The European Commission's science and knowledge service

Joint Research Centre

Measuring migration from FCMs: Scientific and practical challenges

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FPF workshop, Zürich, 5th October 2017

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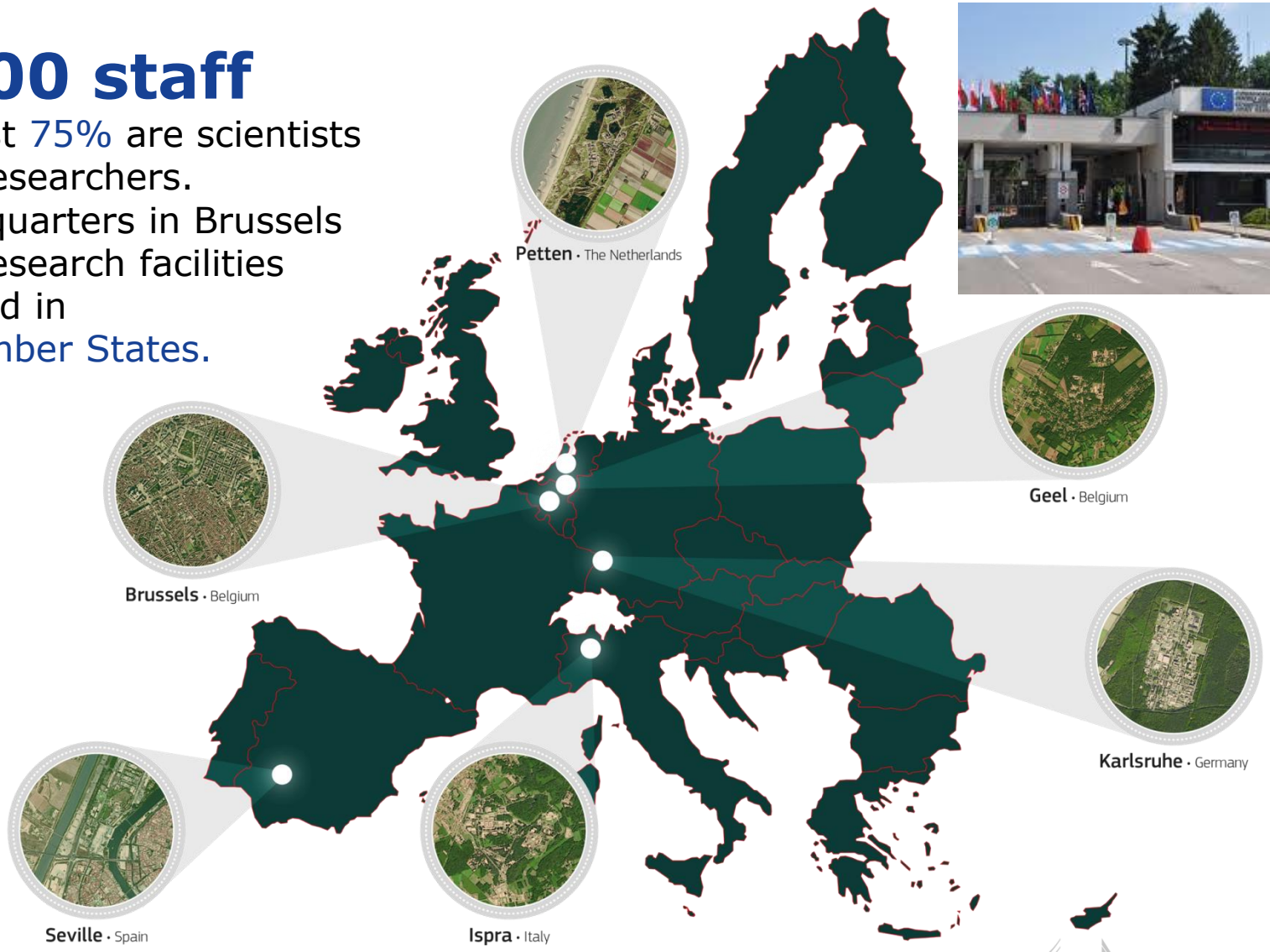
The Joint Research Centre at a glance

3000 staff

Almost 75% are scientists and researchers.
Headquarters in Brussels and research facilities located in
5 Member States.



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Disclaimer

The views presented are purely those of the myself and may not in any circumstances be regarded as stating an official position of the European Commission.

