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Guidance for a food contact status declaration for adhesives

FEICA, the Association of the European Adhesive & Sealant Industry is a multinational association representing the European Adhesive and Sealant Industry. With the support of its national associations and several direct and affiliated company members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard FEICA aims at establishing a constructive dialogue with legislators in order to act as a reliable partner to resolve issues affecting the European Adhesive and Sealant Industry.

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1. Introduction / Objectives

This guideline has been provided by FEICA, Paper & Packaging Working Group. It is primarily aimed at FEICA members and the members of its national association members who are manufacturing adhesives for the food packaging market in the EU. In addition, this guideline can be of interest to users of food contact adhesives such as packaging converters and their downstream users as well as other stakeholders, such as legislators.

For a number of years the EU has set out legislation in relation to food packaging to protect consumers' health, e.g. the Framework Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food. With the Regulation (EC) No 2023/2006 the Commission also defines rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food. The framework regulation sets out the general principles and states that special measures can be implemented for various types and components of food packaging. Several measures are already in place and define the conditions and rules on how the requirements of the framework regulation should be met. Although no such measure exists for adhesives at EU level, the general principles of the framework regulation need to be respected. The area of plastics has been subject to special measures for years, previously by Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs and since 1 May 2011 by Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food. Although this regulation states that adhesives are not plastic and therefore are not subject to a declaration of compliance it also puts the legal obligation on adhesives suppliers to provide adequate information so that compliance can be demonstrated for the final plastic article [(30) of the introduction to this regulation]. FEICA is committed to support the flow of information necessary to ensure the safety of our products in the supply chain, both upstream and downstream, and provides these guidelines especially to support member companies. This guide therefore contains tools, recommendations and answers as to which information needs to be collected from suppliers of raw materials for adhesives, to aid the decision whether a raw material is suitable for a food contact application or not, where to find the corresponding legal texts for further information and provides a decision tree for evaluating the suitability of adhesive for the intended application. FEICA successfully completed a project called 'MIGRESIVES' in 2010 to show that the migration of substances from adhesives can be modelled in a similar way than already demonstrated for plastics. The use of modelling can complement or even replace the more time consuming and costly migration testing without compromising the safety of food packaging. Finally this document explains what information needs to be provided on a food contact status paper so that adequate information is communicated to the next level in the supply chain. By following this guideline adhesives manufacturer should be able to demonstrate that their products fulfil the requirements of the framework regulation by using the various proposed tools.

In order to accommodate the specific performance requirements of the many food contact articles (e.g. bags, pouches, boxes, chopping boards, kitchen furniture, etc.), and the variety of materials employed (e.g. plastic, paper, cardboard, wood etc.) different kinds of adhesives are necessary. Irrespective of the chemistry and the setting mechanism (physical or chemical curing), the set adhesive films consist basically of polymeric organic substances of high molecular weight.¹

¹ More details on terms and definition can be found in the norm EN 923 (2008:06), Adhesives — Terms and definitions, 2.1.1 adhesive.

Adhesive general definition

“An adhesive is a non-metallic substance capable of joining materials by surface bonding (adhesion), and the bond possessing adequate internal strength (cohesion).”² Adhesives set by either evaporating a solvent or cooling or they cure by chemical reactions that occur between two or more constituents.³

2. Regulatory Background

In the area of food contact materials, plastic materials and articles are regulated by a specific measure harmonized at EU level, the Plastics Regulation (EU) No 10/2011. This regulation provides among other requirements a list of authorized substances. Other substance groups as e.g. adhesives, coatings or print inks do not have such specific harmonized legislation yet.

These groups of materials remain subject to the EU Framework Regulation (EC) No 1935/2004 and where existing, to the relevant Member State national legislations.

Since the Plastics Regulation provides an extensive list of evaluated substances, it is used as the main regulatory reference whenever possible. As an alternative and when relevant, reference is made to the opinions of the European Food Safety Authority, to Resolutions of the Council of Europe, to national legislations, and even to NON-European legislations.

The following sections of this chapter provide additional details on most relevant legislations.

2.1. Regulation (EC) No 1935/2004 – The Framework Regulation

The Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, provides general principles to regulate any type of food contact material and is well known as the Framework Regulation.

It indicates that specific measures (EU harmonized legislation) may be adopted for certain food contact material groups (17 in total) as defined in Annex I. A measure establishes the specific rules for materials and articles of a certain material group in order to comply with the requirements of the Framework Regulation. Apart from plastics, also rubber, metal, glass coatings, paper, printing inks and adhesives represent material groups for which specific measures are foreseen. At the current stage no specific measure has been issued to regulate adhesives.

Article 3 of the Framework Regulation stipulates the core requirements that any type of material intended for food contact application should meet. It is worthwhile to note that food contact materials are **ALL** materials and articles intended to come into contact with foodstuffs, including packaging materials but also cutlery, dishes, processing machines, containers etc.

