

# Ensuring the Safety of Adhesives for Food Packaging

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# Agenda

- I Regulatory Background
- II Requirements for Adhesives in Food Contact
- III FEICA Study on Hotmelts for Food Packaging

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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:

- Framework Regulation (EC) No 1935/2004
- Good Manufacturing Practice Regulation (EC) No 2023/2006

# Regulatory Background

Framework Regulation (EC) No 1935/2004

## Article 3

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

Good Manufacturing Practice Regulation (EC) No 2023/2006



# 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)
- Guidance / Guidelines on Regulation (EU) No 10/2011
- 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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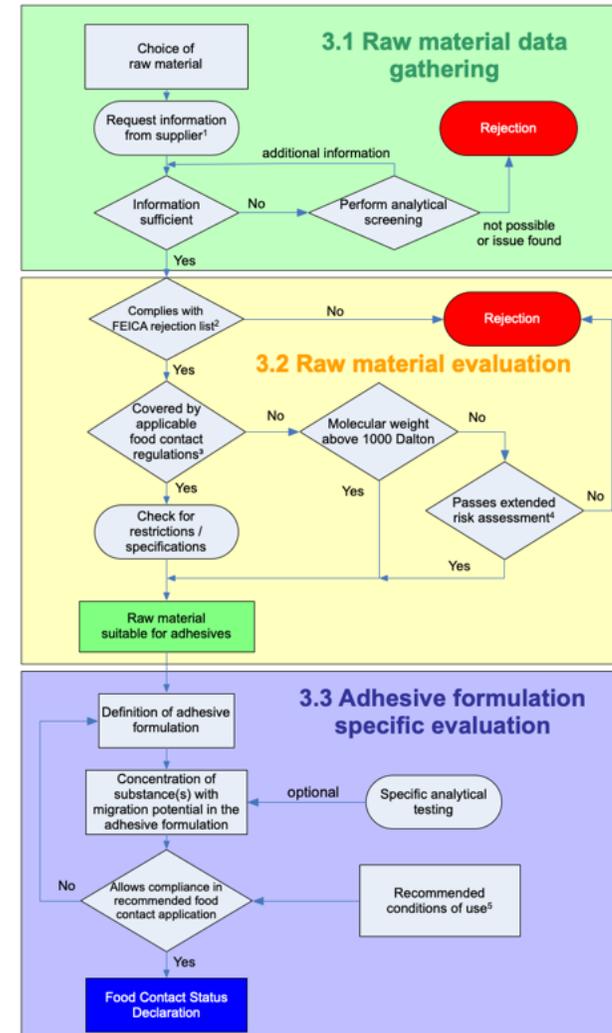
# Requirements for Adhesives in Food Contact

