



## Demonstrating Compliance with the Food Contact Legislation and Responsibilities throughout the Supply Chain

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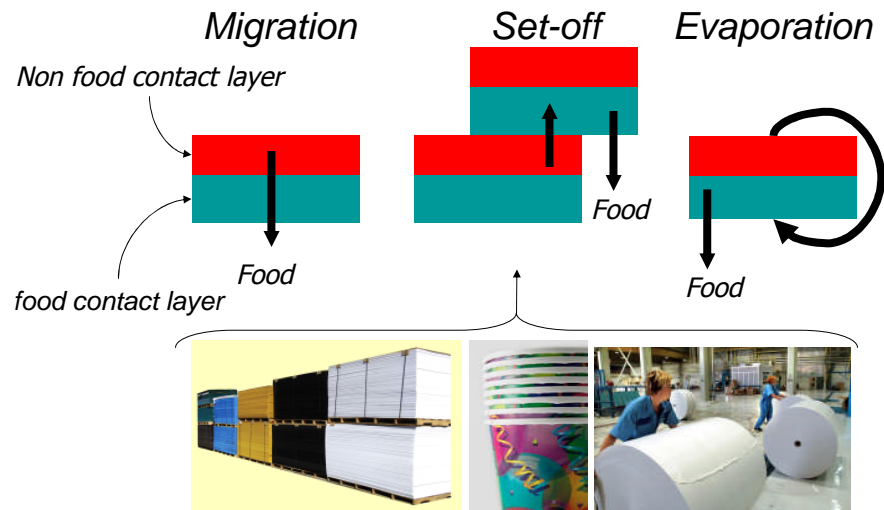
## Agenda

- Introduction
- Demonstrating compliance
- Demonstrating compliance of items without a specific legislation
- Who needs to do what?
- Incoming and outgoing certificates
- Summary



## How Can Components Migrate?

Components may migrate in different ways to the food:



## Why do we perform migration tests?

It is always important to keep in mind the purpose of the migration test:

- Demonstration of conformity or petitioning
- EU or FDA

In this presentation the focus is on EU conformity testing

## Demonstrating compliance

## Route for Lawful Marketing

- How is my material/application defined in the European legislation?
- If a EU measure is not available, is a legislation present at member state level?
- Do I comply with these member state legislations?
- If not can I use other legal vehicles to market lawfully (mutual recognition)?

## What should be demonstrated?

- That the material is safe according Framework Regulation (EC) 1935/2004 (especially article 3)
- That the material is produced under GMP
- That components are present on positive lists if existing
- That the relevant restrictions are met

## Restrictions

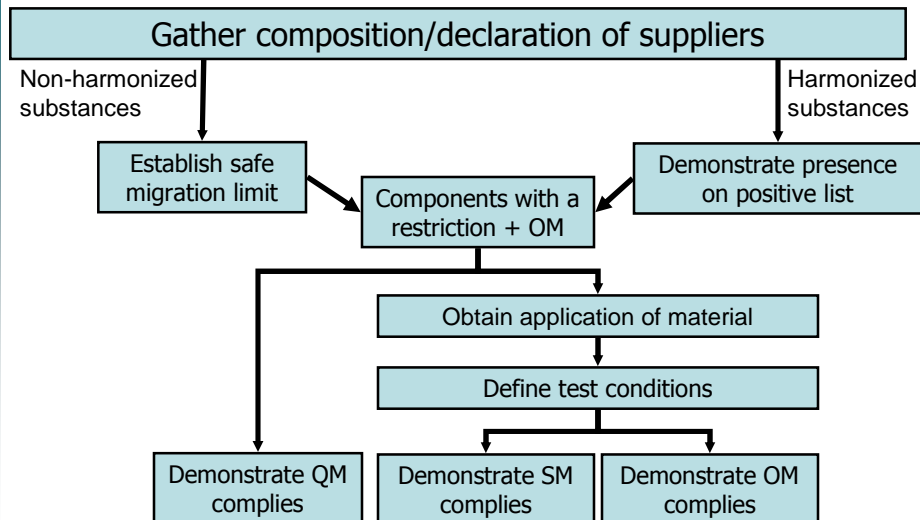
- Restrictions mentioned in plastics directive
  - Ingredients
    - Purity requirements
  - Application
    - e.g. only for certain food types
  - Final article
    - overall migration (OM)
  - Amount of single/group components
    - specific migration (SM or SM(A))
    - residual amount (QM or QM(A))

