

# Why some migration conditions for plastics are not appropriate for other FCMs.

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Representing 18 associations directly or indirectly involved in FCMs

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# Extract from Executive Summary (p9) European Parliament report on 1935/2004 (May 2016)

*'As a general trend, stakeholders who are in favour of further EU level harmonisation recommend that **EU specific measures should establish** a single standard for analytical (testing) methods, such as composition determination, migration testing, risk assessment, but also specific methods for compliance enforcement, thus ensuring that the relevant FCM is tested by companies and competent authorities across the EU with one and the same method. **Furthermore, the EU single standard for analytical (testing) methods should be specific for each FCM, thus reflecting its unique properties and avoiding situations where non-harmonised FCMs are tested with methods developed for harmonised FCMs, which could lead to misleading and debatable test results'***

# DISCLAIMER

- As chair of the 18 associations representing non-plastics, I will try and represent them.
- The initiative started with CEPE, EMPAC and almost immediately CES silicones joined.
- Other associations have joined since then.
- However, I have to understand and work with analytical data, in order to make decisions about and determine the safety of my company's products.
- The work is embryonic, associations are still joining and the final format will certainly be different to that initially envisaged.

# Associations participating in Initiative

- ACE Beverage cartons – paper, plastics and aluminium flexible
- APEAL Steel for rigid metal packaging
- CEFIC-FCA Substance suppliers
- CELIEGE Cork
- CEPE Coatings for rigid metal packaging
- CEPI Paper and paper board
- CES Silicones Europe: Silicone elastomers for household articles
- EAA Aluminium
- EEA Porcelain enamel and porcelain enamelled articles
- EMPAC Rigid metal packaging
- ETRMA Rubbers
- EuPIA Printing inks
- EWF Waxes
- FEC Non-stick treatments and coatings, materials and articles
- FEFCO Carton board
- FEICA Adhesives
- FPE Flexible packaging (non-plastic and multi-material)
- GAE Glass articles, hollow, domestic and flat glass

# The Issue - 1

- In the Plastics Regulation (10/2011) and supporting documentation, (i.e. Migration Guidelines), some of the simulants, times and temperatures are inappropriate for some non-plastic FCMs (Food Contact Materials).
- Why non-plastics rather than non-harmonised?
- Migration conditions for plastics are not used for some harmonised FCMs, such as ceramics or regenerated cellulose.
- However in the absence of harmonised regulations the conditions used in the Plastics Regulation are often applied to non-plastics.

## The Issue - 2

- National Regulations for non-plastic FCMs are tending to adopt the conditions in 10/2011 – example proposed coating regulations for both Netherlands and Belgium, although different in detail.
- Obtaining higher or lower levels of migrants under inappropriate conditions may result in mis-interpreting the results:
  - Plastic simulants and or conditions may cause physical damage / changes to the non-plastic FCM which invalidates the result

## The Issue - 3

- Even if no change the simulants and conditions for plastics were chosen to model plastics and their interaction with foodstuffs. Non-plastics may/will interact differently giving mis-leading results (higher or lower).

## Example of non-stick-coatings

- Non-stick coatings and treatments are unique:
  - Whilst there are industrial and professional uses of the food contact articles, the primary end use applications are intended to be by consumers
  - Potential for repeated use at high temperatures
  - Potential for food contact temperatures from  $<0\text{ C}$  to  $> 250^{\circ}\text{C}$
  - Incompatibilities between some coating materials and existing simulants
- Need for flexibility in selecting test conditions to reflect actual end use conditions



## Industry response - 1

- Members of associations, in the non-harmonised FCM supply chain, have formed a task force to propose testing conditions better adapted to the specificity of various materials / sectors.
- Each sector is assessing the applicability or not of the plastics 10/2011 migration testing guidelines for their own sector.
- In some cases they are applicable, but in other cases they are not
- The Task Force are developing their own compliance guidelines with separate chapters for each non-harmonized FCM.