## Evaluation Steps for Food Contact Adhesives

1. Raw material data gathering

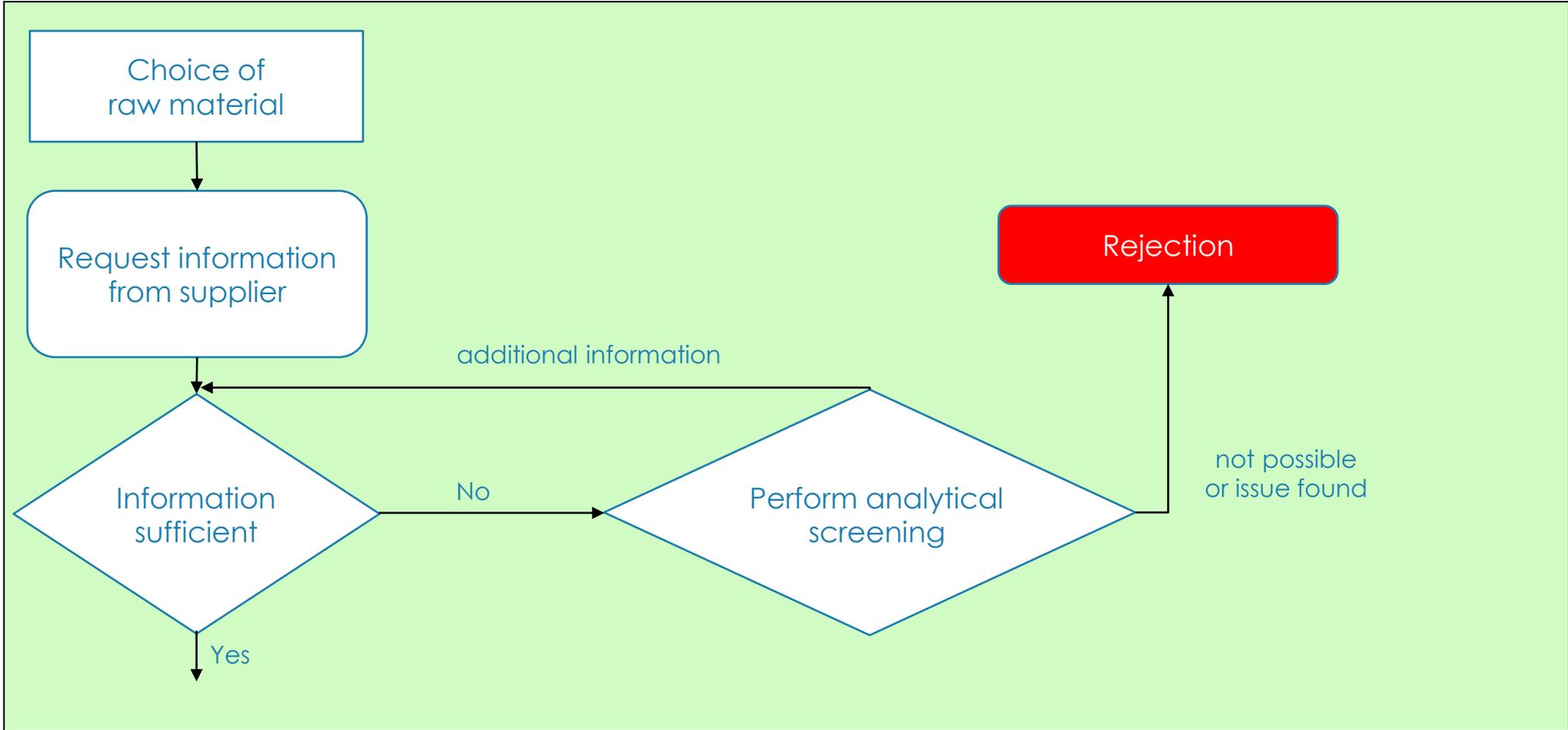
2. Raw material evaluation

3. Adhesive-related evaluation



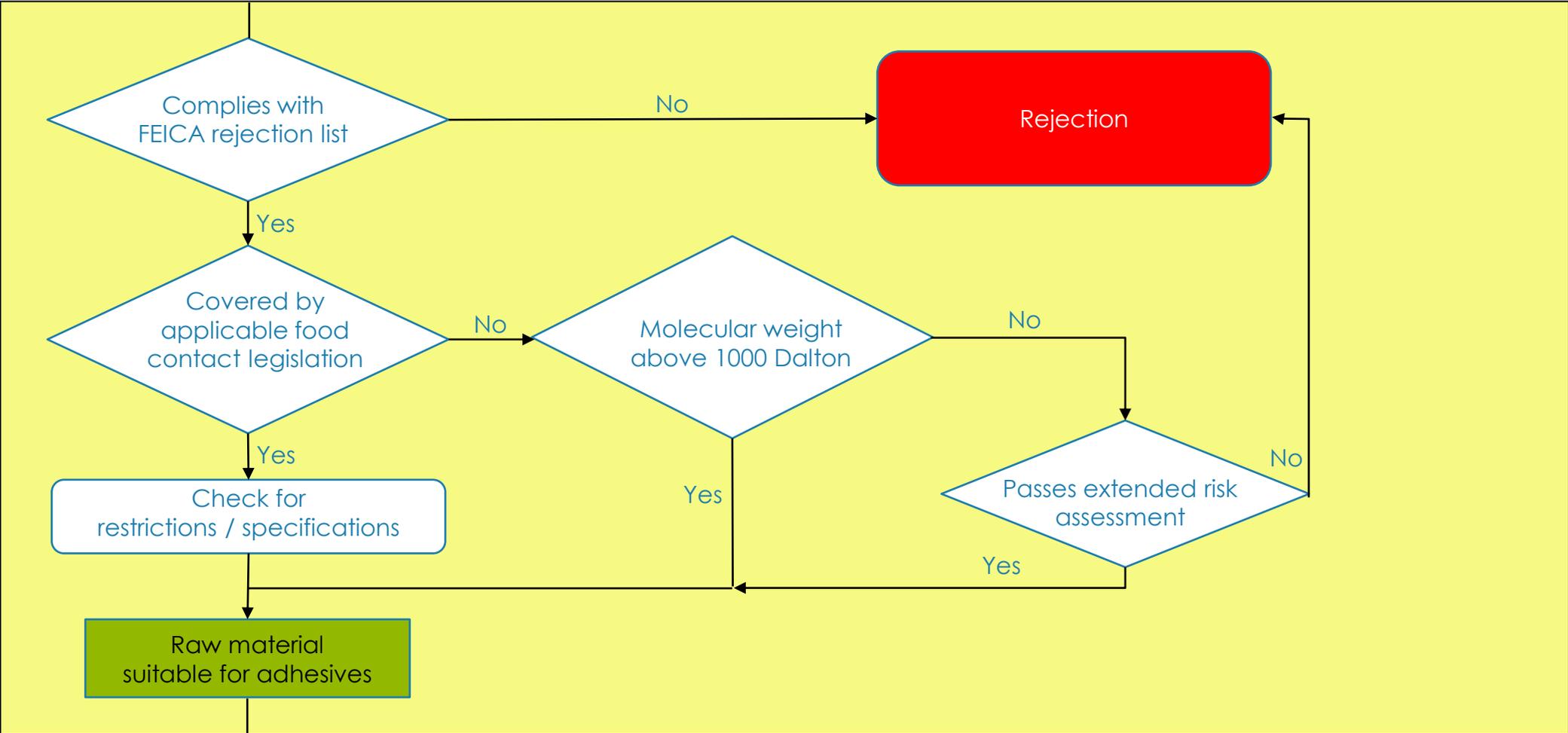
# Requirements for Adhesives in Food Contact