## Restrictions compared

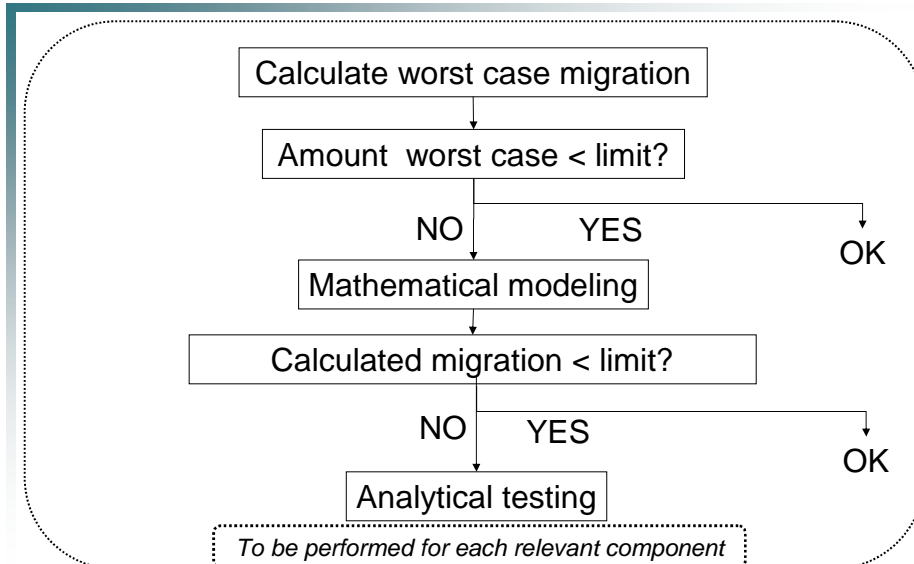
Overall migration	Specific migration	Residual content
Depends on t & T	Depends on t & T	Independent of t & T
Depends on food type	Depends on food type	Independent of food type
Actual sum of migration of all components is determined	Actual migration of 1 (group) component(s) is determined	Actual amount of 1 (group) component(s) in polymer is determined

T = temperature, t = time

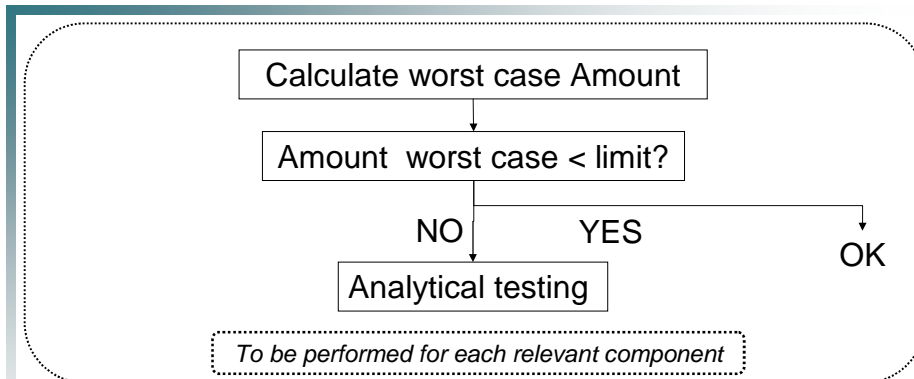
## Approach of Demonstrating Compliance



## Demonstration of SML Compliance



## Demonstration of QM Compliance



## Demonstration of OM Compliance

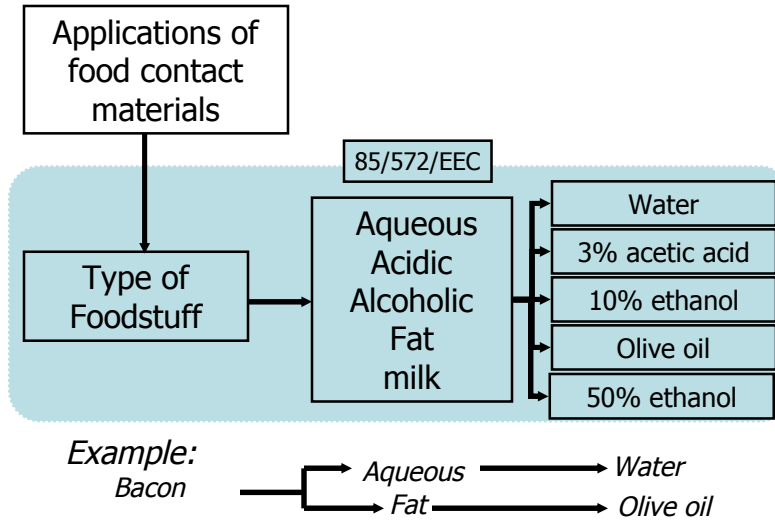
Analytical testing

*To be performed for each simulant*

## Alternatives for analytical testing

- Worst-case calculation (assuming 100% of the material present migrate to the food):
  - Concentration must be known
  - The layer of 0.025 cm in contact with food taken in consideration
- Mathematic modeling:
  - Concentration must be known
  - Component must be homogeneous distributed in the plastic (layer)
  - Not applicable for inorganic components
  - Diffusion parameters of the polymers must be known

