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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.

This guidance provided by the FEICA Paper & Packaging Working Group is primarily provided for the benefit of FEICA members and the members of its national association members who are manufacturing adhesives for the food packaging and food service item sector in the European Union. In addition, this guidance can also be of interest to users of food contact adhesives such as packaging producers and their downstream users as well as other stakeholders involved in regulatory or legislative matters of food contact.

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1. Introduction / Objectives

Food packaging and *food service articles* provide the most visible examples of food contact articles. Food contact, however, occurs in a much wider group of articles, ranging, for example, from tableware, takeout and storage containers, articles used in food preparation to machinery and storage equipment used in industrial food processing.

While food contact materials are not *intended* to become part of food, the possibility of *incidental transfer of chemical substances* from food contact materials onto food needs to be given attention. For a number of years, the EU has therefore set out harmonised legislation for *food contact materials and articles*, such as Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (the '*Framework Regulation*') and Regulation (EC) No 2023/2006, related to good manufacturing practice (GMP).

Separate *material-specific measures* are foreseen to exist under the framework of Regulation (EC) No 1935/2004. While no specific regulation exists to date for adhesives themselves, Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (the '*Plastics Regulation*') affects many articles on which adhesives are used.

Although Regulation (EU) No 10/2011 specifically states that adhesives are not considered as 'plastic' and therefore are *not* subject to a *declaration of compliance*, it places the legal obligation on adhesives suppliers to provide '*adequate information*' so that compliance can be reliably demonstrated for final plastic articles that contain adhesives.

For other materials on which adhesives are used but no material-specific measures exist on the EU level yet, e.g. paper, Resolution CM/Res(2020)9 of the Council of Europe provides general guiding principles, which also require the availability of '*adequate information*'.

FEICA is committed to support the flow of necessary *adequate information* -- both upstream and downstream in the supply chain -- to ensure the safety and safe use of adhesive products in food contact applications. FEICA provides this guidance document to support its member companies in that effort.

This FEICA guidance provides information on where to find relevant legal texts for further information and what food contact compliance related information needs to be gathered for raw materials; it aims to help the adhesives producer in deciding whether a raw material is suitable for adhesives for a given application; it suggests an approach on how to assess the suitability of the adhesive itself; and it provides a template to communicate *adequate information* to the downstream user.

Following this guidance will help adhesives manufacturers to demonstrate that their products can fulfil the requirements of EU food contact regulations and provide *adequate information* to their customers for the safe use of their products.

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).'¹ Adhesives set by either evaporating a solvent or cooling, or they cure by chemical reactions that occur between two or more constituents.²

2. Food contact material measures in Europe³

The term '*food contact materials*' describes materials that come into contact with food at any point of the value chain from production to consumption.⁴ In distinction to *food additives*, food contact materials are specifically *not* intended to become part of the food as a consequence of the contact.

The possibility of *incidental transfer of chemical substances* from food contact materials and articles onto food, however, cannot be excluded entirely. Such transfer of (chemical) substances is typically referred to as *migration*.

Migration occurs because most materials are not fully inert in contact with food. Food itself can – by nature of its composition, such as its acid or fat content – also contribute to the release of substances from food contact materials.

In all cases in which a certain degree of migration from food contact materials into food is unavoidable, it is necessary to manage and *limit potential risks to human health* of such substance transfer. For this reason, food contact materials are the subject of detailed chemical safety regulations in many countries.

For a number of years, the EU has set out *harmonised legislation for food contact materials and articles*, such as Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food (the '*Framework Regulation*') and Regulation (EC) No 2023/2006, related to good manufacturing practice (GMP).

Separate *material-specific measures* are foreseen to exist under the framework of Regulation (EC) No 1935/2004, with the most notable example being Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (the '*Plastics Regulation*').

¹ EN 923:1995, Adhesives — Terms and definitions, 2.1.1 adhesive

² 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

³ This document cites the initial EU legal acts (regulations, directives). Many of these acts have been revised or amended since their original publication. The citations shall therefore be understood as referring to the respective regulations/directives in their current form, as amended.

⁴ Likewise, 'food contact articles' refers to food contact materials, and combinations of such materials, in an application-specific form, such as a package, a cooking utensil or a storage container.

Other substance groups, including adhesives, are not yet governed by a specific harmonised legislation. These food contact materials remain subject to the *Framework Regulation* (and, where applicable, to relevant EU Member State national measures).

Since the Plastics Regulation (EU) No 10/2011 provides an extensive list of evaluated and authorised substances, it can serve as a regulatory reference when adhesives are assessed.