² EN 923:1995, Adhesives — Terms and definitions, 2.1.1 adhesive

³ Hermann Onusseit, Rainer Wefringhaus, Gunther Dreezen, Jürgen Wichelhaus, Joel Schall, Lothar Thiele and Ansgar van Halteren "Adhesives, 1. General" in Ullmann's Encyclopaedia of Industrial Chemistry 2010, Wiley-VCH, Weinheim. doi:10.1002/14356007.a01_221.pub3

ARTICLE 3:

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;*
- b) bring about an unacceptable change in the composition of the food; or*
- c) bring about deterioration in the organoleptic characteristics thereof*

In addition to these requirements Regulation (EC) No 1935/2004 establishes some specific provisions on traceability, the authorization process for new substances, the Declaration of Compliance (DoC) for those substance groups already regulated by a specific measure as well as supporting documentation applicable to all materials covered under the Regulation.

Besides article 3 the most important legal requirements from the Framework regulation relevant to **adhesives manufacturers** are:

- GMP provision (see also GMP Regulation (EU) No 2023/2006)
- Traceability
- Control of release of migrants

It must be emphasised that the full compliance to article 3 of the regulation can only be addressed by the manufacturer of the final packaging material for the real or foreseeable conditions of use.

2.2. Regulation (EC) No 2023/2006 as amended – Good Manufacturing Practice

COMMISSION REGULATION (EC) No 2023/2006, on good manufacturing practice for materials and articles intended to come into contact with food sets out general principles to ensure the suitability of the material or article for the intended end use. It is obligatory for all actors in the food contact supply chain⁴ and is focussing mainly on the principles of a quality assurance system⁵, quality control and appropriate documentation within the manufacturing process.

It is up to the individual companies to define how to fulfil these obligations taking into account the position in the supply chain/size of the business and integrating these requirements with complementary systems within their company, such as ISO 9001. The general intention of this regulation is to ensure that all business operators acting in the area of food contact materials are able to demonstrate the materials they place on the market are in compliance with the Framework Regulation requirements and thus do not endanger human health.

The GMP principles in this regulation are not particularly aimed to cover hygiene requirements.

⁴ Article 2 of Regulation (EC) No 2023/2006 - "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."

⁵ Covering the suitability of starting materials, operation processes, premises and equipment and the qualification of the staff.

2.3. Regulation (EU) No 10/2011 as amended – Plastics Regulation

The Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food consolidates and replaces previous Directive 2002/72/EC with its six amendments and also integrates some former Directives to migration testing, simulants and to Vinyl chloride. ⁶

The scope of the Regulation (EU) No 10/2011 is to provide specific measures for plastics and applies to:

- (a) materials and articles and parts thereof consisting exclusively of plastics;*
- (b) plastic multi-layer materials and articles held together by adhesives or by other means;*
- (c) materials and articles referred to in points a) or b) that are printed and/or covered by a coating;*
- (d) plastic layers or plastic coatings, forming gaskets in caps and closures, that together with those caps and closures compose a set of two or more layers of different types of materials;*
- (e) plastic layers in multi-material multi-layer materials and articles.*

The Plastics Regulation defines several compositional requirements for substances used in plastics. It is common practice to use these requirements also for a first evaluation of substances in adhesives.

The Unionlist set in Table 1 of Annex I: provides a list of authorized monomers, other starting substances and additives, including information on identity and the use of the substance (additive, monomer, polymer production aids etc.). This list includes also restrictions and specifications (SML, purity requirements etc.).

Substances not subject to the Unionlist: e.g. polymer production aids (PPAs) if not covered by the Unionlist yet, aids to polymerization (APs), NIAS (impurities/reaction products) etc. shall be assessed in accordance with internationally recognized scientific principles on risk assessment (article 19).

Substances not listed in the Unionlist: The regulation permits the use of substances not included in the Unionlist provided the substances are not carcinogenic, mutagenic or reprotoxic (e.g. classified in categories 1a, 1b, 2 of the CLP regulation), they are not nanomaterials, and are used behind a functional barrier, whereas the migration of these substances into the food / food simulant is kept below 10 µg/kg.

Further restrictions set in Annex II: The regulation also sets specific restrictions on some metals others than the ones regulated by 94/62/EC and on Primary Aromatic Amines which are of special interest for adhesives manufacturers.

Besides the compositional requirements the Regulation defines provisions on **Declaration of Compliance and supporting documents** (Articles 15 and 16). The Declaration of Compliance represents Information in the supply chain. It applies to the plastic food contact material production chain, to the final article but also intermediate stages down to the starting substances. It should be available at the marketing stage other than retail stage. It should also be available at the importer stage = marketing stage for imports. It represents the information for enforcement authorities. The supporting documentation can consist of all types of documents (e.g. raw materials, information/certificates, analytical data, risk assessment data, etc.) that support the final DoC. Supporting information has to be available at all

⁶ Directive 82/711/EEC and amendments, on Basic rules for migration testing
Directive 85/572/EEC and amendments, on List of simulants
Directive 78/142/EEC, 80/766/EEC and amendments, on Vinyl chloride

stages for all declarations of compliance. The supporting documentation should be kept in-house and made available to authorities upon request.

There is no legal obligation for adhesive manufacturers to provide a declaration of compliance, indeed the adhesive may contain substances which are not authorized by this regulation. However, the **adhesive manufacturer shall provide “adequate information”** with the purpose of enabling the adhesive user to ensure compliance for substances with migration limits. The adequate information might be included into the Food Contact Declaration (A model template is given in section 4 of this guidance).

