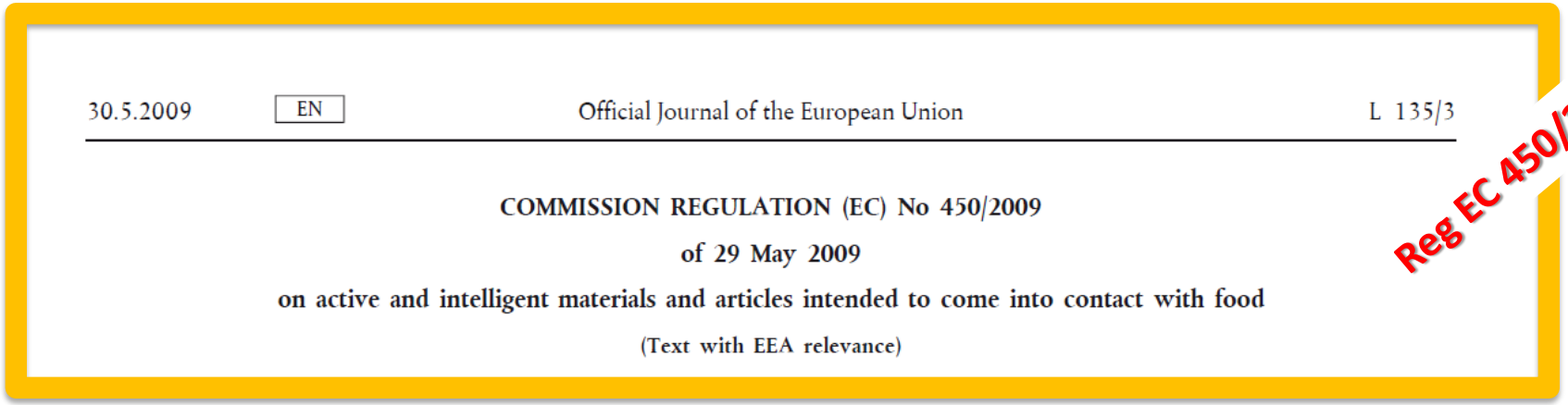
of 27 October 2004

on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

Reg EC 1935/2004

FRAMEWORK REGULATION
EC 1935/2004 → **VALID FOR ALL THE FOOD CONTACT MATERIALS & ARTICLES**

ACTIVE AND INTELLIGENT PACKAGING ARE INCLUDED IN ITS FIELD OF APPLICATION. In 2009 a SPECIFIC MEASURE (Reg EC 450/2009) was adopted



30.5.2009 EN Official Journal of the European Union L 135/3

COMMISSION REGULATION (EC) No 450/2009

of 29 May 2009

on active and intelligent materials and articles intended to come into contact with food

(Text with EEA relevance)

Reg EC 450/2009

Legal requirements

Regulation (EC) No 450/2009 is a specific measure that lays down specific rules for active and intelligent materials and articles to be applied in addition to the general requirements established in Regulation (EC) No 1935/2004 for their safe use.

The substance(s) responsible for the active and/or intelligent function of the material

should be evaluated

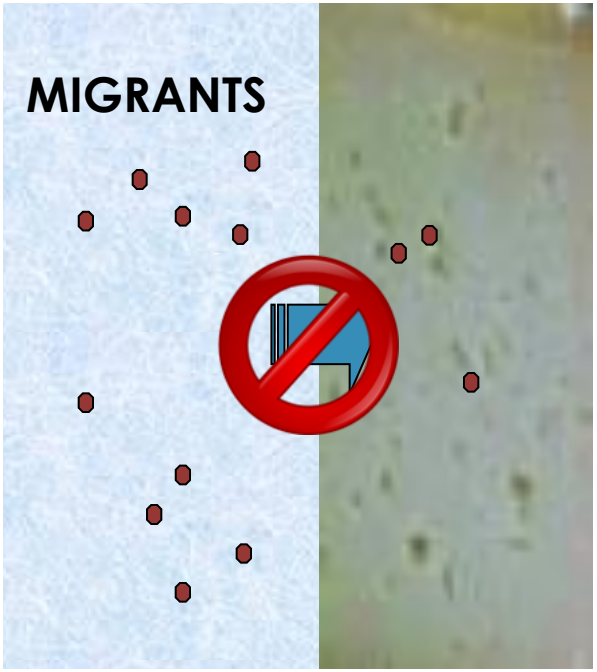
under the regulation (EC) No 450/2009.

