

---

# Testing Requirements to Comply with EU Food Contact Material Regulations

## Topics

---

- Requirements on
  - Migration
  - Extraction
- Test conditions
- Alternatives to testing
- Sensory analyses

# Scope

- How to arrive at the required compliance of a food packaging from the product itself via analytical chemistry?



# Conformity

- A control of the requirements in Art. 3 of the Regulation (EC) No. 1935/2004 is only possible:
  - in the real foodstuffs
  - on expiry of the best-before date
  - following a real contact situation
  - after use
- Which is difficult for the manufacturer of material

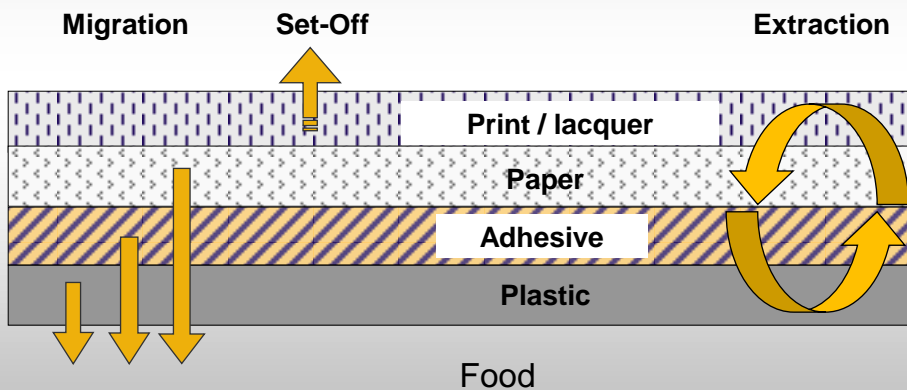
**...and my talk would end here**

## Work for Conformity

- Transfer of substances into food:
  - Determination of contents and modelling
  - Migration tests
  - Transfer onto real food
- Toxicological evaluation:
  - Worst case calculation
  - Evaluated constituents (additives, NIAS)
- Organoleptic effects:
  - Sensory testing
  - Real food

## Food Contact

- Worst case:



## Plastics

- Packers need a declaration of conformity
- The basis for this are migration tests



## Rules for Migration

- A migration test according to the EN 1186 is a simulation of a food contact under defined conditions.
- **Temperature and storage time**
  - Standardized in the law
- **Simulants**
  - Defined for all food types
- The chosen conditions have to be the same as the **foreseeable** application or even a bit stricter

## Overall migration

---

- Overall or global migration
  - Total non-volatile residue in the simulants
  - Limit value: 10 mg/dm<sup>2</sup>
  - Not a toxicologically founded limit value, but a measure of inertness of a package
  - Not required for printing inks
  - Not applicable to materials like paper and board

## Specific migration

---

- Specific migration
  - Defined transfer of substances
  - Limit value: individually defined migration limit (SML)
  - For non-evaluated substances: < 0,01 mg/kg foodstuff
  - Limit values are toxicologically based
  - Evaluated substances not subject to a SML :  
60 mg/kg foodstuff
  - Method is also used for analysis of NIAS

# Overall migration conditions

## Standardized test conditions OM 1-9

OM 1	10 days at 20°C	Frozen and refrigerated conditions
OM 2	10 days at 40°C	Long term storage , 2h at 70°C and 15 min at 100°C
OM 3	2 hours at 70°C	up to 2h at 70°C or up to 15 min at 100°C
OM 4	1 hour at 100°C	Applications up to 100°C
OM 5	2 hours at 100°C or at reflux or 1 hour at 121°C	High temperature applications up to 121°C
OM 6	4 hours at 100°C	All contact conditions with simulants A, B and C exceeding 40°C
OM 7	2 hours at 175°C	High temperature conditions with fatty foods exceeding the conditions of OM 5

# Overall migration conditions

## Standardized test conditions OM 1-9

OM 8	Food simulant E for 2 hours at 175 °C and food simulant D2 for 2 hours at 100 °C	High temperature applications only
OM 9	Food simulant E for 2 hours at 175 °C and food simulant D2 for 10 days at 40 °C	High temperature applications including long term storage at room temperature

Excerpt from Regulation (EU) No. 10/2011, Table 3:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:en:PDF>

## Specific migration Rules

- Examples of migration conditions (Source: I0/2011)