As an alternative and where relevant, opinions of the European Food Safety Authority (EFSA), Resolutions of the Council of Europe, EU Member State national legislation, and even non-EU legislations can be considered as reference points for the assessment of adhesives.

The following sections of this chapter provide details on the most relevant legislative texts.

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

Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food provides general principles to regulate all types of food contact materials, including adhesives.

This regulation is known as the '*Framework Regulation*' since it is a horizontal regulation that does not set out substance-specific limits or concrete methodologies for assessing migration but establishes general principles for all materials and food contact scenarios.

Regulation (EC) No 1935/2004 mandates that *specific measures* (that is, EU harmonised legislation) may be adopted for 17 food contact material groups that are listed in Annex I. The creation of *specific measures* serves to establish specific rules for materials and articles from a certain material group. These rules define how compliance with the requirements of the Framework Regulation is to be assessed.

To date, no specific measure has been adopted for adhesives by the EU.

In terms of the materials that adhesives are typically applied on, plastics are covered by a specific measure (see section 2.3). Paper, board, glass, metals and wood are to date not covered by an EU harmonised material-specific measure. For this reason, this document describes in detail the requirements for adhesive use on plastic materials, referencing the Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (the '*Plastics Regulation*').

Article 3 of the Framework Regulation stipulates the core requirements that any type of material intended for food contact application shall meet. It is worth noting that its scope encompasses *all* materials and articles intended to come into contact with foodstuffs, including packaging materials but also food service items such as cutlery, dishes, processing equipment, containers etc.

ARTICLE 3(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 deterioration in the organoleptic characteristics thereof.*

While adhesives manufacturers can support their customers and provide adequate information for safe use of their products, it must be emphasised that the *final* compliance with article 3 can be verified only by the manufacturer of the final packaging material or food service item, considering the real or foreseeable conditions of use. Adhesive manufacturers cannot perform this verification or provide such assurances as the other materials contained in the packaging or food service item besides the adhesive as well as the conditions of use are not under their control.

In addition to the core requirements of article 3, Regulation (EC) No 1935/2004 also establishes certain specific provisions on traceability (Article 17), the authorisation process for new substances (Articles 8-12) and the requirement of a *Declaration of Compliance* (DoC) document for substance groups already regulated by a *specific measure* (Article 16).

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

Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles lays down the rules on good manufacturing practice (GMP) for materials and articles intended to come into contact with food. It is binding for all actors in the food contact material supply chain.⁵

The overarching intent of this regulation is to ensure that all business operators in the field of food contact materials can demonstrate that the materials they place on the market are of consistent quality and suitable to be in compliance with the *Framework Regulation's* requirements and thus do not endanger human health.

While the focus of the regulation is on the principles of a quality assurance system, quality control measures and *appropriate documentation* within the manufacturing process, Regulation (EC) No 2023/2006 also requires that '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'.

It is up to the individual business operator to define how to fulfil these requirements, taking into account their position in the supply chain/size of the business and to integrate these requirements with complementary systems of their operation, such as ISO 9001. FEICA has created a guideline for good manufacturing practice for adhesives.⁶

⁵ 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'.

⁶ FEICA Guidance Paper 'FEICA Guideline for Good Manufacturing Practice of food packaging adhesives in Reference to Regulation (EU) No 2023/2006'

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

Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (the 'Plastics Regulation') consolidates and replaces the previous Directive 2002/72/EC with its six amendments and also integrates some former Directives to migration testing, simulants and vinyl chloride.⁷ It has been amended numerous times since its inception.⁸

The scope of the Plastics Regulation covers food contact materials and articles both when made solely of plastic and when plastic is combined with other materials. The regulation is binding for the plastic layers in multi-layer and/or multi-material products.

ARTICLE 2(1):

This Regulation shall apply to materials and articles which are placed on the EU market and fall under the following categories:

- (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.

The 'Union List' set out in Table 1 of Annex I provides a list of authorised monomers, other starting substances, and additives, including information on the identity and use of each substance (additive, monomer, polymer production aids etc.). This list also includes restrictions and specifications such as specific migration limits (SMLs), maximum content limits in the final product and purity requirements.

Substances not subject to the Union List such as polymer production aids (PPAs) not covered in the Union List, colorants and non-intentionally added substances (NIAS)⁹ shall be assessed in accordance with internationally recognised scientific principles on risk assessment (Article 19).