## Raw Material Data Gathering



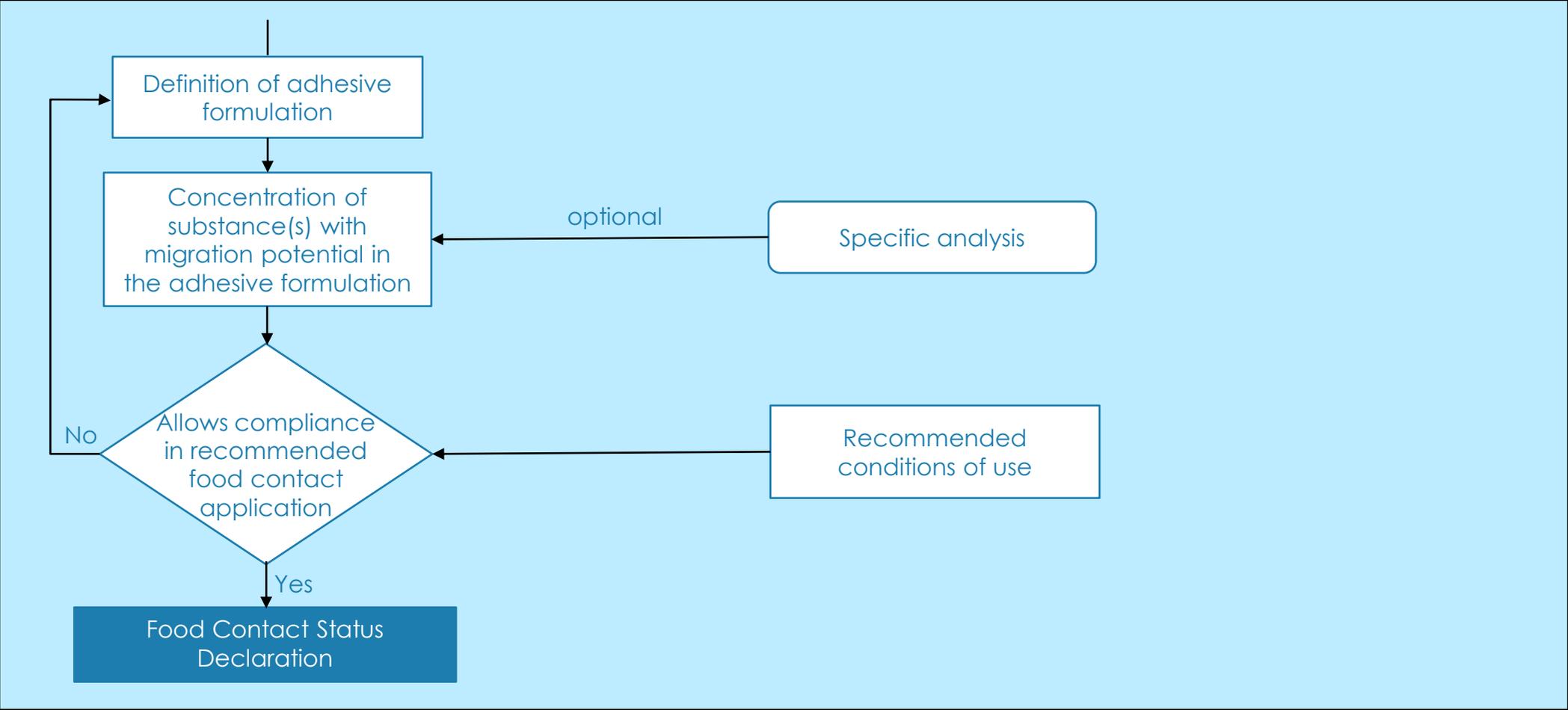
# Requirements for Adhesives in Food Contact