Quotation: recitals 6 and 30

6) Plastic materials and articles may be composed of different layers of plastics held together by adhesives. Plastic materials and articles may also be printed or coated with an organic or inorganic coating. Printed or coated plastic materials and articles as well as those held together by adhesives should be within the scope of the Regulation. Adhesives, coatings and printing inks are not necessarily composed of the same substances as plastics. Regulation (EC) No 1935/2004 foresees that for adhesives, coatings and printing inks specific measures can be adopted. Therefore plastic materials and articles that are printed, coated or held together by adhesives should be allowed to contain in the printing, coating or adhesive layer other substances than those authorised at EU level for plastics. Those layers may be subject to other EU or national rules.

30) Coatings, printing inks and adhesives are not yet covered by a specific EU legislation and therefore not subject to the requirement of a declaration of compliance. However, for coatings, printing inks and adhesives to be used in plastic materials and articles adequate information should be provided to the manufacturer of the final plastic article that would enable him to ensure compliance for substances for which migration limits have been established in this Regulation.

When substances in the Unionlist are used in adhesives the specific limits / restrictions should be followed and information on such limitations / restrictions should be given in the Food Contact Status Declaration. The declaration should also contain possible information to Dual use additives.

Dual use additives

A dual use additive covers a substance that is authorised as additive in plastics and at the same time authorised as food additive or flavouring. The main intention of the legislation is that the user of food contact materials is informed on the presence of a dual use additive in the plastic so that these can be considered in relation to the relevant food legislation or interactions between food and packaging.

Adhesives may contain substances that are not listed in the Unionlist, provided they allow the final article to comply with article 3 of the Framework Regulation and do not endanger human health (i.e. they are not CMR, nanomaterials etc.). Those substances may be subject to other EU or national rules as explained further down in this document.

In the area of Migration Testing the Regulation (EU) No 10/2011 defines Specific Migration Limits (SML) and the Overall Migration Limit (OML), which need to be met by the final material or article; it defines the simulants in accordance to the concerned food and sets the test conditions in correlation to the

intended food contact application. The regulation shows options for screening tests and gives notes to verification of compliance. Migration tests can either be carried out on food simulants or on the food, alternatively the use of modelling is an option to show compliance, provided the method is scientifically recognized as valid.

2.4. EU member states legislations

For substances in the adhesive not listed in EU regulations, EU member states national legislations may be applied to evaluate their suitability for the intended use.

National legislations are legally binding in the specific country where they are issued and should be used to address compliance in that country. National legislations are generally structured following the concept of positive lists (i.e. list of substances authorized to be used in the manufacture of materials intended to be used in the regulated application and their restrictions and/or limitations). In some instances listing of catalysts and/or processing aids is also included.

Currently very little national legislation regulate adhesives specifically but also positive lists relating to other food contact material might be used to assess compliance. The relevant national legislation and restrictions should be referenced in the Food Contact Status Declaration.

The most important national legislations covering various types of materials and in some cases making reference to adhesives are:

- German Bedarfsgegenständeverordnung,
- Dutch Warenwet,
- Italian Decree 21 March 1973 as amended,
- Spanish Royal Decree n. 847-2011 on polymeric materials

The Mutual Recognition Principle

In intra-EU trade in goods, mutual recognition is the principle that a product lawfully marketed in one Member State and not subject to Union harmonisation should be allowed to be marketed in any other Member State, even when the product does not fully comply with the technical rules of the Member State of destination. In practical terms this means that a product / substance that complies with certain legislation in one of the MSs should be considered compliant also in the rest of the EU territory. However each MS can still pose restrictions or bans at national legislation level should any concern for health or the environment be posed for people / environment in that MS by the use of that product / substance (e.g. BPA in France).

For adhesives it would mean, that a substance that is not in the Unionlist, but is listed i.e. in the Dutch Warenwet only, can be marketed also in any other EU member state, provided the country of destination has not posed any bans or restrictions to this substance.

2.5. Others: Recommendations, Resolutions etc.

For substances in the adhesive neither listed in EU regulations nor in national legislation, reference can be made to non-legally binding texts such as:

- EFSA Opinions
- German BfR Recommendations
- Resolutions of the Council of Europe

Germany BfR Recommendations

Despite the fact that they are recommendations (not legislation) and have no legally binding character they are often used as critical tool to assess compliance. Most frequently adhesives are addressed under:

- Recommendation XIV-A on plasticiser-free dispersions -> this one makes cross reference to the Plastic Regulation
- Recommendation XXVIII – on Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials
- Recommendation XXV – on Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics

Council of European Resolutions

No Resolutions specific to adhesives exist. Some of these Resolutions can however be used to assess compositional status of ingredients used in adhesives when not present in the Unionlist or in National Legislations, e.g.:

- Resolution AP (92) 2 on control of Aids to Polymerization in plastic materials and articles
- Resolution AP (96) 5 on surface coatings intended to come into contact with foodstuffs
- Resolution AP (2002) 1 on paper and board materials and articles intended to come into contact with foodstuffs
- Framework Resolution AP (2004) 1 on coatings intended to come into contact with foodstuffs
- Resolution AP (2004) 2 on cork stoppers and other cork materials and articles intended to come into contact with foodstuffs
- Resolution AP (2004) 3 on ion exchange and adsorbent resins used in the processing of foodstuffs (superseding Resolution AP (97) 1)
- Resolution AP (2004) 5 on silicones used for food contact applications

2.6. Non-EU Legislation

If a substance is not listed in any EU Regulation or reference document in the EU (as described above), Non-European Legislation might be used for further evaluation.