Framework Regulation – Article 3

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

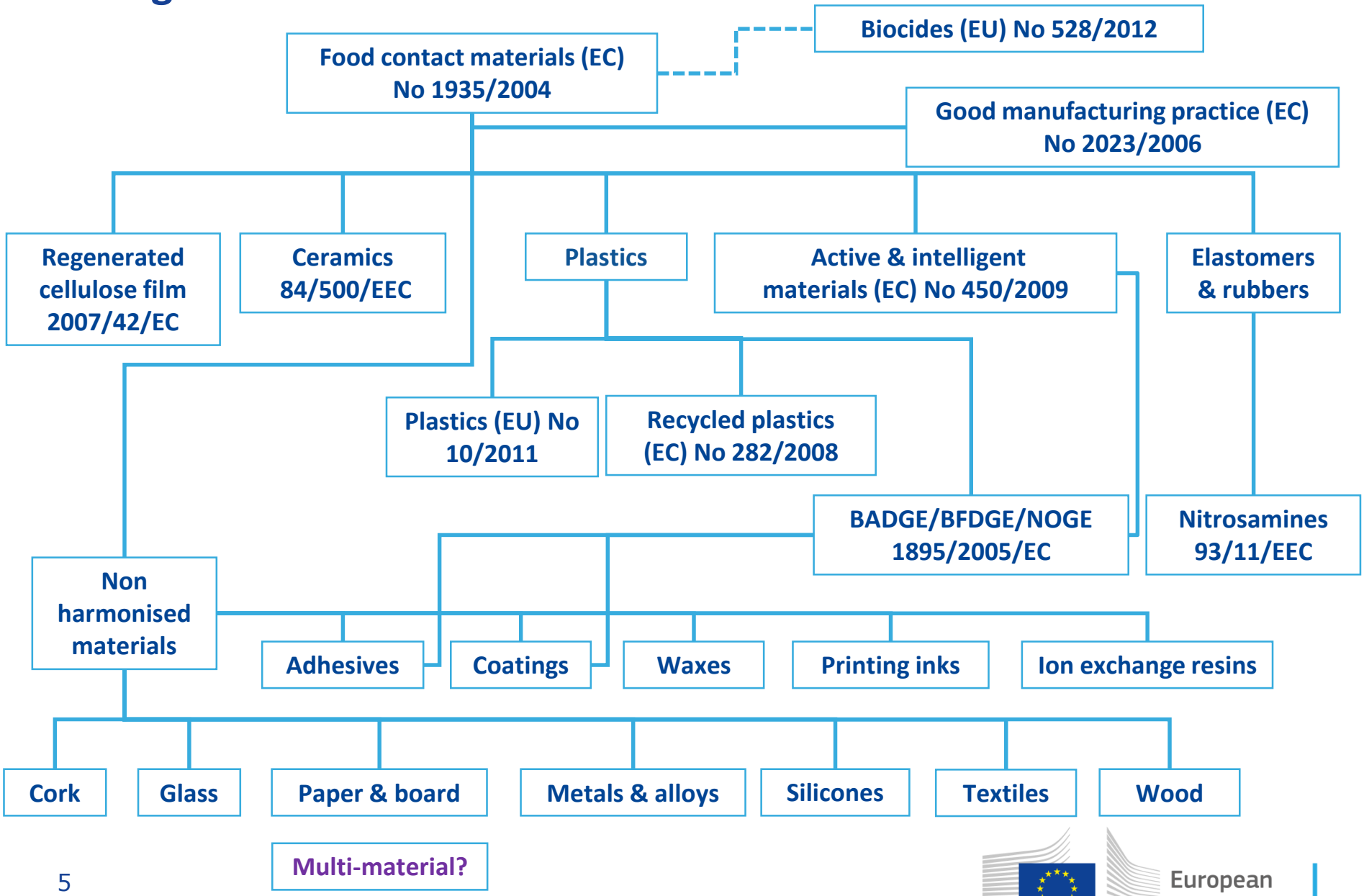
b) bring about an unacceptable change in the composition of the food