## Raw Material Evaluation



# Requirements for Adhesives in Food Contact

## Evaluation of the Adhesive



# Requirements for Adhesives in Food Contact

## Food Contact Status Declaration

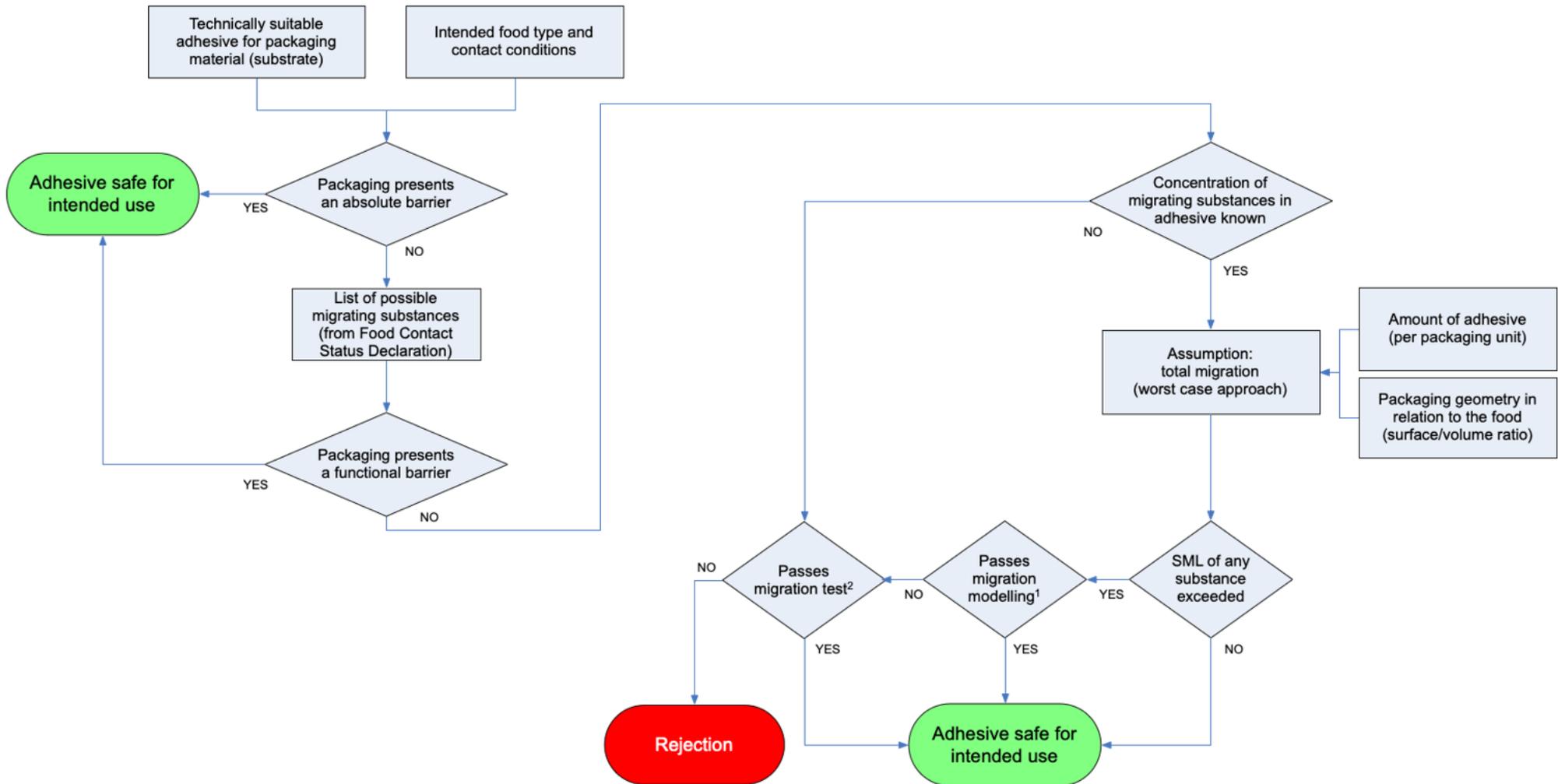
Union Guidance on Regulation (EU) No 10/2011 as regards information in the supply chain:

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.)

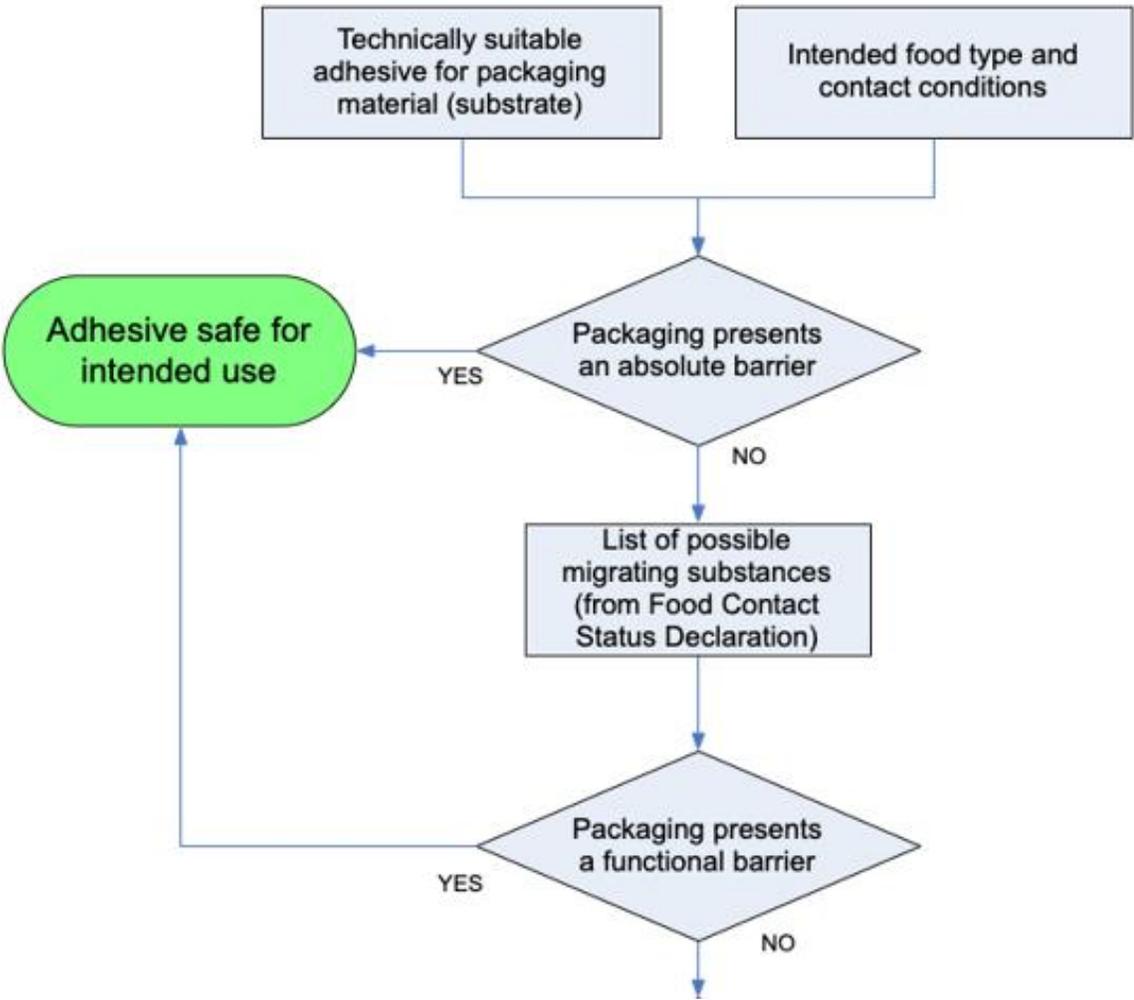
# Requirements for Adhesives in Food Contact