Only substances which are included in the '**Community list**' of authorized substances may be used in components of active and intelligent materials and articles.

Is there a contradiction?

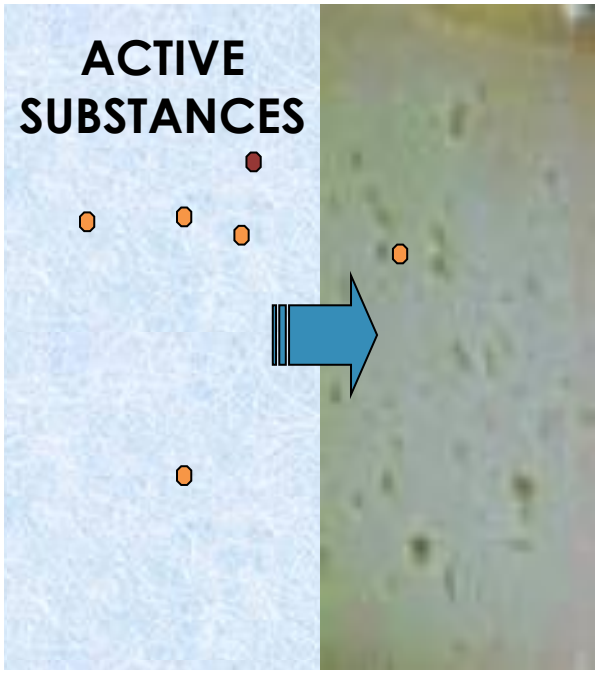
TRADITIONAL PACKAGING:

Migration of ADDITIVES:
REDUCED



ACTIVE PACKAGING:

Migration OF ACTIVE SUBSTANCES:
ENHANCED



A right distinction….for the purpose of safety

- PASSIVE part

Means all material(s) and article(s) **into which** the active component is added or incorporated (such as the primary packaging material into which it is incorporated).

- ACTIVE substance

Means **individual substance** or a **combination of individual substances** which cause the **active function** of a material or article, including the products of *in situ* reaction of these substances.

Some examples…PASSIVE vs ACTIVE

O2 SCAVENGER IN A SACHET

PLASTIC FILM
(i.e. multilayer, monolayer…)

PASSIVE part

The safety must be complied with the European and/or national provisions on the basis of the nature of the material itself (i.e. plastic, paper, ink, adhesive etc.).

Some examples…PASSIVE vs ACTIVE

O2 SCAVENGER IN A SACHET

POWDER

ACTIVE part ???

The substances included in the powder formulation that are directly involved in the absorbing reaction should be considered as components that **cannot be necessarily considered as "active part".**

The **main active ingredients**

iron which reacts with oxygen to form iron hydroxide and iron oxide

water and **sodium chloride**

Other **ingredients:**

silica gel, **activated carbon, monosodium glutamate, potassium acid tartrate, powdered cellulose, malic acid, chabazite**, ecc

All ingredients have been evaluated and approved for use as **additives in plastic food contact materials**, as **food additives** or **food supplements.**

Some examples…PASSIVE vs ACTIVE

O2 SCAVENGER IN A SACHET

POWDER

ACTIVE part ???