The Food and Drug Administration – FDA is an agency of the US Department of Health and Human Services. Among other areas the FDA is responsible for protecting public health through the regulation and supervision of food safety. Two examples of FDA section which might be relevant for adhesives in food contact are the following:

- 21CFR175.105 Adhesives, where INDIRECT Food Contact Compliance implies, that the material is separated from food by another material (functional barrier)⁷
- 21CFR175.300 Resinous and Polymeric Coatings, where DIRECT Food Contact compliance allows direct contact with the film or coating

Due to the different approach of FDA and EU regulations and the complexity of this subject, it will not be covered in detail here.

⁷ Functional barrier in the context of FDA is defined differently from the functional barrier in the context of EU legislation.

3. Requirements for adhesive producers

As one part in the supply chain for food contact materials, the adhesive producer needs to fulfil the applicable regulatory requirements and is obliged to check the general suitability of the adhesive for the intended food contact application. An appropriate evaluation of the adhesive is possible, if provided with enough information from the raw material supplier as well as the final food contact application is available.

This chapter describes the process for the gathering of data for raw materials, the raw material evaluation and finally the adhesive related evaluation for the intended application (see flow sheet 1 attached). The second flow sheet presents a decision tree for the adhesive user in order to evaluate the suitability of the concerned adhesive for the intended food contact application.

3.1. Raw Material Data Gathering

To choose the right raw materials for a new adhesive, the raw material supplier should not only provide a technical or a safety data sheet, but also send up-to-date information, which covers the chemical identity and food contact compliance aspects (see RM request template in Annex I). FEICA has recently developed a "Rejection list" of substances in order to check the status of the raw materials against further critical substances (Annex II), which should also help for the evaluation of the raw material. In case the information received from the supplier is not sufficient (e.g. no chemical identity, no compliance information, etc.) the raw material can either be rejected or checked by analytical screening.

3.2. Raw Material Evaluation

If the raw material does contain substances of the Rejection list, the raw material should be rejected. The received information regarding the compliance of food contact regulations shall be checked in detail (received information from supplier due to the Supplier Request Template, Annex I).

Adhesives are not necessarily composed of the same substances as plastics. Therefore plastic materials and articles that are held together by adhesives should be allowed to contain in the adhesive layer other substances than those authorised at EU level for plastics. Those layers may be subject to other EU or national rules (quotation from (EU) No 10/2011, whereas (6)).

For all substances listed in the Unionlist or otherwise authorized through the Regulation (EU) No. 10/2011, specific restrictions (e.g. SML, QM) or specifications (as recorded in column 10 of Table 1 of Annex I of Regulation (EU) No 10/2011) need to be considered in the further evaluation process. If one or more substances are not covered by the (EU) No 10/2011, this does not automatically result in the rejection of the raw material. As described above other EU or national regulations or recommendations can be used for the evaluation. Restrictions from these regulations should be considered for the further evaluation process, too.

The polymer as such is an inert high molecular weight structure. As substances with a molecular weight above 1 000 Da usually cannot be absorbed in the body the potential health risk from the polymer itself is minimal. (Quotation: Reg. (EU) No 10/2011, whereas (8)).

Components of the raw material which are not authorized by any of the above described sources might contain substances with a molecular weight below 1000 Dalton.⁸In this case an extended risk assessment needs to be carried out. Parts of this assessment could be toxicological results like LD (lethal doses) values, DNEL (derived no effect limit), work place exposure limits, ADI (acceptable daily intake) or data on toxicodynamic or toxicokinetic behaviour of the substance(s) of concern. The risk assessment should be done in accordance with internationally recognised scientific principles.

⁸ The size of the fraction with molecular masses below 1 000 Da should be considered.

Depending on the results the raw material might be evaluated as "generally suitable" or will be rejected, if it has failed. The list of options for an extended risk assessments does not aim to be complete and might be modified in future due to the upcoming EU Commission guidance for risk assessment, which is expected to be published soon.