c) bring about a deterioration in the organoleptic characteristics thereof

Two general principles

1. Inertness
2. Safety

EU legislation



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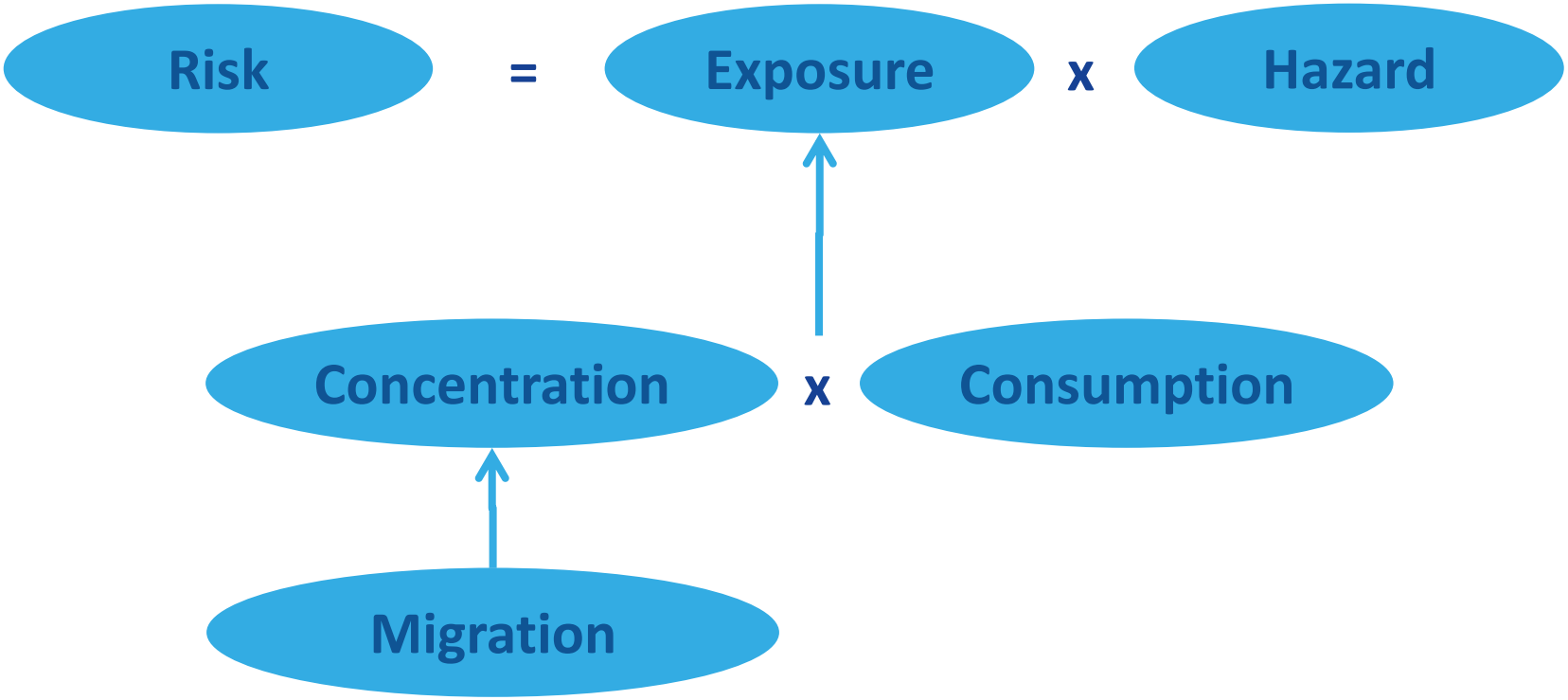
Risk



FACET final release is available:
https://ec.europa.eu/jrc/en/scientific-tool/flavourings-additives-and-food-contact-materials-exposure-tool

Chemical safety of food contact materials

Chemical

Food

Material

Migration

Time

Temperature

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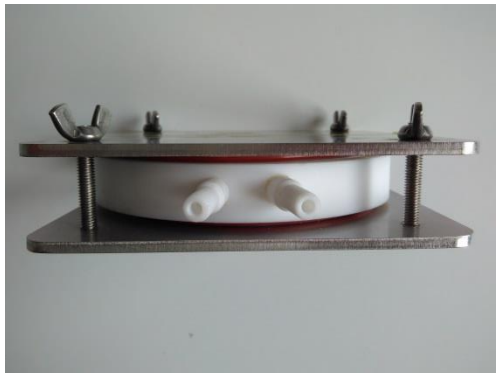
Requirements for migration test

- **Sample preparation**
  - ✓ **e.g. cut test specimen**
- **Test type**
  - ✓ **e.g. total immersion, article fill, migration cell, pouch**
- **Relevant food → food simulant(s);**
- **Worst case contact time and temperature conditions**
- **Worst case surface-to-volume ratio (S/V)**
- **Repeated use or not**

Migration test approaches



Article filling

Immersion

Pouch

Cell

Boiling?