## Industry response - 2

- Gaps or lack of feasibility of implementations are identified and expertise collected and shared to offer technical solutions for improved compliance testing.
- Test proposals are based on technical / scientifically demonstrated justification.
- Common introduction available.
- The majority of association's guidelines are/will be on their web-site. For those that aren't it will be necessary to contact their secretariat for them
- The guidelines will be based on the following format:

# New Guidelines – common format - 1

- Introduction
- FCM specific chapter containing:
  - Scope
  - Uses
  - Definitions
  - Material Specific Properties to be considered when testing this class of FCM
  - Brief outline as to why plastic testing guidelines may be inappropriate
  - Test Procedures
  - Evaluation of test results

## New Guidelines – common format - 2

- Annexes
  - Annex 1: Reasons why plastic guidelines are not suitable for this class of FCM.
  - Annex 2: References
- The amount of detail in each sector's chapters will vary considerably, e.g. silicone thermoplastics are relatively specific, whereas adhesives cover the majority of adhesives with different issues for different adhesives.
- Coatings cover many areas and associations as can be seen from the following slide:

# Different Coatings

1. Can – EMPAC / CEPE
2. Heatseal – EuPIA / FEICA / FPE
3. Coldseal - EuPIA / FEICA / FPE
4. Coatings on plastic film
5. Porcelain enamel coating on metal - EEA
6. Non-stick treatments and coatings (PTFE and Sol-Gel based) – FEC
7. Coatings on Paper and board – CEPI / CITPA
8. Heavy duty – CEPE
9. Coatings on metal foil – FPE
10. Polymeric Coatings on glass
11. Passivation coatings on metals – APEAL
12. Others

# Substrates covered by coatings

Coating	paper	Aluminium foil	Metal packaging	Plastic	Kitchen ware	Glass	Metal, plastic, concrete	Wood	Textiles
1			X						
2	X	X	X	X					
3	X			X					
4				X					
5					X				
6					X				
7	X								
8							X		
9		X							
10						X			
11			X						
12	X	X	X	X	X	X	X	X	X

## FCM cross sector involvement

- During meetings, different FCM sectors found that other sectors had similar problems with some simulants, times or temperatures.
- In addition many FCMs are multi-material, hence different associations needed to work together.
- It has to be recognised that there are not always easy answers to issues raised.
- There is still debate as to whether to tackle the subject substrate by substrate or material by material e.g. baking paper as paper or as fluoro-polymers, silicones etc.
- Some examples of the issues and proposed solutions follow.