The substances included in the powder formulation that are directly involved in the absorbing reaction should be considered as components that **cannot be necessarily considered as "active part".**

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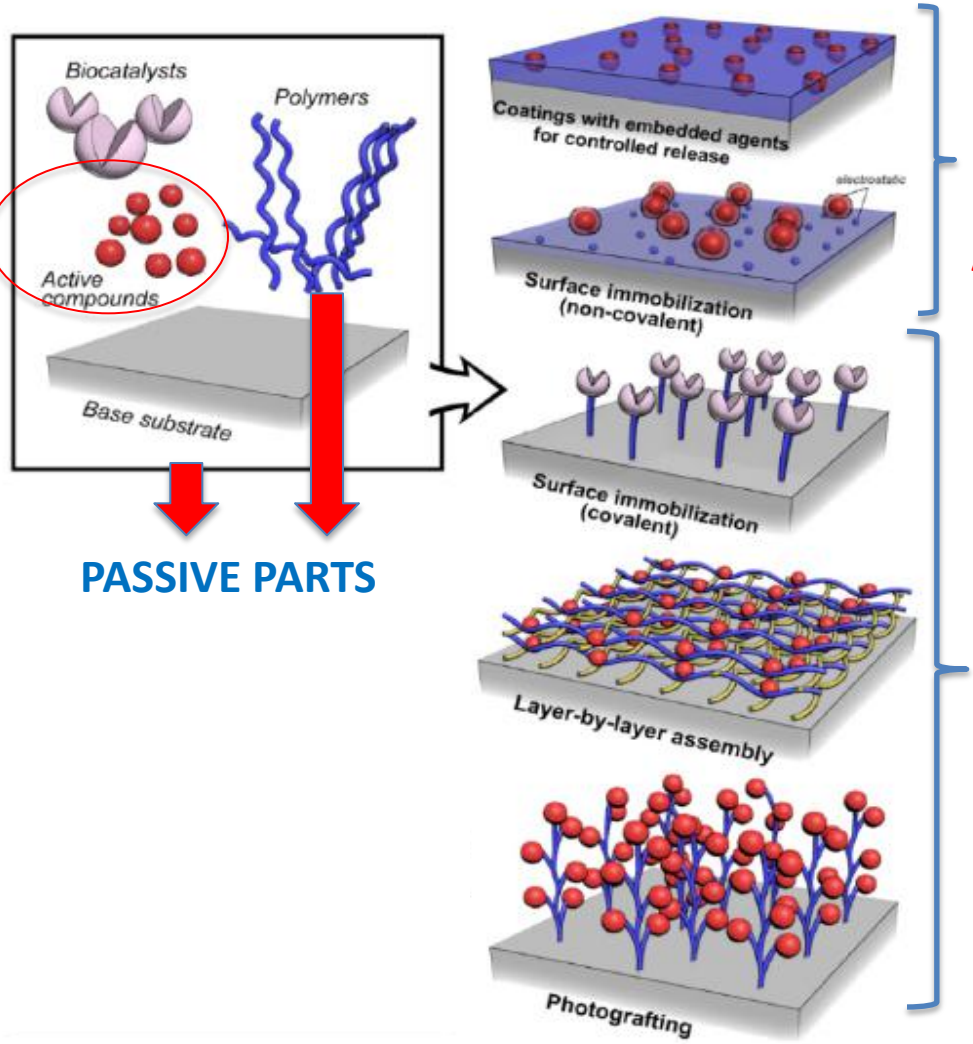
Other **ingredients:**

silica gel, **activated carbon, monosodium glutamate, potassium acid tartrate, powdered cellulose, malic acid, chabazite**, ecc

As the active system is based on solid ingredients, only **MIGRATION THROUGH THE HEADSPACE IS EXPECTED**. If it no occurs and new substances are not generated, THE RISK ASSESSMENT by EFSA is not requested

Some examples…PASSIVE vs ACTIVE



ACTIVE COMPONENT

PASSIVE PARTS

ANTIMICROBIAL IN A COATING

ACTIVE CONCEPT: if it's released from the material

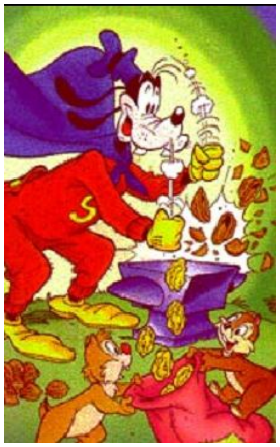
ANTIMICROBIAL IMMOBILIZED AND INCORPORATED BY GRAFTING

ACTIVE CONCEPT: If deliberately influences the conditions of food without intentional migration

Bastarrachea et al., 2015. Coatings 2015, 5, 771-791

Question: WHICH SUBSTANCES CAN BE CONSIDERED ACTIVE?