Substances subject to but not listed in the Union List are permitted, provided the substances are not carcinogenic, mutagenic or toxic to reproduction (that is, not classified in the respective categories 1a, 1b, 2 of the Classification, Labelling and Packaging [CLP] Regulation) and not

⁷ 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

⁸ To date, by Commission Regulations (EU) No 321/2011, (EU) No 1282/2011, (EU) No 1183/2012, (EU) No 202/2014, (EU) No 865/2014, (EU) 2015/174, (EU) 2016/1416, (EU) 2017/752, (EU) 2018/79, (EU) 2018/213, (EU) 2018/831, (EU) 2019/37, (EU) 2019/988, (EU) 2019/1338, (EU) 2020/1245

⁹ Article 3 of Regulation EU 10/2011: ' "non-intentionally added substance" means an impurity in the substances used or a reaction intermediate formed during the production process or a decomposition or reaction product'.

nanomaterials, and provided that they are used behind a functional barrier and that the migration of these substances into the food or food simulant is kept below 0.01mg/kg.

Further restrictions set out in Annex II include restrictions on the migration of certain metals and on primary aromatic amines (PAA), which are of special interest for adhesives manufacturers.¹⁰

As they are not considered as plastics, adhesives used in plastic articles may contain substances that are not listed in the Union List, provided they allow the final article to comply with article 3 of the *Framework Regulation* and thus do not endanger human health. Substances in adhesives may be subject to other EU or national rules as explained further below in this document. Where this is not the case, it is common practice to use the authorisations and restrictions set out in the Union List in Regulation (EU) No 10/2011 also for a first evaluation of substances in adhesives.

Concerning migration testing, Regulation (EU) No 10/2011 defines *Specific Migration Limits (SMLs)* and the *Overall Migration Limit (OML)*, which need to be met by the final plastic material or article;^{11,12} it defines food simulants to be used for migration testing in dependence on the type of food; and it defines the test conditions in dependence on the intended food contact application.

FEICA has created a guidance paper¹³ on migration testing of adhesives and a specific guidance related to mineral oil hydrocarbons and primary aromatic amines.^{14,15}

As an alternative to migration testing, the use of *migration modelling* is provided as an option to demonstrate compliance, provided the method is scientifically recognised as valid.

FEICA successfully completed a project called 'MIGRESIVES' in 2010 to show that the migration of substances from adhesives can be modelled in a way similar to that 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.

For a detailed guidance on the interpretation of the provisions of Regulation (EU) No 10/2011, a specific document is available from the European Commission.¹⁶

Besides compositional requirements and limits to migration, Regulation (EU) No 10/2011 defines provisions on the **Declaration of Compliance and supporting documents** (Articles 15 and 16). The Declaration of Compliance represents information passed along in the supply chain. It applies to the whole plastic food contact material production chain, that is, to the final article but also to intermediate stages and back to, but excluding, the starting substances.

¹⁰ The limits for PAA have recently been updated by Regulation (EU) 2020/1245, amending Regulation (EU) 10/2011.

¹¹ Including any contributions to migration originating from non-plastic parts of the article, such as adhesives

¹² The requirement of the overall food contact article to meet SML and OML values does not apply if the article contains additional materials besides plastic, for which no harmonised specific measure exists at the EU level. See Regulation (EU) 2020/1245, Recital 34 and EC Document 'Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food'.

¹³ FEICA Guidance Paper 'Migration testing of adhesives intended for food contact materials'

¹⁴ FEICA Guidance Paper 'FEICA guidance on evaluating the food contact status for adhesives containing mineral oil hydrocarbons'

¹⁵ FEICA Guidance paper 'FEICA recommendation to adhesive suppliers and users on the assessment of PAAs in polyurethane adhesives intended to be used in food packaging'

¹⁶ EC Document 'Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food'

The provisions on the Declaration of Compliance require adequate information on the presence of substances that are subject to restriction in the Plastic Regulation, including the restrictions in Annex II. Adequate information is also required regarding the presence of intentionally used substances for which genotoxicity has not been ruled out.

The Declaration of Compliance should be made available on all marketing stages other than the retail stage and represents information for enforcement authorities. It should also be available for imports.

Supporting documents can consist of all types of documents (e.g. raw material, information/certificates, analytical data, risk assessment data) that have informed and support the final *Declaration of Compliance*. Supporting information must be available at all stages and for all *Declarations of Compliance*. Supporting documentation may be kept confidential and be made available only to authorities, upon request.