# Issues with 3% Acetic Acid for Overall Migration



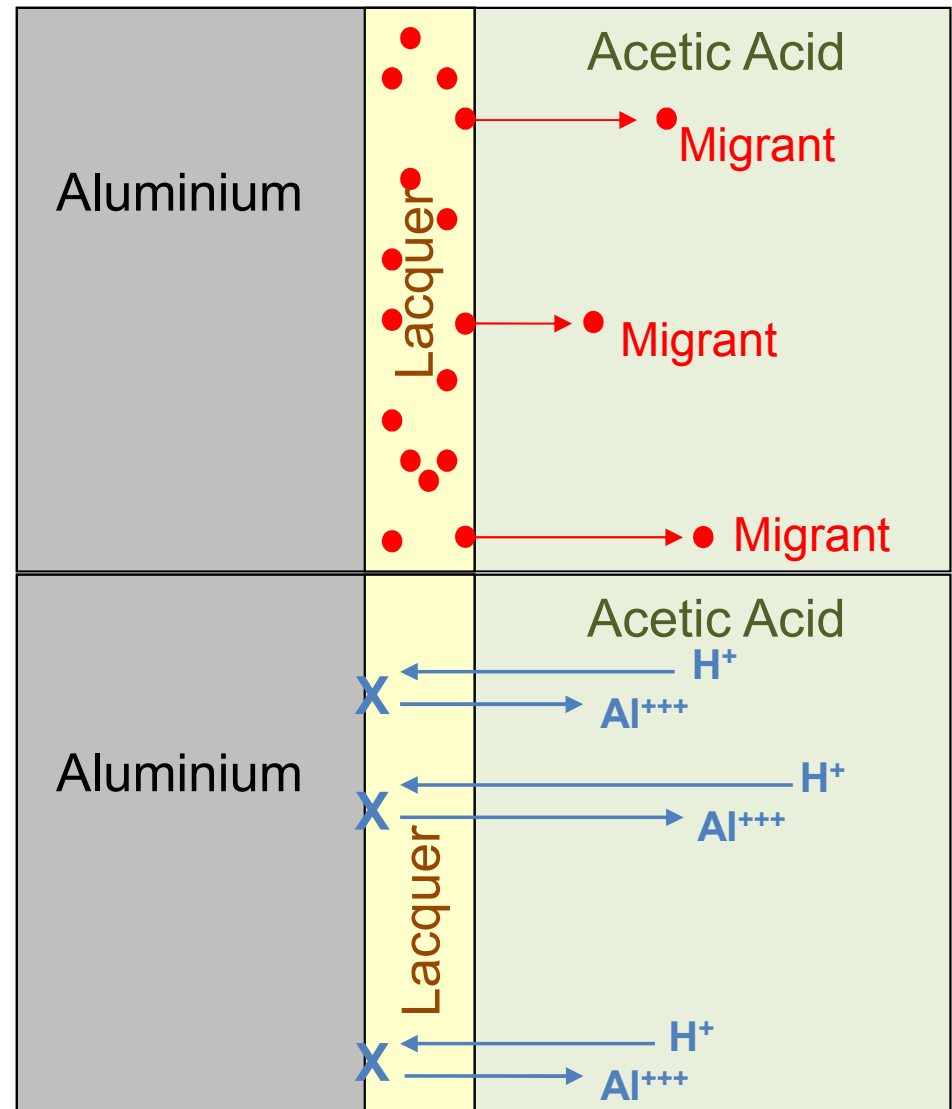
## 3% Acetic Acid – 1

- A general issue common to many FCM sectors is the use of 3% acetic acid for overall migration (OM).
- OM is NOT a measure of safety, but of inertness of polymeric materials.
- Acetic acid corrodes aluminium, either as a coated substrate or foil layer in a multi-layer FCM.
- Acetic acid also corrodes coated tin plate.
- There is an issue but no solution has yet been found, BUT options are being investigated