## Selection of Test Simulants



## Selection of Test Time & Temperature

82/711/EEC and amendments		Contact temp	Test temp
Contact time	Test time	<5°C	5°C
< 5min	Actual use	5°C-20°C	20°C
5min-0.5h	0.5h	20°C-40°C	40°C
0.5h-1h	1h	40°C-70°C	70°C
1h-2h	2h	70°C-100°C	100°C
2h-4h	4h	100°C-121°C	121°C
4h-24h	24h	121°C-130°C	130°C
>24h	10d	130°C-150°C	150°C
		>150°C	175°C

*Example: Storage for 3 months at room temperature:  
Test conditions: 10 days at 40°C*

## Simulation of Food Contact

Bring the food contact article in contact with simulant using:

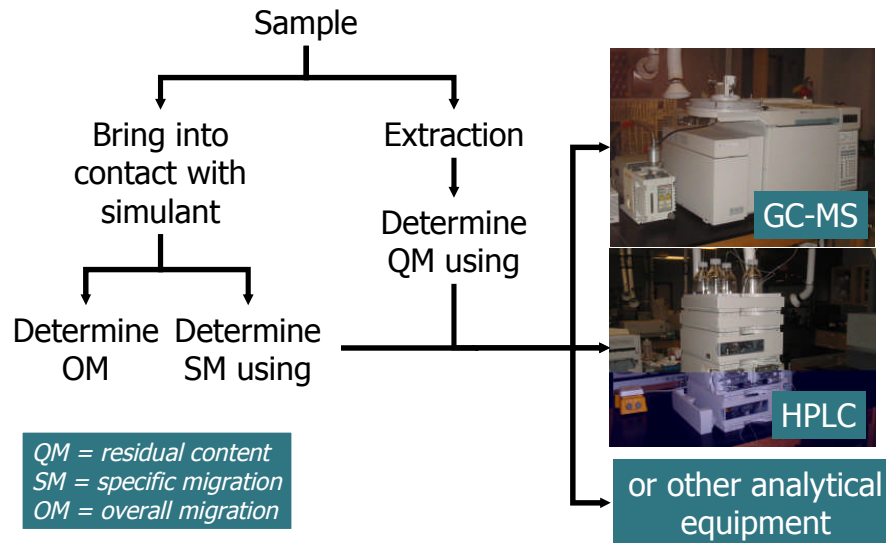
- Filling of article
- Immersion
- Pouch
- Reversed pouch
- Migration cell

## Migration Cell

Important for multilayers: single side contact



## Determination of OM, SM & QM



## Demonstrating compliance of items without a specific legislation

## What Components are involved?

- Components that are used in the manufacturing process but are excluded in the legislation (e.g. solvents)
- Components that are used in materials without a specific measure (e.g. printing inks)
- Not Intentionally Added Substances (NIAS) present in the finished product (e.g. reaction products, impurities)

## How to Determine Them?

Two analytical approaches:

- Target analysis (searching for known components) + toxicological evaluation
- Non-target analysis (searching for everything) + toxicological evaluation

Remember: it is the dose that makes the poison

## How Much is Too Much?

- Depends on toxicity
- Depends on toxicity information available
- Depends on level found in the migration
- Depends on consumption of the food in the packaging

## Solution

- Use a tiered approach: the more favorable toxicological information is available the higher the exposure can be
- Different approaches are published:
  - Cheeseman et al.
  - Kroes et al.
  - Sue Barlow et al.
  - ILSI

## Who needs to do what?

## Distinguish:

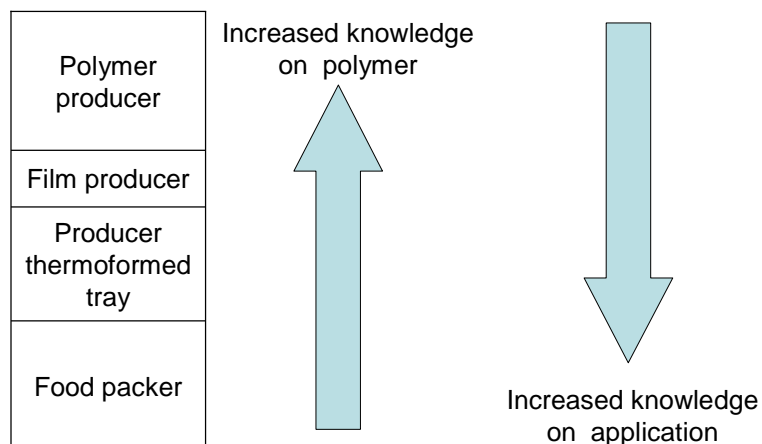
- Legislative requirements  
What needs to be done!
- Customer requirements, service, marketing  
What does your customer want (to see)?

