Adhesives for Food Packaging
GMP and MIGRESIVES

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Pack4Food
Gent, 17. April 2012
GMP
Good Manufacturing Praxis


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
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Article 3

General requirements

1. 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.
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Article 5

Specific measures for groups of materials and articles
1. For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended in accordance with the procedure referred to in Article 23(2).
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ANNEX I
List of groups of materials and articles which may be covered by specific measures

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood
COUNCIL DIRECTIVE

OF 23 NOVEMBER 1976

ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS

( 76/893/EEC )
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ARTICLE 2

MATERIALS AND ARTICLES MUST BE MANUFACTURED IN COMPLIANCE WITH GOOD MANUFACTURING PRACTICE, SO THAT, UNDER THEIR NORMAL OR FORESEEABLE CONDITIONS OF USE, THEY DO NOT TRANSFER THEIR CONSTITUENTS TO FOODSTUFFS IN QUANTITIES WHICH COULD:

ENDANGER HUMAN HEALTH,

BRING ABOUT AN UNACCEPTABLE CHANGE IN THE COMPOSITION OF THE FOODSTUFFS OR A DETERIORATION IN THE ORGANOLEPTIC CHARACTERISTICS THEREOF.
COMMISSION REGULATION (EC) No 2023/2006

of 22 December 2006
on good manufacturing practice for materials and articles intended to come into contact with food
(Text with EEA relevance)
Subject matter

This Regulation lays down the rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food (hereafter referred to as materials and articles) listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles.
Article 2
Scope
This Regulation shall apply to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.
Article 3
Definitions
For the purpose of this Regulation, the following definitions shall apply:
(a) ‘good manufacturing practice (GMP)’ means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof;
Article 3
Definitions
For the purpose of this Regulation, the following definitions shall apply:
(c) ‘quality control system’ means the systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system;
**Article 5**

**Quality assurance system**

1. The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system. That system shall:
   
   (a) take account of the adequacy of personnel, their knowledge and skills, and the organisation of the premises and equipment such as is necessary to ensure that finished materials and articles comply with the rules applicable to them; .................

2. Starting materials shall be selected and comply with pre-established specifications that shall ensure compliance of the material or article with the rules applicable to it.

3. The different operations shall be carried out in accordance with pre-established instructions and procedures.
Food Packaging
Interaction of food packaging material

Food Safe Packaging
Food Packaging
Interaction of food packaging material

Ideal packages:

100% protection against the environment

No interaction with the food (inert)
Food Packaging
Interaction of food packaging material

What is safe?
When there is no risk from contaminants out of the packaging
What is risk?

Hazard x Exposure

Toxic profile (e.g. SML Values)  Migration
Risk = Hazard x Exposure
Food Packaging
Interaction of food packaging material

Migration

Migration: \( f = (\text{quantity, molecular size, temperature, time, partitioning, volume/surface ration,..}) \)
Food Packaging
Interaction of food packaging material

Permeation (through the packaging material)

Migration (out of the packaging material)
Food Packaging
Interaction of food packaging material

Molecular diffusion, often called simply diffusion, is the thermal motion (random walk of molecules) of all (liquid or gas) particles at temperatures above absolute zero (Brownian Movement). Driving force is a difference in the chemical potential between two adjacent media. The rate of this movement is a function of temperature, viscosity of the fluid and the size (mass, structure, polarity) of the particles. Diffusion explains the net flux of molecules from a region of higher concentration to one of lower concentration, but it is important to note that diffusion also occurs when there is no concentration gradient. The result of diffusion is a gradual mixing of material. In a phase with uniform temperature, absent external net forces acting on the particles, the diffusion process will eventually result in complete mixing.
Food Packaging
Interaction of food packaging material

• Mathematical laws can describe the diffusion phenomenon

• FICK’s LOW

\[ F = -D \frac{\partial C}{\partial x} \quad \iff \quad \frac{\partial C}{\partial t} = D \frac{\partial^2 C}{\partial x^2} \]

• These equations give the evolution in time \( t \) of the local concentration \( C \) of a molecule in a one dimension \( x \) diffusion system.
• Several parameters (linked to the geometry of the system and to the molecules involved) determine the results.
Food Packaging
Interaction of food packaging material

Migration is the movement of one atom or one molecule from one position to another, from one material into another material.

How much migration?

How fast is the migration?
Food Packaging
Interaction of food packaging material

\[ D_P = D_0 \times e^{\frac{-E_A}{RT}} \]

- \( D \) – Diffusion coefficient [cm²/s]
- \( D_0 \) – Pre-exponential factor
- \( E_A \) – Activation energy [J]
- \( R \) – Gas constant [8,314 J/molK]
- \( T \) – Temperature [K]

Speed of Migration?
Food Packaging
Interaction of food packaging material

Barrier properties
D = 0
Food Packaging
Interaction of food packaging material

\[ K_{P,F} = \frac{C_{P,\infty}}{C_{F,\infty}} \]

- **K** – Partition coefficient
- **c** – Concentration
- **P** – Packaging material
- **F** – Foodstuff

**Quantity of Migration?**
Food Packaging
Interaction of food packaging material

In chemistry a partition coefficient (K) is the ratio of concentrations of a compound (a chemical substance) in the two phases of a mixture of two immiscible solvents at equilibrium.