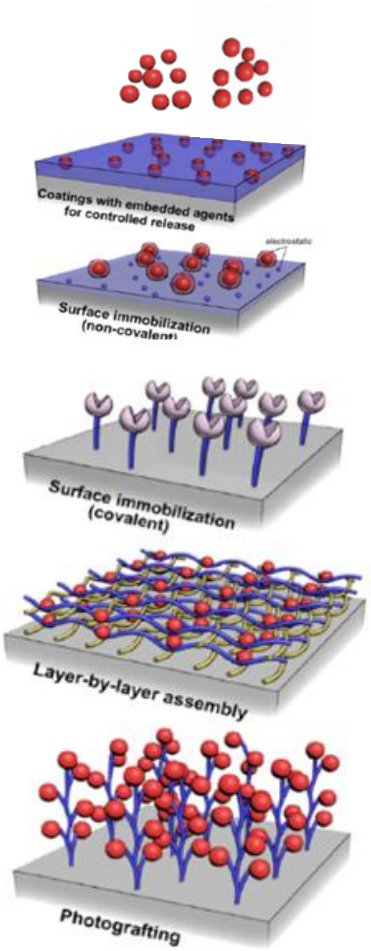
Answer: ONLY THOSE SUBSTANCES THAT HAVE A TECHNOLOGICAL EFFECT ON FOOD QUALITY AND SAFETY



YES, BUT …IN DETAIL…WHICH SUBSTANCES??
…AND…WHICH OF THEM CAN BE EVALUATED UNDER REG EU 450/2009 FOR THE CREATION OF THE UNION LIST?

WHICH SUBSTANCES are considered ACTIVE….

ACTIVE substances that have technological effects on the food



a) PRESERVATIVES/FOOD ADDITIVES/ ENZYMES

Should be used under relevant EU or national provisions.

Commission Regulation EC 1333/2008 + **Reg 1129/2011** and **Reg 1130/2011** that amend Annex II and III

Legislation on food additives, enzimes and flavouring

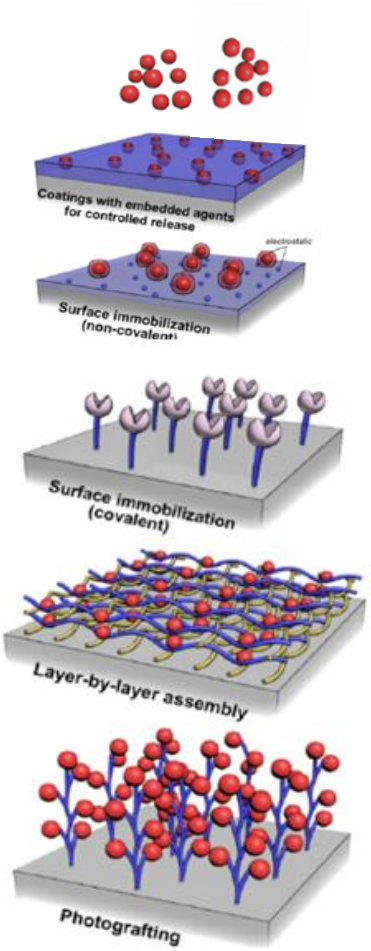
→ With applicable restrictions and conditions

New substances (new food additives or a request for an extension of use) are subject to an **authorization procedure laid down in Reg EU 234/2011**

They **will not be included** in the **UNION LIST** of active and intelligent materials and articles as they fall under the relevant EU or national provisions for their use in the food

WHICH SUBSTANCES are considered ACTIVE….