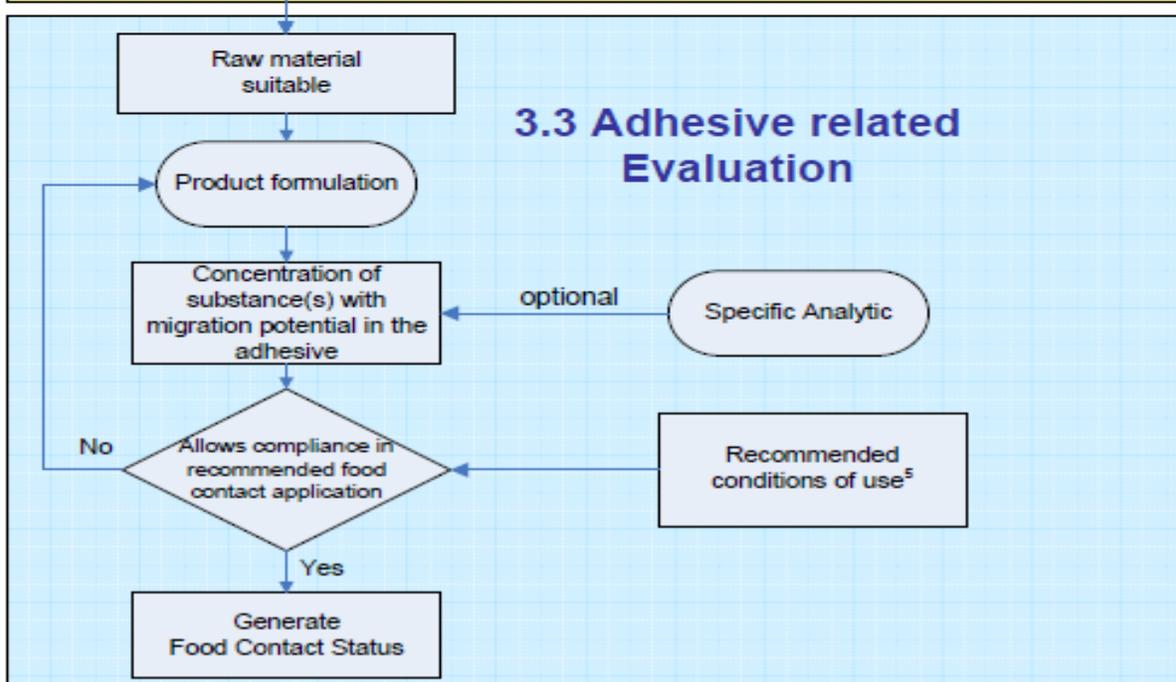
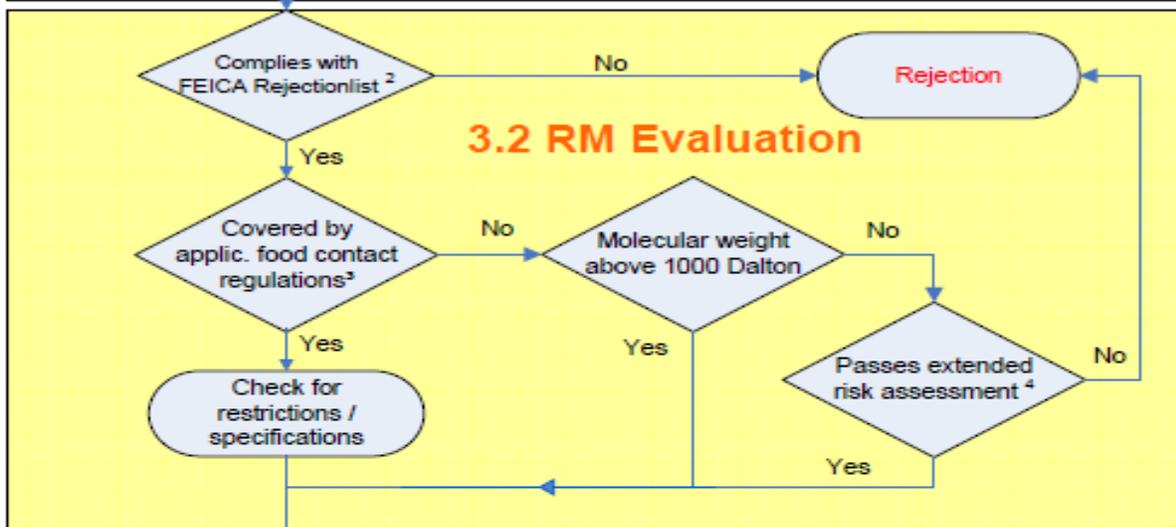
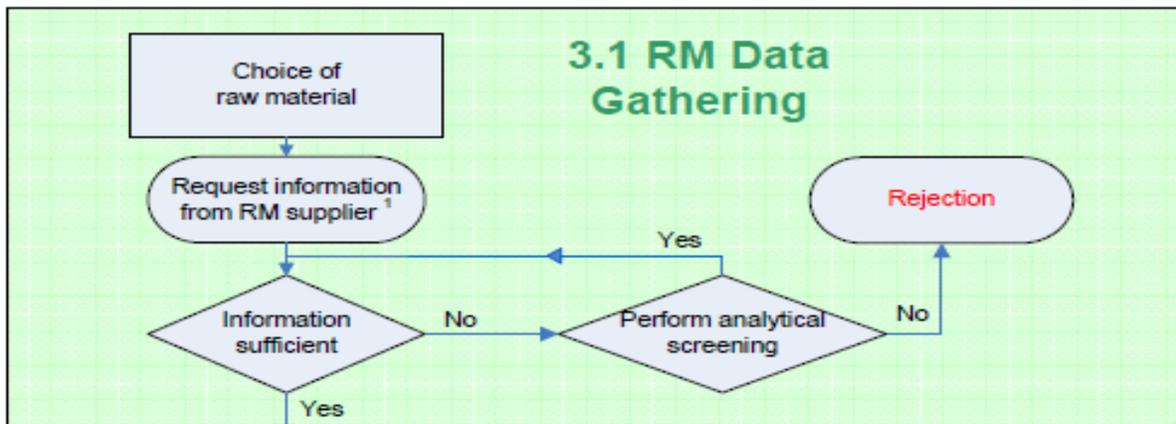
3.3. Adhesive related Evaluation

When all information is collected and does not raise major concerns, the raw material is assessed as "generally suitable", and might be used in a new adhesive formulation. Major focus should be given on potential restrictions (following column 8 or 9 of the Plastics Regulation) and / or specifications (column 10). If the concentration of a substance with a certain migration potential cannot be evaluated with the given information, specific analytical tests might provide further details.