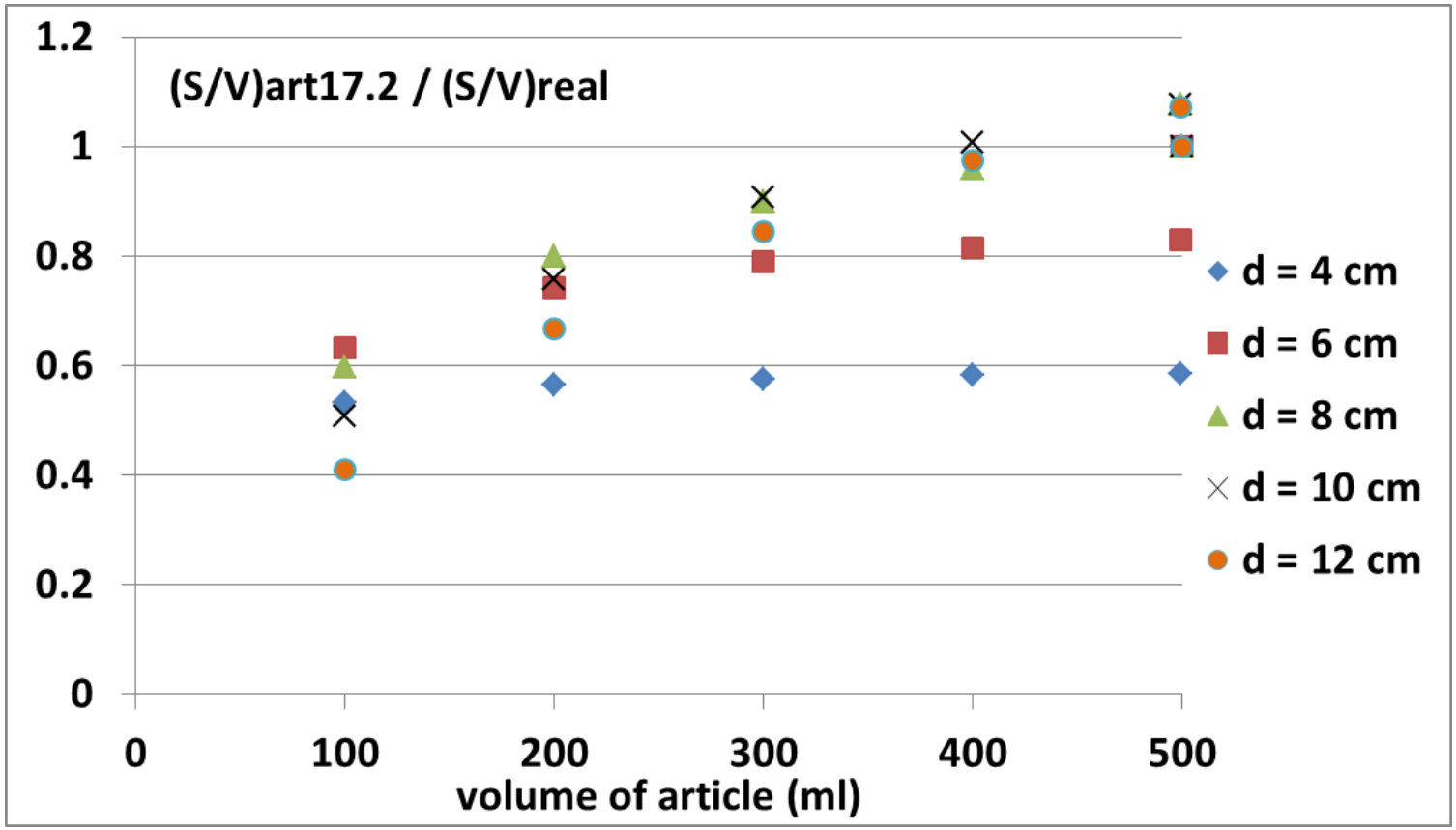
Reverse pouch

Requirements for migration test in EU legislation

	Plastic	Ceramic	Rubber	Cellulose
sample preparation	remove dust	washing warm soap/ tap+demi water Wax non-food contact area	boiling water	-
test type	4	fill/immersion	immersion	-
food simulant(s)	6	1	1	-
t-T	>>>	24 h @ 22°C	24 h @ 40°C	-
surface to volume ratio (S/V)	Real or 6 dm^2/kg food	Real or mg/ref. surface dm^2	-	-
repeated use	+	-	-	-
SML	mg/kg food	mg/kg food or mg/dm^2	mg/kg rubber	-
Standard	(EN 1186 series)	EN 1388-1 ISO 6486-1 (ISO 8391-1 cookware)	EN 12868	-

Surface-to-volume – specific migration

$$M_{SML} = M_{real} \frac{S/V_{art17}}{S/V_{real}}$$



Plastics: under estimation of exposure for adults

Surface-to-volume ratio – overall migration

- OML = 10 mg/dm^2
  - measurement uncertainty: 3 mg/dm^2 for oil; 2 mg/dm^2 for aqueous FS
- For children: OML = 60 mg/kg

Example:

- Packaging with S/V = 5 mg/dm^2
  - E.g. h=10 cm; ø= 10 cm → V=800 ml
- OM = 15 mg/dm^2
- Not compliant for general use (>12-13 mg/dm^2)
- OM x S/V = 75 mg/kg
- Compliant for FCM in contact with oil: OML=78
- Not compliant for FCM in contact with aqueous FS: 12x6=72

Inertness of plastic FCM intended for food for children not always better

Temperature control

300 mL

Identification
(LC-qTOF-MS)

Quantification
(HPLC-FLD)

Critical point 1
Simulant preheating

- 75 °C for 12-16 h
- Schott bottles
- No simulant losses
- Calibrated data logger