ACTIVE substances that have technological effects on the food

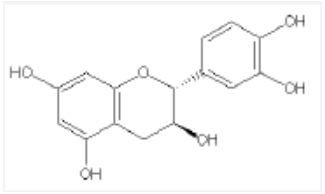


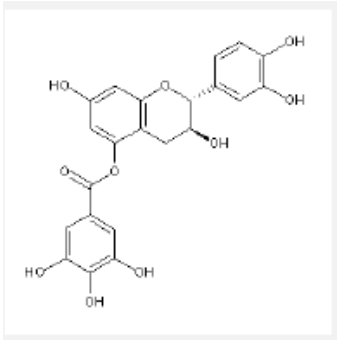
Example:

b) EXTRACTS (i.e extract of rosemary, nisin produced by fermentation… etc)

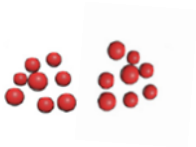
If the substances function as preservatives, they have to comply with the existing legislation on food additives, enzimes and flavouring

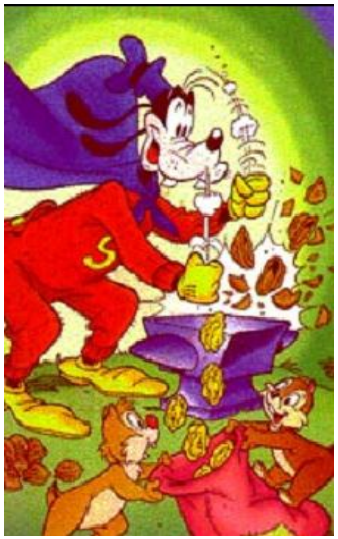
New substances (new food additives or a request for an extension of use) are subject to an **authorization procedure laid down in Reg EU 1331/2008 and not under Reg 450/2009**





WHICH SUBSTANCES are considered ACTIVE….





b) OTHER SUBSTANCES (THE MOST IMPORTANT FOR US!!!!!)

If the active function implies **INTERACTION** between different substances leading to the enhancement of the specific function (i.e. antioxidant, scavenger, etc) or the **GENERATION of new substances** responsible for that specific function, thus these substances (i.e. the **COMPLEX**) are considered as «active substances».

These substances (COMBINATION OF SUBSTANCES) are subject to **authorization under Reg EU 450/2009.**

This means that a **RISK ASSESSMENT** will be carried out by EFSA to support the authorization process.

After the positive opinion of EFSA and the authorization by the EU Commission, they **will be included** in the **UNION LIST** of active and intelligent materials