Under consideration of the recommended adhesive application (adhesive layer thickness, surface volume ratio, substrate) worst case calculations could give a hint to the compliance of the final food contact material with respect to the adhesive. The recommended conditions of use should be communicated to the user within the food contact status declaration and/or via the technical documentation. Finally all relevant compliance information is summarized in the FOOD CONTACT STATUS DECLARATION which is issued by the adhesive producer.

For non-plastics parts the Plastics Regulation (EU) No 10/2011 does not set out an obligation to issue a Declaration of Compliance. However, as the Plastics Regulation requires that migration of authorised substances and certain other substances should not exceed the established migration limits it is necessary that "Adequate Information" is provided by the adhesive manufacturer, allowing the manufacturer of the final plastic article to establish compliance with the Plastics Regulation for these substances.

This "Adequate information" should enable the downstream user to evaluate the suitability of the adhesive for their application (Template for Food Contact Status Declaration see paragraph 6).



- 1 Request template for Supplier, see Annex I
2. FEICA Rejection list, see Annex II
3. (EU) No 10/2011 and national legislations or recommendations as e.g. BfR, CoE Resolutions, FDA
4. For extended risk assessment see explanations under 3.2
5. Recommended conditions of use, see explanations under 3.3

3.4. Evaluation of the adhesive by the downstream user

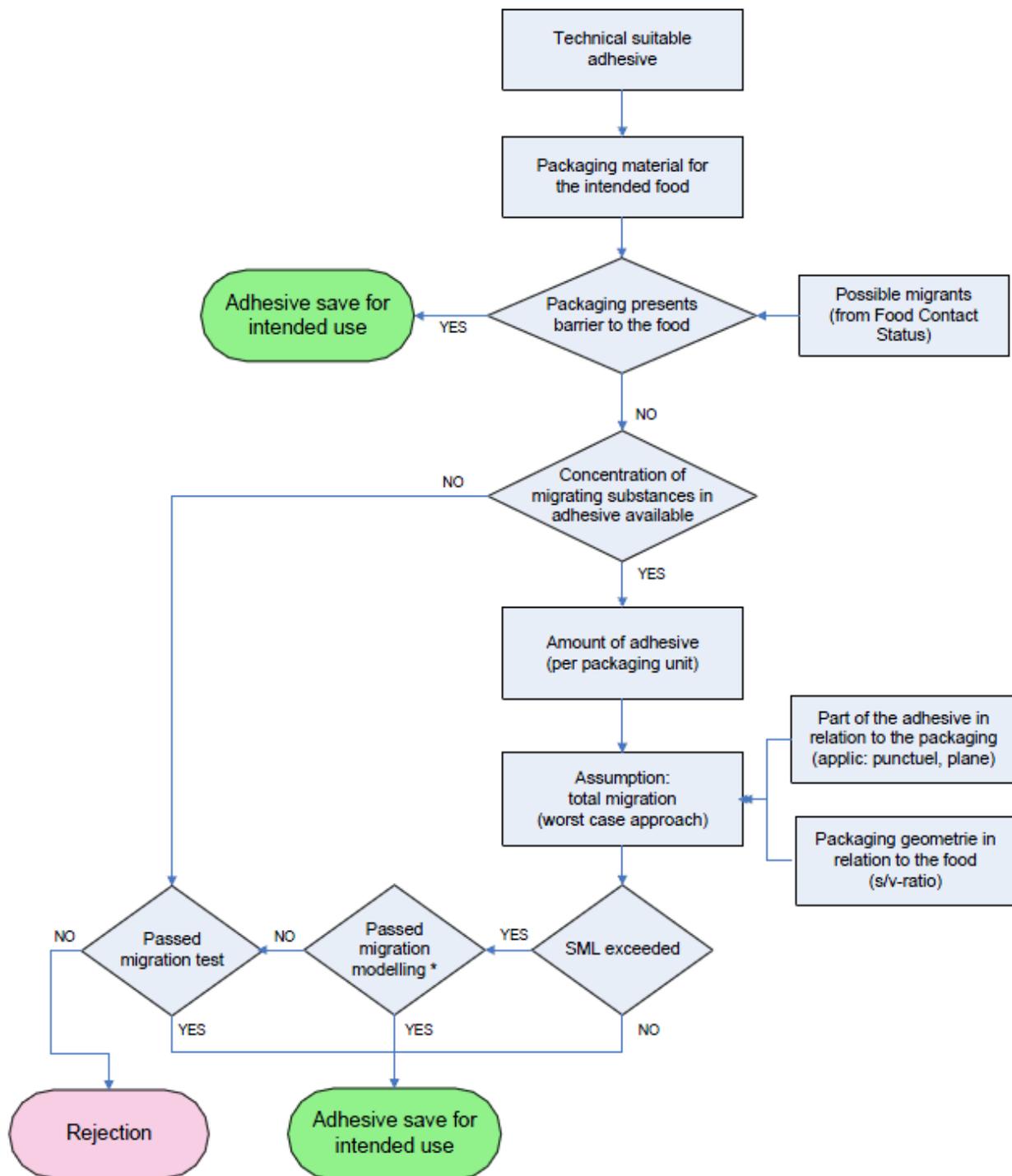
In the majority of cases the adhesive is applied on a substrate, which might build a part of the packaging or any other food contact material or article. This substrate generally separates the adhesive from the food and can either represent a total barrier (no migration into the food possible), a functional barrier (ensures that the final material or article complies with given SML limits including the 10 ppb limit for non-authorized substances) ⁹ or almost no barrier – as e.g. paper (possible migrants could easily migrate through the substrate into the food).

