Ensuring the Safety of Adhesives for Food Packaging

Dr Monika Tönnießen, Henkel AG & Co. KGaA

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I Regulatory Background

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I  Regulatory Background
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Regulatory Background

In Europe there is no specific legislation for adhesives for food packaging but there are Regulations valid for all food contact materials:

Regulatory Background

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:

- endanger human health
- bring about an unacceptable change in the composition of the food
- bring about a deterioration in the organoleptic characteristics thereof
Regulatory Background

Brussels, 1 March 2015

Regulatory Background

How can adhesive manufacturers fulfil the legal requirements for food contact applications?
Regulatory Background
Regulatory Tools for Risk Assessment

European Level

- Harmonised legislations for specific food contact materials, e.g. Plastics Regulation (EU) No 10/2011
- Substance-specific legislations for the restriction or prohibition of specific substances, e.g. (EC) No 1895/2005 (BADGE, BFDGE and NOGE, valid for plastics, coatings & adhesives)
- European Food Safety Authority (EFSA) Opinions
- Resolutions of the Council of Europe, e.g. Resolution AP (92) 2 on Aids to Polymerization
Regulatory Background

Regulatory Tools for Risk Assessment

National Level

- Germany: Consumer Goods Ordinance (Bedarfsgegenständeverordnung)
- The Netherlands: Warenwet
- Italy: Decreto Ministeriale of March 21 1973 as amended
- Spain: Royal Decree 847/2011 on polymeric materials
- Germany: BfR Recommendations, e.g. XIV. Recommendation on plasticiser-free dispersions or XXVIII. Recommendation on cross-linked polyurethanes as adhesive layers for food
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Requirements for Adhesives in Food Contact
Evaluation Steps for Food Contact Adhesives

1. Raw material data gathering

2. Raw material evaluation

3. Adhesive-related evaluation
Requirements for Adhesives in Food Contact

Raw Material Data Gathering

- Choice of raw material
- Request information from supplier
  - Information sufficient
    - Yes
    - No
      - Perform analytical screening
        - Rejection
          - Additional information
            - Not possible or issue found
          - Information sufficient
            - Yes
            - No
Requirements for Adhesives in Food Contact
Raw Material Evaluation

Complies with FEICA rejection list

Covered by applicable food contact legislation

Molecular weight above 1000 Dalton

Passes extended risk assessment

Check for restrictions / specifications

Raw material suitable for adhesives

Yes

No

Yes

No

Yes

No

Yes

No

Rejection

Raw material suitable for adhesives

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Henkel
Requirements for Adhesives in Food Contact
Evaluation of the Adhesive

Definition of adhesive formulation

Concentration of substance(s) with migration potential in the adhesive formulation

Allows compliance in recommended food contact application

Food Contact Status Declaration

Recommended conditions of use
Specific analysis
optional

No

Yes
Requirements for Adhesives in Food Contact

Food Contact Status Declaration

Union Guidance on Regulation (EU) No 10/2011 as regards information in the supply chain:

Recommendation for adequate information for ‘Non-Plastic Intermediate Materials’ (inks, adhesives, coatings)

- Identity and address of the supplier
- Identity of the non-plastic intermediate material
- Date of the document
- Confirmation of relevant requirements of the Framework Regulation (GMP, traceability)
- Information on substances with restrictions
- Information on dual-use substances
- Information to support the risk assessment of the downstream users (suitable types of food, specification of time and temperature, necessity of a functional barrier, own toxicological assessment, migration test results, etc.)
Requirements for Adhesives in Food Contact
Evaluation of the Adhesive by the Downstream User

- Technically suitable adhesive for packaging material (substrate)
- Intended food type and contact conditions

Adhesive safe for intended use

Packaging presents an absolute barrier

List of possible migrating substances (from Food Contact Status Declaration)

Packaging presents a functional barrier

Concentration of migrating substances in adhesive known

Assumption: total migration (worst case approach)

Amount of adhesive (per packaging unit)

Packaging geometry in relation to the food (surface/volume ratio)

Passes migration test

Passes migration modelling

SML of any substance exceeded

Rejection

Adhesive safe for intended use

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Requirements for Adhesives in Food Contact
Evaluation of the Adhesive by the Downstream User (I)

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Requirements for Adhesives in Food Contact
Evaluation of the Adhesive by the Downstream User (II)

1. For example, using INRA (‘Migresives’ project), FABES MIGRATEST, SML Advanced of AKTS AG
2. Internal or external testing, preferably at an accredited laboratory
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FEICA Study on Hotmelts for Food Packaging
Composition of Model Hotmelt Formulations Used for Study