## Bad Components List

Assurance requests often go well beyond food-contact and are not always related to the composition of the material

- Heavy Metals
- BSE
- PFOA
- Kosher, Halal
- Phthalates
- GMOs
- ITX
- Latex
- BPA
- Endocrine Disruptor
- Organotins
- Melamine
- And much more.....

## Distribution of Information



## Sharing Information

Polymer producer	<ul style="list-style-type: none"> <li>•State that composition complies</li> <li>•Specify which specific migration determinations have to be made in finished product (FP)</li> <li>•Test residual content</li> </ul>
Film producer	<ul style="list-style-type: none"> <li>•State that composition complies</li> <li>•Specify which specific migration determinations have to be made in FP</li> </ul>
Producer of thermoformed tray	<ul style="list-style-type: none"> <li>•State that composition complies</li> <li>•Test specific migration</li> <li>•Test overall migration</li> </ul> <p><b>The final article must be statement that final material complies for which intended purposes!</b></p>
Food packer	<ul style="list-style-type: none"> <li>•Make sure that food packaging can be used for the purpose (contact time, contact temperature and food types)</li> </ul>

Information & documentation



## Sharing Information

- Suppliers in the beginning of the chain want to provide as little information as possible
- Users at the end of the chain wants to have as much information as possible
- Information can be delivered under confidentiality agreements, different approaches possible
- Documentation is important and will become more important over the years
- Declaration of compliance must be submitted for some materials

## Directive 2002/72/EC Art. 9

- “ 1. At the marketing stages other than the retail stage, plastic materials and articles as well as the substances intended for the manufacturing of those materials and articles, shall be accompanied by a written declaration
  
2. The declaration referred to in paragraph 1 shall be issued by the business operator and shall contain specified information”

## Declaration of Compliance

- Identity and address of business operator
- Identity of the materials/articles
- Date of declaration
- Confirmation compliance with (EC) no. 1935/2004
- Adequate information regarding migration restriction/specifications of substances
- Adequate information regarding substances with food additive restrictions
- Specification regarding use of material (types of food, temperature, time, min food/area ratio)
- Conformity of barrier with requirements (if used)
- Presence of recycled plastic (registration number)

## Directive 2002/72/EC Art. 9

"3. Appropriate documentation to demonstrate that the materials and articles as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Directive shall be made available by the business operator to the national competent authorities on request. That documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance."

## Different Approaches

Information on compliance with limitations – your choice:

- Do testing yourself to assure your customers that limitations will be met
- Do testing yourself and suggest that the limitations will be met, but state that it is the customer's responsibility to comply
- Make your customers aware of any applicable limitations, but do no testing and make no statements of migration compliance (not for FP)

## Voluntary Submission of DoC

Even in cases where a DoC is not legally required, suppliers often must provide their customers assurance as to the regulatory status and safety of their material

Largely a customer assurance statement should contain the same information as a DoC

## Incoming Certificates

- Request Certificate of Compliance from all (raw) material suppliers
  - Carefully review to ensure completeness
  - Is the certificate adequate?
  - Was the certificate authorized?
    - (Watch out for: "Tell me what you need and I'll sign it.")
  - Is testing required to ensure compliance?
  - Controlled at central office or at local plants?

## Incoming Certificates

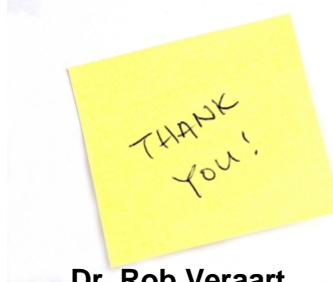
- Does certificate apply to use or can it be extended to cover intended use(s)?
  - Statement that material complies with Directive 2002/72/EC may be sufficient even if not used in entirely plastic article
- Compliance with single Member State adequate?
  - Mutual recognition?
  - How are limits communicated to your customers?

## Submitting Documentation

- Be specific, describe detailedly:
  - identity of the material (name of product, from which plant)
  - Use restrictions (time/temperature/food types, use-level etc)
  - What the responsibility of the purchaser
- Be sure that the statement is supported by supporting documentation
- Keep track of documents issued
- Limit and specify the people who can change and sign documents

## Summary of Evaluation

- How is the material/application considered in the legislation?
- Is the application covered by EU measures?
- Is the substance covered by EU measures?
- If no (implemented) EU measures apply, does National legislation exist?
- If restrictions apply, must they be determined analytically? Who has to confirm this?
- Which requirements can be covered by documents from suppliers?
- What information should I put in the declaration of conformity?
- Do I have supporting documentation?
- Documents issued also results in legal liability



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