The possibility of invisible set-off should be considered (in a reel the outer layer is in direct contact to the inner layer).

A functional barrier ensures that all possible migrants are migrating in amounts not sufficient to exceed their relative migration limits (e.g. SML, SML(T), Non-detection limit : 10 ppb). If the substrate does not present a functional barrier to the possible migrants of the adhesive, a worst case calculation should be carried out, where the amount of adhesive in the packaging and the surface volume ratio of the packaging to the food should be taken into account. The needed parameter referring to possible migrants could be provided by the adhesive supplier. Alternatively the adhesive supplier could calculate the worst case on his own and provide the maximum possible coat weight up to which the SML will be respected.

⁹« 'functional barrier' means a barrier consisting of one or more layers of any type of material which ensures that the final material or article complies with given SML limits"; Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food

3.4 Evaluation of the adhesive by the downstream user (Decision Tree)



* Migration test – internal or external, preferable at accredit. labs
 Migration Modeling – e.g. Modelling Software INRA („Migresives“),
 FABES Software, SML Advanced of AKTS AG etc.

4. Template for a Food Contact Status Declaration

1. Date
2. Identity and address of the adhesive supplier
3. Product name
4. Product Compliance Status with EU and non-EU Regulations
 - a. (EC) No 1935/2004 – GMP & traceability , Article 3 as applicable
 - b. (EC) No 2023/2006 – GMP regulation
 - c. (EU) No 10/2011 – Plastics regulation
 - i. Listed in the Unionlist? (all / some / not all)
(If not all substances are listed see paragraph d. for further options to evaluate the risk)
 - ii. Information on substances with restrictions (SML, SML(T)), specification etc. in accordance with Annex I and Annex II (e.g. PAAs) of the regulation
 - iii. information on dual use additives ,if food additive or flavouring substance has a restriction in food (Identity of substance as listed in the European legislation on additives, (EC) No 1333/2008, or flavourings (EC) No 1334/2008 : Substance name, E-number or FL number)
 - iv. Information on non-authorized substances if evaluated as relevant
(e.g. NIAS, reaction by products)
 - d. Compliance Status with other legislation and measures
(optional if compliance under c(i) can already be confirmed and/or if requested)
 - i. National legislation EU-member states (Warenwet, Italian Ministry 21/3/72 etc.) and / or
 - ii. Recommendations:
e.g. EFSA opinions , BfR recommendation, CoE Resolutions, etc. and/ or
 - iii. Non-EU Legislation:
 1. FDA (e.g. 175.105, 175.300, 176.170, 176.180, 177.1390 etc. ...)
 2. Swiss Ordinance
 3. Other
 - e. Demonstrate compliance by other measures
If none of the above listed options can be applied to demonstrate the suitability of the product or one of its components, a risk assessment in accordance with internationally recognised scientific principles should be carried out. This could for example cover migration tests under the simulated conditions of the intended food contact application.
5. If the information given under 4 is not sufficient, the adhesive supplier might need to recommend the application of a (functional) barrier.
6. If the adhesive is used in the scope of the regulation (EU) No 10/2011, the compliance with the migration limits should be assessed by the manufacturer of the final food contact material or article in accordance with the intended conditions of use (time, temperature, food simulants). Tests should be carried out following the rules laid down in regulation (EU) No 10/2011. The downstream user also needs to evaluate the possible influence on the organoleptic properties of the food.

Disclaimer:

Please note that these details are based on the information given to us by our own suppliers by the date of this document and assessed with the best of our knowledge. It applies only for the recommended conditions of use and does not represent a warranty.

5. Summary

This FEICA guideline provides information with regards to food contact compliance information to be gathered for raw materials. It aims to help the adhesives producer to decide whether a raw material is suitable for adhesives for the given application. It also explains how to assess the suitability of the adhesive system and offers a template to communicate adequate information to supply the downstream user.

By following this guide the downstream user putting the final article on the market should be able to demonstrate compliance with the Framework Regulation (EC) No 1935/2004 for his article including the adhesive system under the given conditions of use. However, it should be noted that this guide is not a legal document but merely advice given by FEICA.

The guide is primarily aimed at FEICA members and members of the national associations who manufacture adhesives for food contact but also at downstream users who want to assess the adhesives systems they use.