Contact temperature	Test temp.	Contact temperature	Test temp.
$5^{\circ}\text{C} < T \leq 20^{\circ}\text{C}$	20°C	$70^{\circ}\text{C} < T \leq 100^{\circ}\text{C}$	100 °C
$20^{\circ}\text{C} < T \leq 40^{\circ}\text{C}$	40°C	$100^{\circ}\text{C} < T \leq 121^{\circ}\text{C}$	121 °C
$40^{\circ}\text{C} < T \leq 70^{\circ}\text{C}$	70°C	$150^{\circ}\text{C} < T \leq 175^{\circ}\text{C}$	175 °C

## Specific migration Rules

- Examples of migration conditions (Source: I0/2011)

Contact time	Test time	Contact time	Test time
$5 \text{ min} < t \leq 0,5\text{h}$	0,5 h	$2 \text{ h} < t \leq 4 \text{ h}$	4 h
$0,5 \text{ h} < t \leq 1 \text{ h}$	1 h	$4 \text{ h} < t \leq 24 \text{ h}$	24 h
$1 \text{ h} < t \leq 2 \text{ h}$	2 h	$3 \text{ d} < t \leq 30 \text{ d}$	10 d

## Food simulants

- Aqueous foods
  - (A) 10 % ethanol,
  - (B) 3 % acetic acid,
  - (C) 20 % ethanol
- Fatty foodstuffs
  - (D2) olive oil and other fats
- Dry foodstuffs
  - (E) Tenax
- Simulant for dairy products
  - (D1) 50 % ethanol



## Food simulants

- Water as a foodstuff
  - Water itself, not the simulant
  - is covered by 10 % ethanol
- Replacement simulants for fat
  - 95 % ethanol or isooctane, Tenax



Currently not in the scope of the Regulation (EU) No. 10/2011, but current state of technology for testing according to the upcoming Guidelines



## Test Methods

- Migration testing can be applied to many other materials:
  - Adhesives, Printing inks, lacquers, metal, glass
- However, migration testing is often unsuitable:
  - Paper, board, nonwoven, cork, wood, textiles

## Simulants for moist and fatty food

Table 2 food category specific assignment of food simulants

(1) Reference number	(2) Description of food	(3) Food Simulants					
		A	B	C	D1	D2	E
06	Animal products and eggs						
06.01	Fish:						
	A. Fresh, chilled, processed, salted or smoked including fish eggs	X				X/3(**)	
	B. Preserved fish:						
06.02	I. In an oily medium	X				X	
	II. In an aqueous medium		X(*)	X			
	Crustaceans and molluscs (including oysters, mussels, snails)						
	A. Fresh within the shell						
	B. Shell removed, processed, preserved or cooked with the shell						
	I. In an oily medium	X				X	
	II. In an aqueous medium		X(*)	X			

# Simulant for Dry Food

Table 2 food category specific assignment of food simulants

(1) Reference number	(2) Description of food	(3) Food Simulants					
		A	B	C	D1	D2	E
01	Beverages						
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		
01.04	Miscellaneous: undenaturated ethyl alcohol		X(*)			Substitute 95 % Ethanol	
02	Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares						
02.01	Starches						X
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)						X
02.03	Cereal flour and meal						X
02.04	Dry pasta e.g. macaroni, spaghetti and similar products and fresh pasta						X

**ISEGA**

Dr. Derra

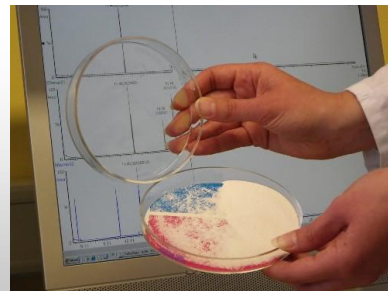
19

# Migration into Tenax

## Migration into modified Polyphenylenoxide (EN 14338)

Simulant for dry, non-fatty foodstuffs,  
also suitable for powdery, fatty foodstuffs

- Convention testing
- No relation to real physics
- Test conditions: 10d, 40°C
- Measurement of the migrating substances
- Comparable to real results