Critical point 2
temperature control/migration

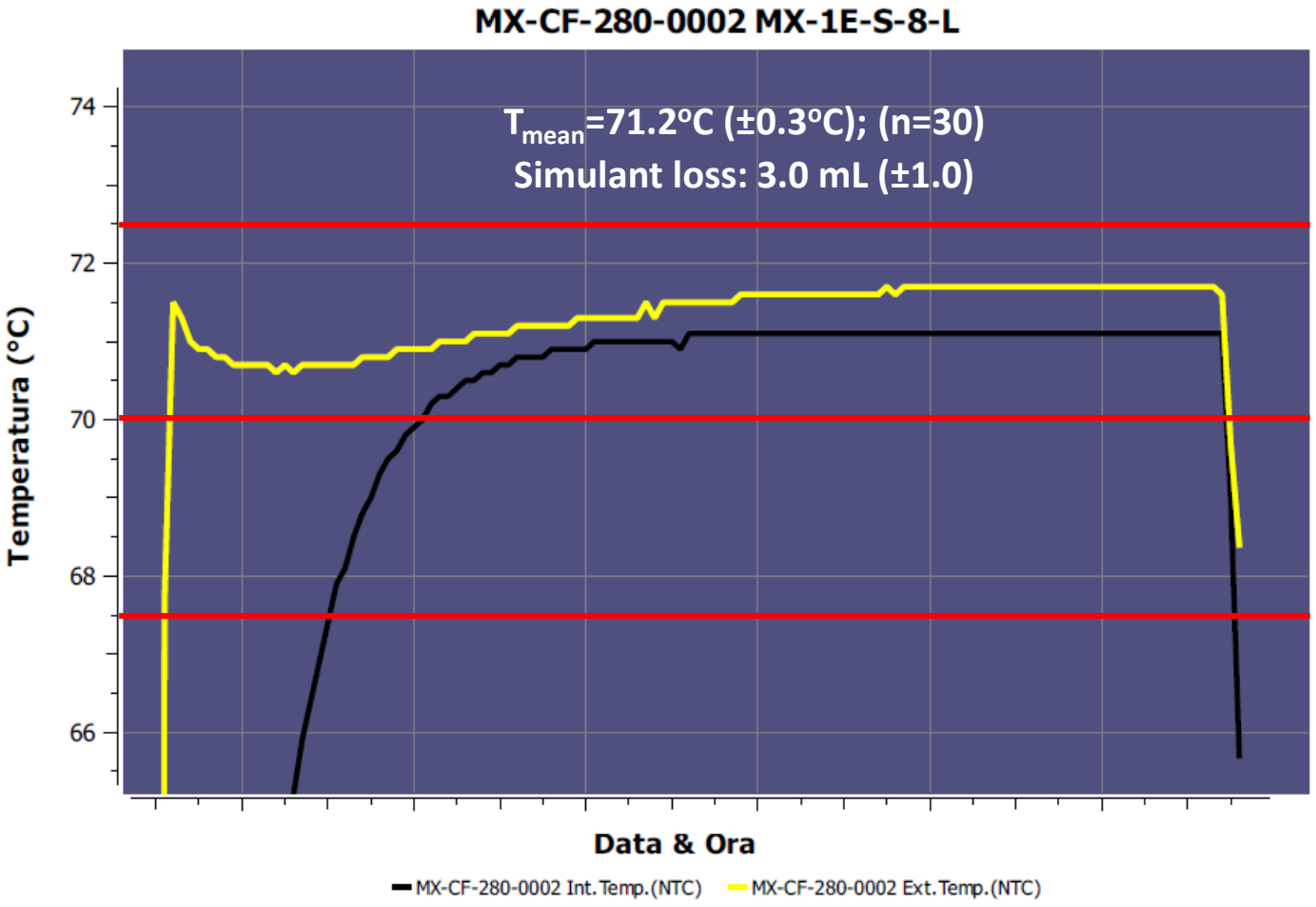
Fan operation:

- Fast oven temperature equilibration time (2-3 min)
- Higher throughput (10-15 migrations/h)

Critical point 3
identification/quantification

- Migration test FS A, C and D1
- LC-MS screening
- 2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene (FCM 500) (fluorescent, with a SML of 0.6 mg/kg)
- A HPLC-FLD method FS D1