Hence these coefficients are a measure of differential solubility of the compound between these two solvents.
Food Packaging
Interaction of food packaging material

How to control the transfer of constituents from a food contact material into food?
Food Packaging
Interaction of food packaging material

2 ways of control

MIGRATION TEST

PREDICTION MODELS
Transfer of Constituents to Food

Control of Transfer

Objective of the test:

Measurement of the quantity of substances, that migrates from the food contact article into the food.
Transfer of Constituents to Food
Control of Transfer
Transfer of Constituents to Food
Control of Transfer
Transfer of Constituents to Food
Control of Transfer

Migration of HotMelt Component 1a from a Laminate into EOH95 @ 20 °C
Transfer of Constituents to Food
Control of Transfer

PREDICTION MODELS
Transfer of Constituents to Food
Control of Transfer

General case for adhesives in food packaging

• Multi actors process
  • Needed knowledge for simulations are frequently scattered in packaging industry (raw material supplier, producer, converter, filler, …).
  • **Communication between actors is then absolutely necessary.**

• Specific utilization
  • Final migration level in food depends on specific utilization of adhesive or packaging during the whole life of the product.
    • Packaging assembly process (temperature, time, percentage area covered by adhesive, …) and used materials (barrier layer, …)
    • Storage time and temperature of laminate before packaging
    • Filling conditions (packaging geometry, filling volume, nature of food, temperature, …)
    • Final condition of use (temperature,…)
Transfer of Constituents to Food
Control of Transfer

General case for adhesives in food packaging

- Multi-layers system
  - For most of adhesive applications in food contact material, diffusion modeling can be made on a 3 layers system:

  ![Diagram](image)

  - In this kind of system, a lot of parameter values are needed:
    - Geometry and initial state parameters (generally known)
    - Diffusion parameters: $D$ and $KL/P$ for each potential migrant in the 3 layers (L1, Adhesive and L2)
  - The chances to predict all needed values to simulate a real case are weak. Simplified safe scenarios can be developed.
Transfer of Constituents to Food
Control of Transfer

Research programme on migration from adhesives in food packaging materials in support of European legislation and standardisation
EU Project FP 6 Collective Research COLL--CT--2006--030309
[Pre-competitive research in support of small and medium size enterprises]

www.migresives.eu
## Transfer of Constituents to Food
### Control of Transfer

<table>
<thead>
<tr>
<th>Objective</th>
<th>achieved by</th>
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<tbody>
<tr>
<td>➢ To develop a pragmatic, science based concept to allow economic compliance evaluation and to ensure consumer safety related to adhesives used in food contact materials.</td>
<td>➢ Development of a simple approach to allow a mathematical modelling using a way developed and used for plastics  &lt;br&gt; ➢ Analytical migration testing and comparison with results from calculations</td>
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<tr>
<td>➢ To establish European consensus and recognition of the concept</td>
<td>➢ Development and verification of model in joint project with different partners from all over Europe  &lt;br&gt; ➢ Development of freely available software for model calculations (<a href="http://sfpp3.agroparistech.fr">http://sfpp3.agroparistech.fr</a>)  &lt;br&gt; ➢ Presentation of results on international conferences and discussion with European authorities</td>
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Transfer of Constituents to Food
Control of Transfer

**Migration Experiments**

Equilibrium experiments
(determination of partitioning coefficients)

Kinetic migration studies

Concentration profiles
Transfer of Constituents to Food
Control of Transfer

Mathematical Modelling

Solve Fick’s Equation for a Multilayer by e.g. numerical methods

D and K coefficients derived by fitting experimental results

Diffusion coefficients calculated using the Piringer equation
Transfer of Constituents to Food
Control of Transfer

![Diagram showing the transfer of constituents from packaging to food](Image)

- Concentration: C (mg/Kg)
- Diffusion: D
- Multi-Layer Packaging
- Migrant
- Food
- Migration
- Migration coefficient: $K_{PP}$
- Migration coefficient: $K_{PF}$
- Concentration at the food: $C_f$ (mg/Kg)
- Distance: X (mm)
Transfer of Constituents to Food
Control of Transfer

Simulation tools

• Different software
  • SFPP3 (Migresives)
  • MIGRATEST© (Fabes)
  • SML Software (AKTS)
• …
Transfer of Constituents to Food
Control of Transfer

Adhesive producer
- Buys raw materials
- Makes formulation
- Prepare adhesive

Converter, Packaging producer
- Chooses box design and material
- Makes the boxes
- Use adhesive

Packer
- Fills the boxes

Distributor, Consumer

Adhesive

Empty packaging

Full packaging

Choices of determinant factors for migration phenomenon
Migration process

Choices of determinant factors
for migration phenomenon
Transfer of Constituents to Food
Control of Transfer

MIGRESIVES
RTD experimental results

DATABASE
K and D values

OTHER DIFFUSION WORKS
Scientific Publications

Needed values
exist

Needed values
can be estimated
(safe overestimation)

DIFFUSION MODELING
POSSIBLE

No knowledge
for needed values

NO DIFFUSION
MODELING POSSIBLE
Transfer of Constituents to Food
Control of Transfer

D values ?

• Literature (similar cases)
• Overestimated values
  • Piringer’s approach
• Experimental measurements
Transfer of Constituents to Food
Control of Transfer

K values?

• Very few results published about K
• Large overestimation generally used
Transfer of Constituents to Food
Control of Transfer

- Mathematical modelling is applicable to multilayer with adhesives and plastics, paper and board layers.
  - State of the art for plastic layers
  - New for adhesive layers and paper & board layers

- Partial adhesives application in geometrical structures like folding boxes, seams in pouches can be considered.

- Various application scenarios can be calculated within short term

- Mathematical modelling is a cost saving way to estimate migration from packaging and especially from adhesives.
  - For the adhesive producer, to explore conformity related to various applications e.g. during product development
  - Conformity evaluation of existing products (supporting documents)
  - For the packaging producer/converter and food industry to calculate migration and evaluate conformity for the given application.
GMP and MIGRESIVES
Adhesives for Food Packaging

... any questions?