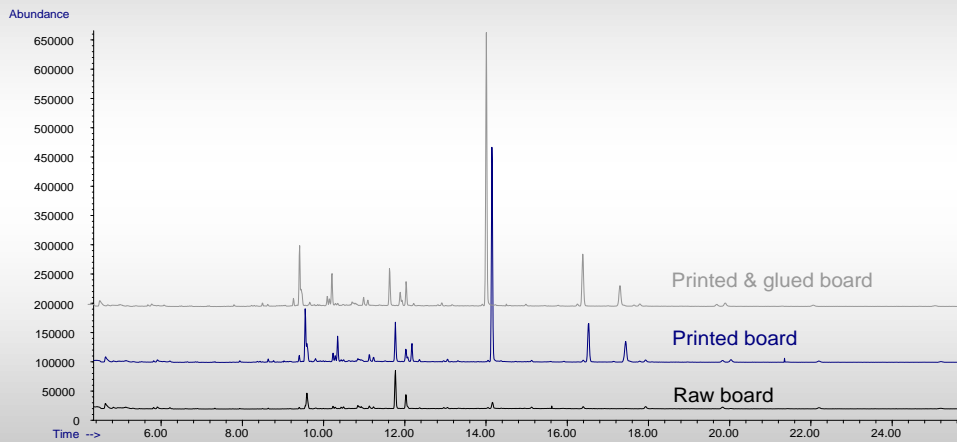


**ISEGA**

Dr. Derra

20

## Migration into Tenax



## Migration Model Calculations

- The migration potential can be calculated based on the residual content of a substance in a material
- Migration model calculation by means of diffusion models
- Several commercial or freeware programs available  
<http://www.akts.com/sml-diffusion-migration-multilayer-packaging/download-diffusion-prediction-software.html>
- Complicated for multi-layer or inhomogeneous systems

## Toxicology

- Toxicological evaluation of a product is crucial for the SML
- Specific migration < 0,01 mg/kg food
  - **For non-evaluated substances**
- Specific migration < 0,05 mg/kg food
  - **3 mutagenicity tests**
- Specific migration < 5 mg/kg food
  - **Feeding studies**

## Example: Plastic container

- **Known intended purpose:** facilitates choosing test simulants
  - Mayonnaise: fatty test simulant
  - Gherkins: 3 % acetic acid (v/v)
- **Storage:** based on the best-before date given  
e.g. 10 days, 20°C
- **Test procedure:** Interior surface of test piece
- **Reporting of test result:** in mg/kg food  
(starting at a capacity of 500 ml)
- **Depending on the formulation:**  
SML or QM testing



➔ Migration testing

## Example: Folding Box

- **Known intended purpose:**
  - Powdery foodstuff: Tenax
  - Inner packaging: Tenax
- **Storage:** based on the best-before date given  
lack of standardized relation
- **Test procedure:** Food contact side
- **Reporting of test result :** in mg/kg food  
Surface / volume ratio has to be estimated
- **Depending on the formulation:**  
SML or QM testing



➔ Extraction testing or Tenax migration

## Sensory Analysis

- Apart from chemical influences, Regulation (EC) No. 1935/2004 also bans organoleptic (pertaining to taste and odour) deterioration
- Sensory evaluation of the food contact article itself is not possible
- Testing models for the **transfer of active substances** onto a test food
- There are standardized methods for the simulation of food contact:
  - DIN 10955, EN 1230, ISO 13302 for odour and taste
- Sensory packaging test are more conclusive on the finished product.

## Odour

Evaluation of the inherent odour of the food contact material itself



- A defined amount of sample is placed loosely into an empty glass flask
- Storage for 24 hours in the dark
- Recording of the odour and its intensity directly after opening the vessel

## Off-Flavour

- The food contact material is stored in direct or indirect contact with food, preferably applying the real conditions
- Subsequently, the deviation of the taste (and/ or odour) of the food is evaluated in comparison to a blank food (reference) not stored with the food contact material



## Off-Flavour

---

- Use of the actual food (whenever possible)
- Switching to **test foods** while increasing sensitivity:
  - Little inherent taste
  - Large (amplified) active surface
- Reasons: lack of knowledge, inhomogeneity, intended contact with different foods, etc.

## Sensory Testing of Food Packaging

---

- Thorough knowledge of the raw materials and extensive analytical testing required
- Compilation of individual declarations of conformity is not always sufficient
- The overall combination has to comply with legal provisions as well
- Additional testing on the finished product is not always necessary
- Examination scope in accordance with the intended purpose
- Results have to be in compliance with Art. 3 of the Regulation (EC) No. 1935/2004