Temperature profile during the migration test



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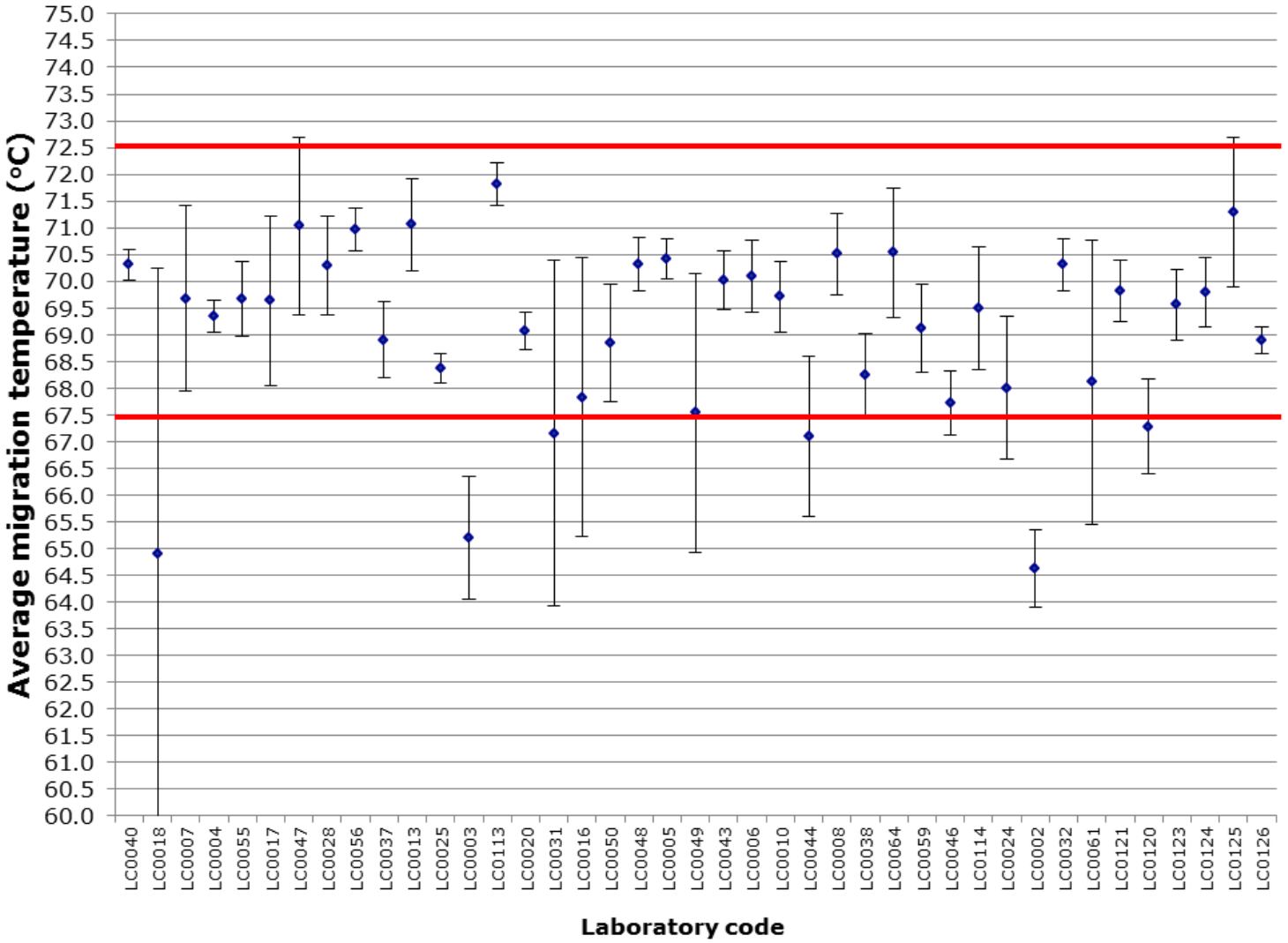
Average temperature during migration test



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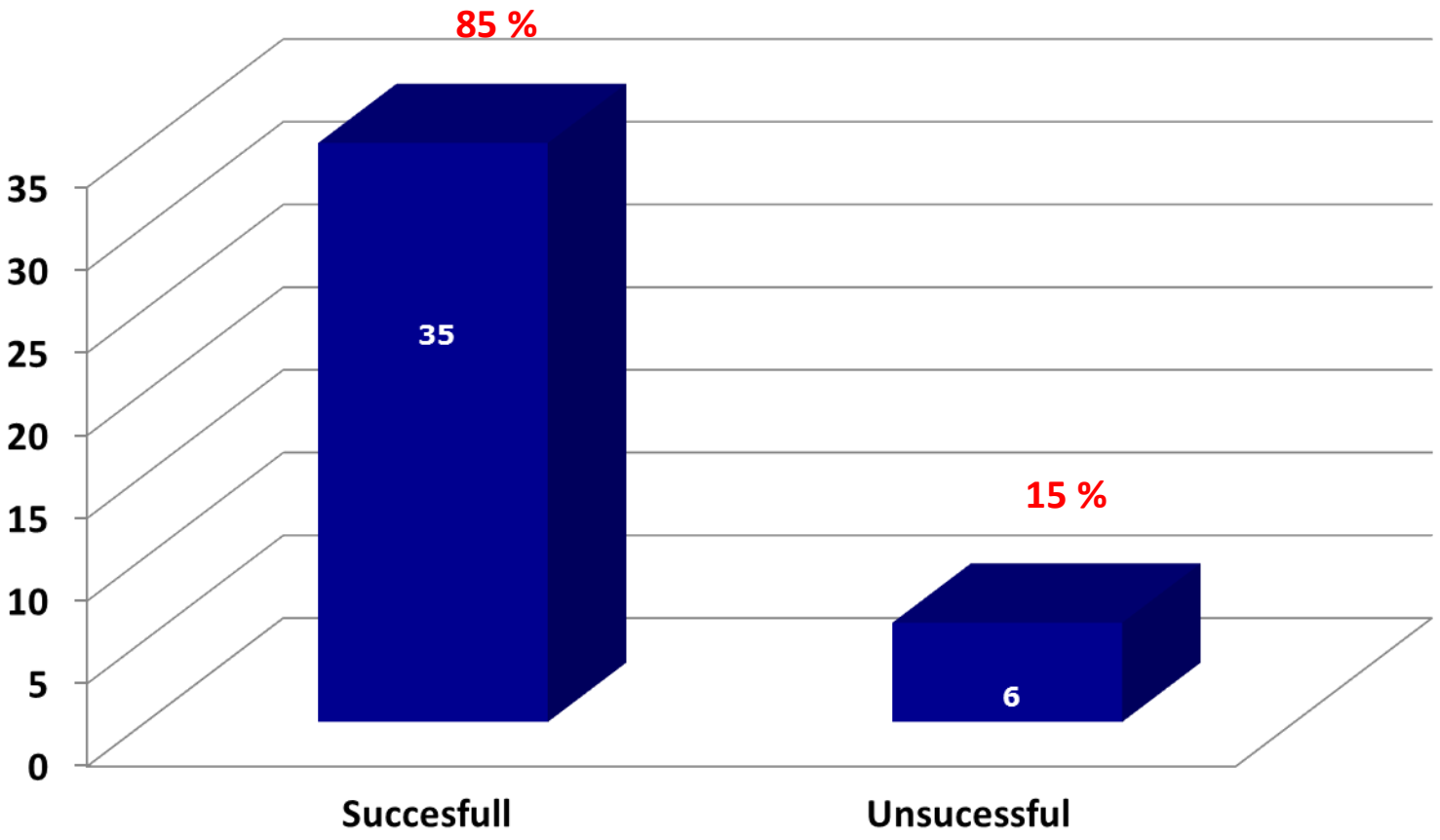
Temperature control – Mean temperature in range