6. Contact

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Annex I: REQUEST information from RM-Suppliers

1. Date
2. Identity and address of the raw material supplier
3. Chemical Identification (e.g. CAS, PM Ref, FCM, EINECS, typical molecular weight)
4. Compliance Status
 - a. Regulation No 1935/2004 on materials and articles intended to come into contact with food– Traceability, article 3 (as far as applicable)
 - b. (EC) No 2023/2006 – GMP regulation (as far as applicable)
 - c. (EU) No 10/2011 – Plastics regulation:
 - i. Substances on Unionlist with restriction, incl. max. residual concentration
 - ii. Non-authorized substances incl. NIAS¹⁰ if it can be reasonably expected to migrate, max. residual concentration, risk assessment (e.g. other food contact legislations / toxicological evaluations / CMR studies)
 - iii. Dual use additives¹¹, incl. max concentration (Identity of substance as listed in the European legislation on additives, (EC) n° 1333/2008, or flavourings (EC) n° 1334/2008: Substance name , E-number or FL number)
 - d. Others (EU member states legislation, Swiss Ordinance, BfR etc.) including restrictions
 - e. FDA (e.g. 175.105 etc.) including restrictions
5. Compliance with Rejection list FEICA

¹⁰ NIAS are non-intentionally added substances, like impurities, reaction by products, degradation products, oligomers (substance consisting of a finite number of repeating units which has a molecular weight of less than 1000 Da)

¹¹ "Dual use additive" means additives as listed in Annex I to this Regulation and which are also authorised as food additives and flavourings and subject to a restriction in food in Regulations (EC) No 1333/2008 and (EC) No 1334/2008

Annex II: Rejection List

Following substances should not be used for the manufacturing of adhesives intended for food contact materials in amounts exceeding the respective restrictions. The supplier of raw materials should confirm the compliance with the following provisions:

1. Substances and preparations should not be classified as CMR – category 1A or 1B and 2 following CLP-Regulation (EC) no. 1272/2008, unless substance or components of the preparation are already regulated in the Unionlist of Regulation (EU) No. 10/2011.
2. Article 11 of Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste whereas the sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm in total.
3. Res AP (89) 1, complying with the absence of metals and metalloids in pigments (restrictions for antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium)
4. Alkanes, C10-C13 (CAS 85535-84-8), short chain chlorinated Paraffins ,should not exceed concentrations above 0,1% [according to Annex XIV of Regulation (EC) no. 1907/2006]
5. Phthalates should not exceed concentrations above 0,1% [according to Annex XVII of Regulation (EC) 1907/2006].
6. Azocolourants should not exceed concentrations above 0,1% [according to Annex XVII of Regulation (EC) 1907/2006].
7. Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
8. Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food
9. Restrictions to nonylphenol (Registry of submitted SVHC intentions, based on Regulation (EC) No. 1907/2006)
10. Regulation (EU) No 412/2012 to Dimethylfumarate
11. Directive 2011/65/EU (ROHS), complying with restrictions to Polybrominated biphenyls (PBB) and Polybrominated diphenyl ethers (PBDE).

Annex III: Useful Links

Europe

- European Food Safety Authority/EFSA: <http://www.efsa.europa.eu/>
(EFSA opinions: <http://www.efsa.europa.eu/en/publications.htm>)
- Council of Europe resolutions: http://www.coe.int/t/e/social_cohesion/soc-sp/public_health/food_contact/COE's%20policy%20statements%20food%20contact.asp#TopOfPage
- [Food contact materials, food additives and food flavourings databases \[on EU website\]](#)
- References of [EU Directives and Regulations](#) :
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/ReferencesEurNatLeg_20091026.pdf
- EU Guidance on Regulation (EU) No 10/2011:
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/10-2011_plastic_guidance_en.pdf
- EU Guidance on information in the plastics supply chain:
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/guidance_reg-10-2011_en.pdf
- Summary of national legislation on food contact materials and articles on EU website:
http://ec.europa.eu/food/food/chemicalsafety/foodcontact/sum_nat_legis_en.pdf
- German Bundesinstitut für Risikobewertung, Database BfR Recommendations on Food Contact Materials: http://bfr.zadi.de/kse/faces/DBEmpfehlung_en.jsp?filter=clear
- Netherlands, Warenwet:
http://wetten.overheid.nl/BWBR0003276/geldigheidsdatum_wijkt_af_van_zoekvraag/geldigheidsdatum_01-05-2008#Aanhef

Other

- US Government Printing Office, texts of regulations:
<http://www.gpo.gov/fdsys/browse/collectionCfr.action?collectionCode=CFR>
- US Food and Drug Administration
 - o Food contact notifications:
<http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/default.htm>
 - o Threshold of regulation exemptions:
<http://www.fda.gov/food/ingredientpackaginglabeling/packagingfcs/thresholdregulation/exemptions/default.htm>
 - o GRAS notices inventory:
<http://www.accessdata.fda.gov/scripts/fcn/fcnavigation.cfm?rpt=graslisting>
 - o List of indirect food additives:
<http://www.accessdata.fda.gov/scripts/fcn/fcnavigation.cfm?rpt=iaListing&displayAll=true>
 - o Everything added to food in the USA:
<http://www.accessdata.fda.gov/scripts/fcn/fcnavigation.cfm?rpt=eafusListing&displayAll=true>
- Swiss Ordinance [full texts available in French, German and Italian, few translations into English]
 - o Printing inks Annex 6: http://www.admin.ch/ch/f/rs/817_023_21/app6.html

All hyperlinks are up-to-date at the time of publication.