## Evaluation of the Adhesive by the Downstream User



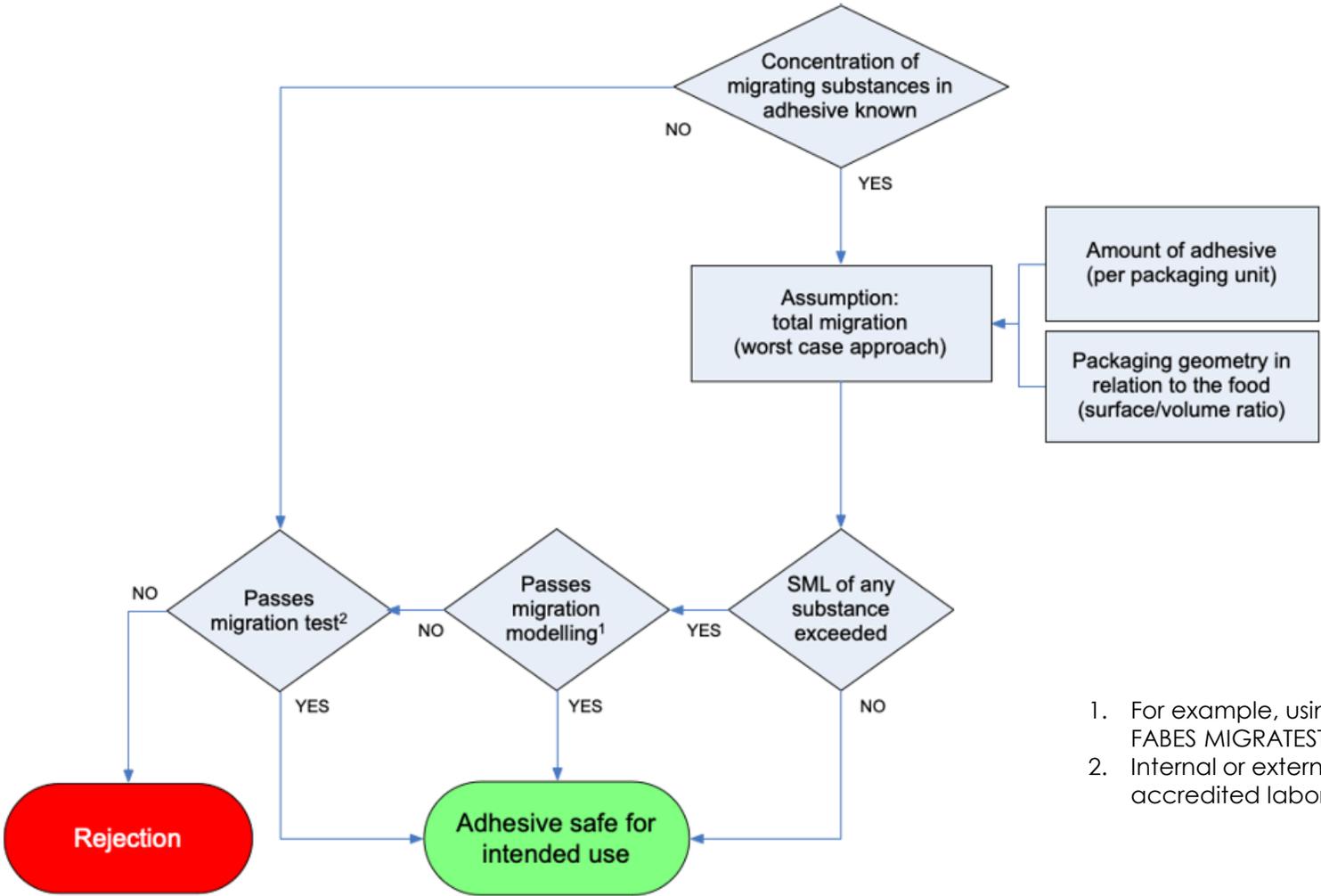
# Requirements for Adhesives in Food Contact