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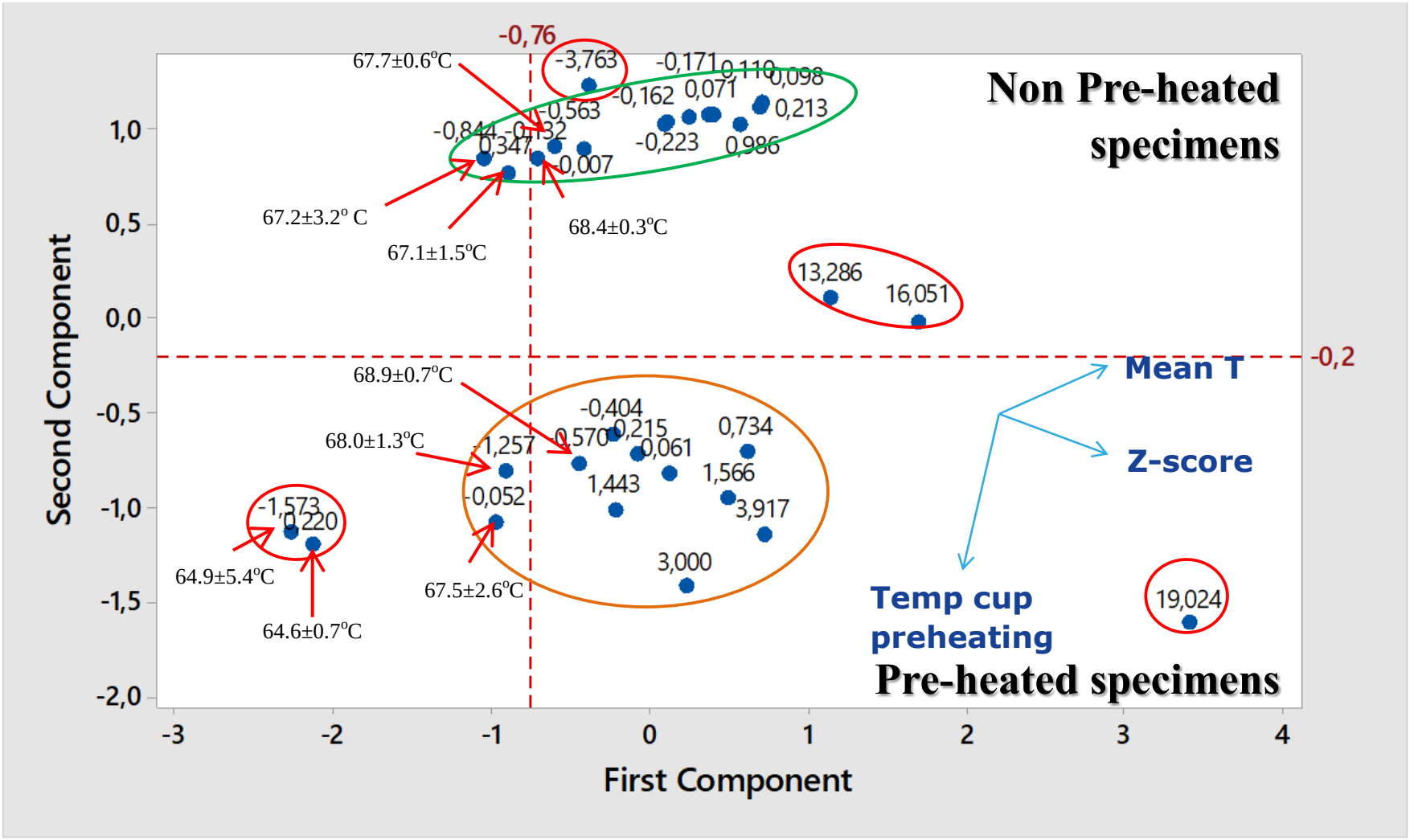
Principle component analysis