**Resin**
- Fully hydrogenated C9
- Partially hydrogenated C9
- Fully hydrogenated C5
- Fully hydrogenated DCPD
- Partially hydrogenated DCPD

**Polymer**
- EVA
- PE

**Wax**
- Paraffinic (mp: < 70 °C)
- Paraffinic (mp: > 70 °C)
- Synthetic
FEICA Study on Hotmelts for Food Packaging

Extraction Test

- Extraction by direct contact with n-hexane 1 h at 50 °C
- Advantage: rapid method, easy to do
- Disadvantage: dissolving and / or partial decomposition of the hotmelts
- Result: test identifies the total number of hydrocarbons, not the migratable part
  severe overestimation (≈ 10 – 50 times higher than real migration)

⇒ Extraction test not suitable to estimate the real conditions for hotmelts in
  paper and paperboard packaging
FEICA Study on Hotmelts for Food Packaging

Migration Simulation

- Migration simulation with a free hotmelt film 10 days at 40 °C, food simulant: MPPO (Tenax), simulation of dry food contact at room temperature for 12 months

- Vapor phase transition of hydrocarbons

- Advantage: considers different parameters like matrix effect of the formulation, volatility of different compounds, contact area

- Result: compromise between rapid extraction test and long-term storage study slight overestimation of the real conditions (up to factor 2)

⇒ Migration simulation represents a good opportunity to predict real migration from hotmelts to dry foodstuff
FEICA Study on Hotmelts for Food Packaging

Storage Test

- Migration on real food (oat flakes) packed in virgin fiber cardboard under real conditions at room temperature up to 12 months

- Advantages: closest conditions to the real transfer, clear information regarding the contribution of hotmelts to MOH fractions

- Disadvantages: very time-consuming with great effort

⇒ Storage test confirms the suitability of migration simulation as worst-case scenario to estimate the real migration
FEICA Study on Hotmelts for Food Packaging

Outcome of the Study

- Study represents a correlation between extraction, migration simulation and testing on real foodstuff
- Results prove that the migration of hydrocarbons from hotmelts into food is very low
- Results show that certain hotmelt raw materials (resins, waxes) contribute to the MOSH/MOAH fractions even though these materials are not mineral oil sources
- Standard MOSH/MOAH analysis (LC-GC-FID) cannot differentiate between real MOH substances and hydrocarbons from hotmelts
Differentiated analytical techniques allowed to distinguish between hydrocarbons from hotmelts and real mineral oil substances.

Storage tests with real food show slight increase in the MOSH fraction (< 3 mg/kg food) at the end of the test; the MOAH values are at very low level, from below the detection limit of 0.1 mg/kg food up to 0.3 mg/kg after one year of storage.

Study shows slightly different migration values depending on the variation of polymer types, wax types and resins.

⇒ The safety of typical hotmelts for food packaging could be demonstrated by the study.
Summary

- Adhesive manufacturers have to evaluate their products under the scope of the Framework Regulation and the Good Manufacturing Practice Regulation. Further tools for the evaluation are different legislations on EU and national levels.

- The task starts with collecting raw material data, followed by raw material evaluation, and ends with adhesive evaluation.

- Adhesive manufacturers have to summarise the results of their evaluation in a food contact status declaration to support the downstream users to make the risk assessment for the final food contact material.

- An intensive study on the transfer of hydrocarbons from hotmelt adhesives used for cardboard packaging into food could demonstrate the safety of these products.
FEICA Guidance Papers
Overview of General Guidance Papers

• FEICA guidance for a food contact status declaration for adhesives (2014)
  Also available in French, German, Spanish, Italian and Dutch (on demand)

• FEICA guidance for Good Manufacturing Practice - GMP (2015)
  Also available in French, German, Spanish, Italian and Dutch (on demand)

• FEICA guidance on migration testing of adhesives intended for food contact material (2016)
  Also available in French, German, Spanish and Italian

• FEICA guidance related to the food contact status of adhesives and mineral oil hydrocarbons (2017)
  Also available in French, German, Spanish and Dutch (on demand)
FEICA Guidance Papers
Overview of Substance-specific Papers

• Study on oligomeric hydrocarbons from hotmelt adhesives used in cardboard packaging (2021)

• FEICA recommendation to adhesive suppliers and users on the assessment of PAAs in polyurethane adhesives intended to be used in food packaging (2020)

• FEICA risk assessment of cyclic esters in polyester adhesives Press Release (2020)

• FEICA recommendation to substitute GLYMO by the end of 2020 in applications intended for food contact (2019)

• ILSI Europe Report on Adhesives for Food Packaging Materials (2018)
Other interests or questions?
Contact us at info@feica.eu