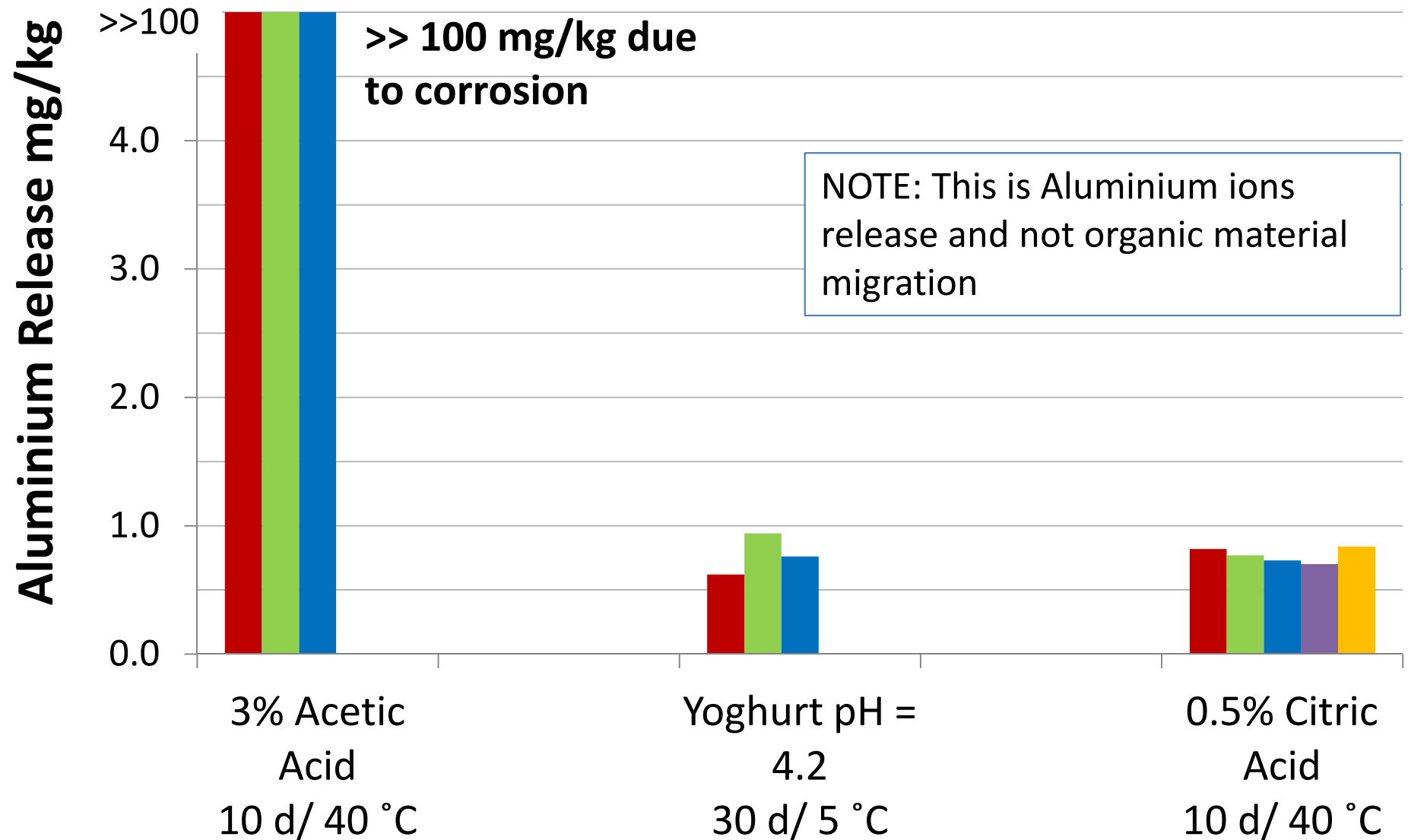
# 3% Acetic Acid - 2

- Two quite distinct processes are happening during the test
  - True **Migration** – a physical transfer of substances from the **organic** lacquer into the food simulant
  - **Corrosion** – a chemical reaction between acetic acid and the aluminium foil/substrate causing the formation of aluminium acetate and the release of aluminium ions into the food simulant

Schematic Illustration



# Acetic Acid – 3: Al<sup>+++</sup> Release from Lacquered Aluminium Foil (Courtesy FPE)



## 3% Acetic Acid – 4

- High test results can be obtained, because when the simulant is evaporated to dryness and the residue weighed, the residue is largely aluminium acetate salts
- This increases the weight of the residue, for example:
  - Aluminium molecular weight = 27
  - Aluminium triacetate molecular weight = 204
- Hence up to 87% of the measured result is due to the simulant, not to the aluminium (ions) released.

## 3% Acetic Acid – 5

- For FPE the overall migration from coated aluminium foil is a major issue.
- Coatings for rigid metal packaging also have a major issue with 3% acetic acid being used for overall migration.
- The use of citric acid has been proposed, but this has the drawback that in practice, for the organic migrants, it is not volatile enough for a gravimetric determination of overall migration by evaporation.

## 3% Acetic Acid – 6

- For can coatings based upon 4 different chemistries – epoxy, acrylic, polyester, organosol – and applied to tin plate substrate the comparing chloroform soluble part to the results using silver foil, showed that this approach was inappropriate.
- Using stainless steel panels gave rise to insurmountable practical problems.
- The same exercise is being repeated for coated (same 4 coating types) aluminium substrate.

## 3% Acetic Acid – 7

- The conclusion for can coatings, subject to confirmation from aluminium coated panels is that the use of 3% acetic acid is inappropriate for overall migration as found by CEN TC 194 many years ago.
- This does not mean that it cannot be used for specific migration.
- As overall migration is a measure of inertness and not safety, the light metal packaging chain recommend that 3% acetic acid is not used for overall migration.
- Other simulants give a measure of inertness and are generally used for compliance testing

# Issues with Olive Oil and Silicone Elastomers



# Silicone Elastomers - 1

- Silicones are exempted from (EU) N° 10/2011 given that elastomers have different physico-chemical properties compared to plastics
- Problems for silicone elastomers arise mainly with compliance testing for baking moulds

## Silicone Elastomers - 2

- Olive / vegetable oils contain components which can penetrate into the silicone elastomer matrix, which results in an overestimation of migration compared to real food. The same applies to substitutes iso-octane and 95% ethanol.
- Absorbed oil must be removed by soxhlet extraction with a non-polar solvent, which may in turn cause additional extraction of components from the silicone, thereby skewing the results further from reality.