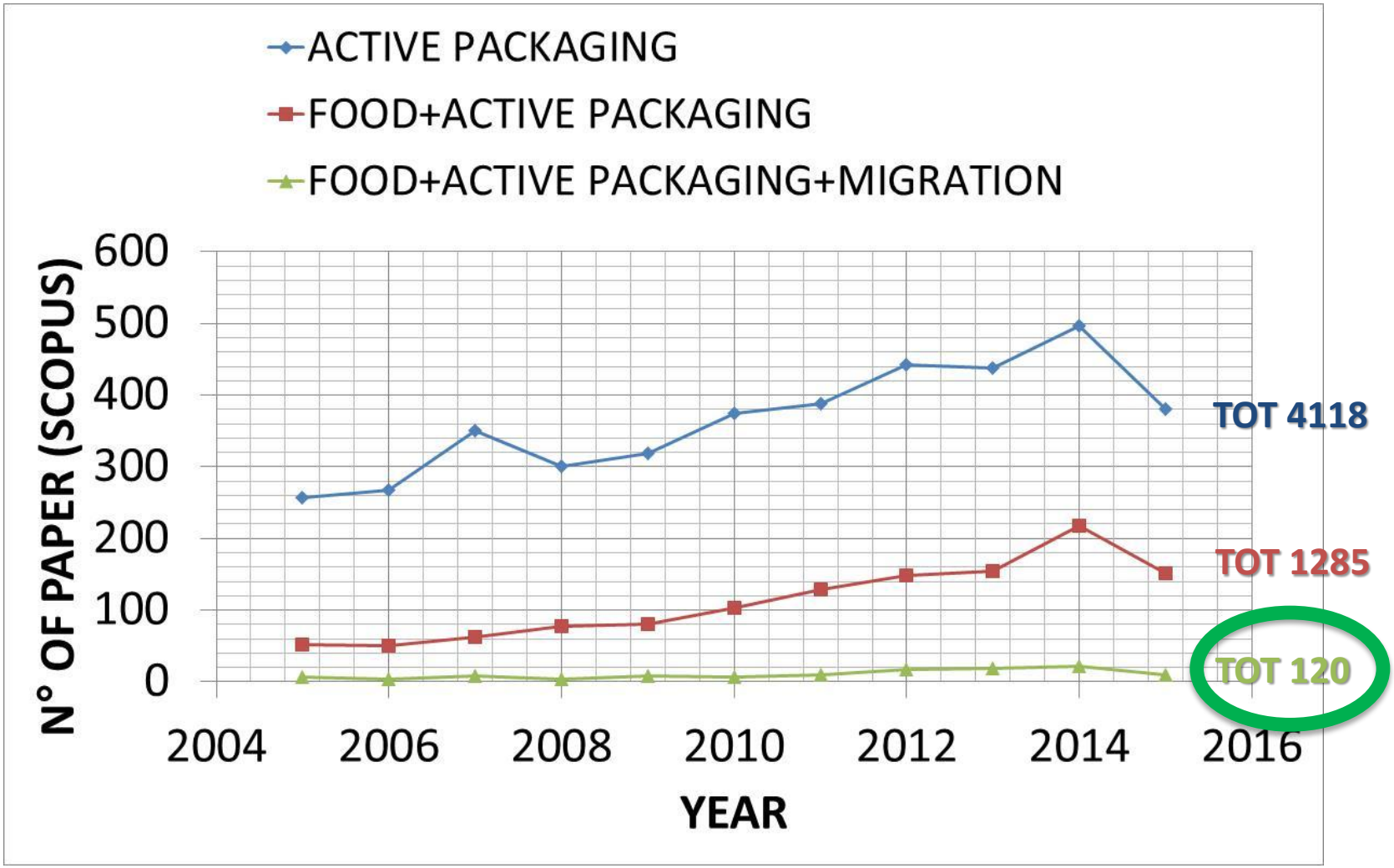
FINAL REMARKS

..from LEGISLATION some suggestions to ORIENT scientific research

and **VICE-VERSA**

…from SCIENTIFIC RESEARCH some suggestions to SUPPORT legislation

FINAL REMARKS: open issues



DATA from SCOPUS 2005-2015

The KEY-words of AP safety…

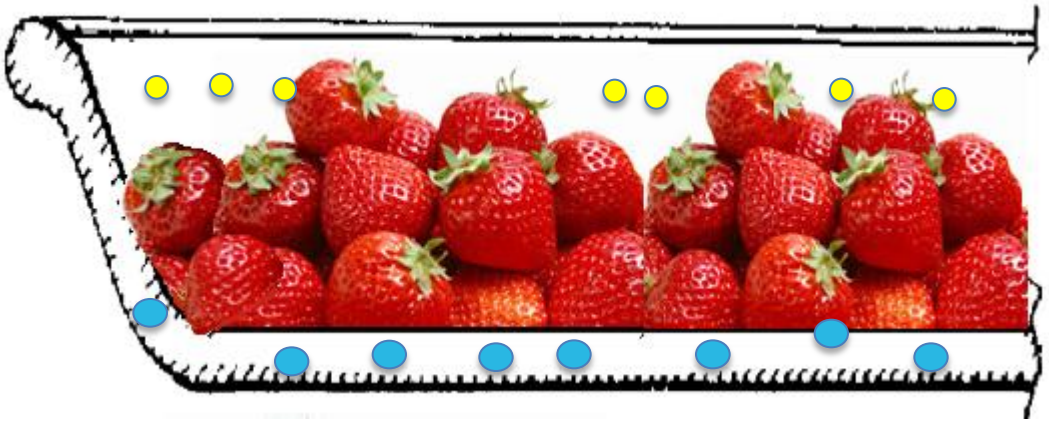
TESTING

MODELING

ANALYTICAL METHODS

MIGRATION

SIMULANTS



RISK ASSESSMENT

TOXICOLOGY

NON INTENTIONALLY ADDED SUBSTANCES

CONSUMER EXPOSURE

NANOFORM SUBSTANCES

THANK YOU FOR YOUR ATTENTION