## Evaluation of the Adhesive by the Downstream User (I)



# Requirements for Adhesives in Food Contact

## Evaluation of the Adhesive by the Downstream User (II)



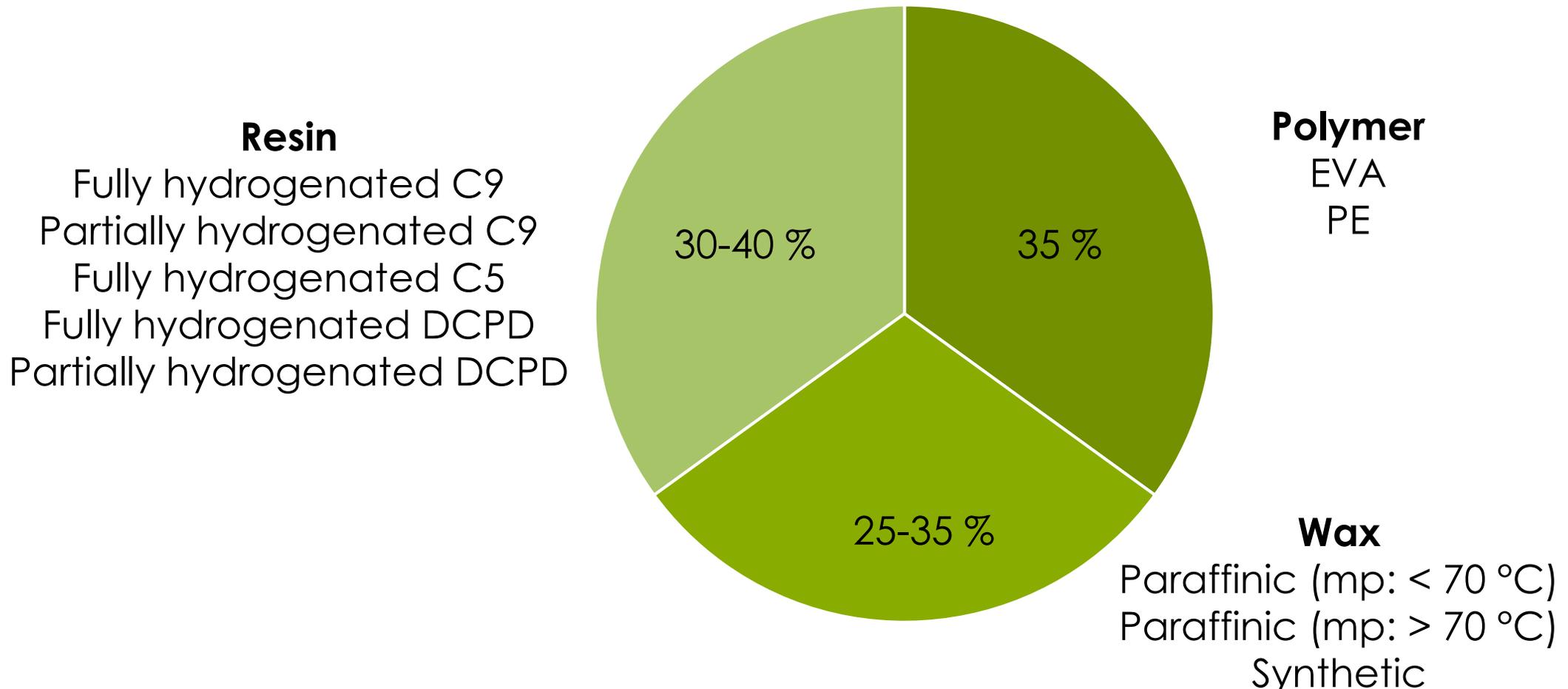
- 1. For example, using INRA ('Migresives' project), FABES MIGRATEST, SML Advanced of AKTS AG
- 2. Internal or external testing, preferably at an accredited laboratory

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# FEICA Study on Hotmelts for Food Packaging

## Composition of Model Hotmelt Formulations Used for Study



# 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 ( $\approx 10 - 50$  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

# FEICA Study on Hotmelts for Food Packaging

## Outcome of the Study

- 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 \(2018\)](#)

# THANK YOU

Other interests or questions ?  
Contact us at [info@feica.eu](mailto:info@feica.eu)