# Silicone Elastomers - 3

- A proposed solution is to use Tenax which does not penetrate the silicone elastomer matrix.
- Tenax was an accepted substitute under Directive 97/48/EC but its use as a substitute under 10/2011, lacks clarity (according to CES).
- Tenax also overestimates migration compared to normal bake ware (e.g. muffins, marble cake) but if the reduction factor of 5 is applied, the results are comparable to standard bake ware.

# Silicone Elastomers - 4

- The most important criteria to determine suitability of silicone moulds for food contact is the limit for volatile substances (0.5%) as mandatory according to Recommendation XV of the BfR and the French legislation.
- In appropriately post-cured materials meeting the limit for volatiles  $<0.5\%$  the majority of migrants consist of cyclic siloxanes with  $M_w > 1000\text{Da}$  which according to present knowledge, are not expected to endanger human health.

# Issues of paper and board with aqueous simulants

# Paper & Board (P & B) - 1

- As a general rule P & B is only used for dry or frozen foodstuffs.
- P & B consists of cellulosic fibres which are moisture sensitive and porous.
- For contact with 'wet' foodstuffs at least one additional layer is between the P & B and the foodstuff – e.g. polythene laminate (milk carton).
- Also like liquid foods, P & B liquid simulants (10/2011 types) will be absorbed and not even recovered in some cases or the surface may be damaged or physically disintegrate in others, due to the porous nature of P&B.

## Paper & Board -2

- Papers for fatty food may be treated with fluorinated chemicals and testing in ethanolic simulants would result in total extraction.
- This is because the chemicals are applied from an alcoholic solution.
- Other simulants for fatty foodstuffs need to be used.

# Issues with 50% Ethanol



# 50% Ethanol - 1

- Some polyester based coatings show delamination and swell when tested under severe time/temperature conditions (e.g. 2 h 130 °C) with simulant D1 (50 % ethanol).
- The same polymeric coatings do not show any physical changes when they are in contact with milk products under equivalent sterilisation conditions.
- Overall migration tests and most specific migration tests cannot be carried out in milk products instead of simulants.

## 50% Ethanol - 2

- Proposal: Compliance of coatings which are not resistant to 50 % ethanol can be demonstrated by
  - decreasing testing time and/or temperature to a level where no physical changes of the coating film occur
- or
  - migration testing with simulant A (10 % ethanol) and D2 (vegetable oil) rather than 50 % ethanol

# Dissemination

- Presentations have been made to:
  - DGSante
  - Member States
  - National Reference Laboratories & JRC
  - Cefic-FCA
  - FPF Workshop which included NGOs and academics
  - Industry PIRA
  - FIP Network (today)
- The objective is to make people aware of this initiative ahead of the migration guidelines for plastics being published

# Migration Guidelines for 10/2011 - 1

- Industry requested that the guidelines contain a clear statement to the effect that they only apply for harmonised (plastic) FCMs and are not necessarily appropriate for non-harmonised (non-plastic) FCMs.
- This is because in the absence of unequivocal statements, packers & fillers, control labs, test houses and many in the supply chain want compliance with 10/2011 in order to safeguard themselves.

# Migration Guidelines for 10/2011 - 2

- In the guidelines released for consultation, many sectors of industry felt that whilst there is a statement to this effect it is still unclear to many outside of the regulatory community.
- The non-plastic FCM sectors would like to see a statement along the following lines: 'These technical guidelines are written in the framework of the scope of Regulation (EU) No 10/2011 (Article 2) **and are only applicable for plastic materials and articles under this scope.**'

# Migration Guidelines for 10/2011 - 3

- We need something in place by the time the 10/2011 guidelines are published to minimise any mis-use of the 10/2011 guidelines.
- Some associations have put their draft guidelines on their web-sites.
- This allows them to be easily updated etc.
- The guidelines for non-plastic FCMs will be shared with the commission ( DG Sante and JRC ).
- Discussions are also anticipated with the experts of the Member States and some members of the Council of Europe.

# Acknowledgements

- Thank you for your attention
- All members of this task force for their inputs.
- In particular, for this presentation, Christa Burger, Michelle Callow, John Dixon, Beate Ganster, Ulrich Nehring, Catherine Simoneau, Richard Whitaker.

THANK YOU FOR YOUR ATTENTION