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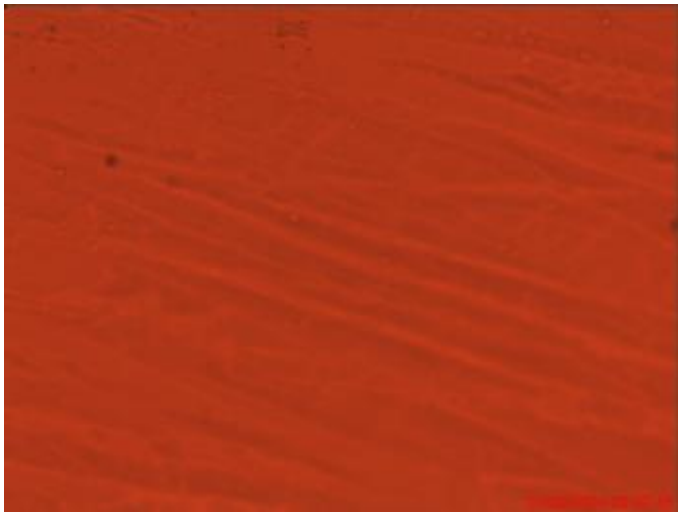
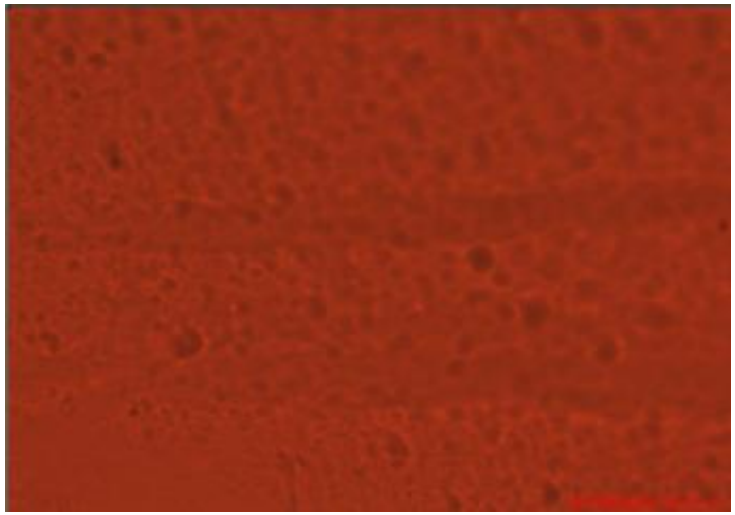
Effect preheating of test item

- Cups were pre-heated in-house
- These cups were analysed by
  - ✓ thermal gravimetric analysis
  - ✓ differential scanning calorimetry
  - ✓ optical microscopy



x50



No-preheating

Preheating at 75°C

Preheating of the FCM, before migration, shall be avoided

Available analytical methods and calibrants

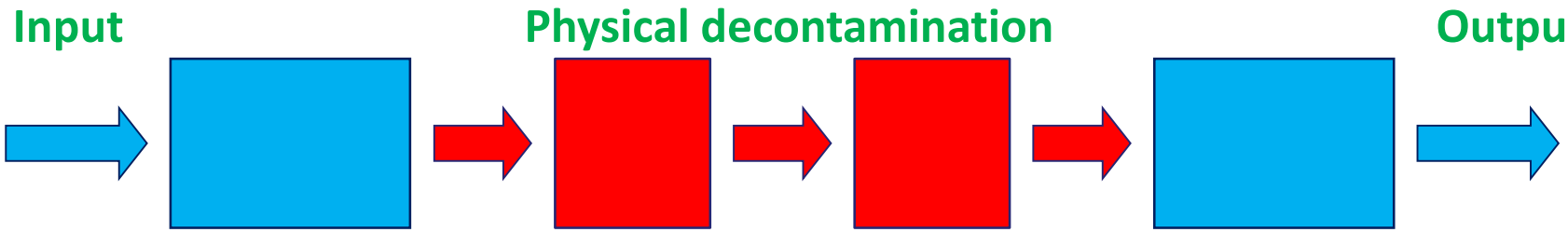
	FCM substances	Calibrant	Method	Calibrant + method
No SML	441	267	53	31
SML=ND	31	28	21	20
SML	270	195	159	125
Group SML	146	101	50	41
SML + group SML	10	7	5	3
Total	878	586	278	214

Consolidated version of 10/2011 including Regulation (EU) No 2016/1416

Other issues to be considered

- Overestimation of migration by food simulant D1 and E
- Microwave heating
  - ✓ Temperature at the interface
- Multi-component/assembled articles
  - ✓ Test individual components
  - ✓ Test assembled article
- Labelling vs. foreseeable use
- Identification/quantification of
  - ✓ Chemical mixtures
  - ✓ non-intentionally added substances

Recycling process plastic



Open questions

- The 5% non-food consumer products limit
- Imports and production out-side of the EU
- The present contamination level
- Other issues, such as actual decontamination, systemic contamination sources…

Conclusions

- Testing multi-layer plastics/materials sometimes difficult at boiling temperatures
- Recalculation of migration test results to real S/V are relevant for using in exposure scenarios
- Temperature control during migration testing is essential
- Preheating of the FCM, before migration, shall be avoided

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