As adhesives are not in the scope of the Plastics Regulation and not yet covered by a specific EU legislation, adhesive manufacturers are not subject to the requirement to provide a Declaration of Compliance. Instead, according to the Plastics Regulation,¹⁷ the **adhesive manufacturer shall provide 'adequate information'** with the purpose of enabling the adhesive user to ensure compliance for substances for which migration limits have been established. This adequate information is typically included into the *Food Contact Status Declaration* for the adhesive.¹⁸

¹⁷ Recital 30 and EC Document 'Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain'. See box below

¹⁸ A model template is given in Section 4 of this guidance.

Regulation (EU) No 10/2011, 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.

Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain:

The manufacturer of the final plastic material or article has to issue a DoC for his product, which may be composed of plastic layers and non-plastics such as adhesives, printing inks and coatings. For components of the plastic layers, he will receive DoCs. For the non-plastics parts, the Plastics Regulation does not set out an obligation to issue a DoC. However, as the Plastics Regulation requires that migration of authorised substances and certain other substances should not exceed the established migration limits, it is recommended that Adequate Information is provided by the manufacturers of adhesives, printing inks and coatings that allows the manufacturer of the final plastic article to establish compliance with the Plastics Regulation for these substances. This Guidance document gives recommendations on the information considered adequate to be provided by manufacturers of adhesives, printing inks and coatings to the plastics converters.

When substances in the Union List are used in adhesives, the specific limits or restrictions should be followed. Therefore, information on such limitations or restrictions shall be provided in the *Food Contact Status Declaration*.

The *Food Contact Status Declaration* should also contain information on the presence of so-called *dual use additives*.¹⁹ A dual use additive is a substance that is authorised as an additive in plastics and at the same time authorised as a *food additive* or *flavouring*. The user of food contact materials should be informed of the presence of a dual use additive in the plastic so that it can be considered in relation to the relevant food legislation or possible interactions between food, and packaging or food service items.

¹⁹ See box below for the definition of 'dual use additives'.

Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain:

A substance is defined as a 'dual use additive' if the chemical identity of the plastic additive matches that of an authorised food additive or flavouring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic.

For a detailed guidance on Declarations of Compliance and adequate Information under Regulation (EU) No 10/2011, a specific document is available from the European Commission.²⁰

2.4. EU member states legislations

For substances in the adhesive not listed in EU regulations, EU member states national legislation 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 typically structured following the concept of positive lists (that is, they contain a list of substances authorised to be used in the manufacture of materials intended to be used in the regulated application with any applicable restrictions and/or limitations). In some instances, additive materials such as catalysts and/or processing aids are also included in such lists.

Currently, very little national legislation regulates adhesives specifically. Positive lists relating to other food contact material can, however, serve as a reference to assess compliance of adhesives with the requirements of Article 3 of the EU Framework Regulation. The referenced national legislation and restrictions stated therein should be mentioned in the Food Contact Status Declaration.

The most important national legislations covering various types of materials and in some cases also adhesives are:²¹

- Bedarfsgegenständeverordnung (Germany)
- Warenwet (The Netherlands)
- Decreto Ministeriale del 21/03/1973 (Italy)
- Real Decreto 847-2011 on polymeric materials (Spain)

When dealing with EU member state national legislation, the mutual recognition principle may also be considered.²²

²⁰ EC Document 'Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain'

²¹ A very complete overview as of 2017 is provided by the report '*Non-Harmonised Food Contact Materials in the EU: Regulatory and Market Situation, Baseline Study: Final Report.*', European Commission Joint Research Centre.

²² The application of the mutual recognition principle generally requires the article to be placed on the market first in the EU Member State, whose national legislation has been used to establish compliance.

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 Member States should be considered compliant also in the rest of the EU territory. However, each Member State can still pose restrictions or bans at the 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., [bisphenol A] BPA in France).

For adhesives, this means that a substance that is not on the Union List but is listed, e.g. 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 on this substance.

2.5. Others: Recommendations, Resolutions etc.

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

- European Food Safety Authority (EFSA) Opinions
- German Federal Institute for Risk Assessment (BfR) Recommendations
- Resolutions of the Council of Europe

These documents can also serve as references for adhesive applications on substrates that are not yet subject to EU harmonised specific measures, such as in the case of paper.

In addition to the material-specific resolutions listed below, Council of Europe Resolution CM/Res(2020)9 on the safety and quality of materials and articles for contact with food provides guiding principles for food contact materials that are not covered by specific European legal provisions or other measures at the EU level, such as paper. It establishes an approach for these materials that is comparable to that of Regulation (EU) 10/2011 for plastics.²³

²³ For example, on risk assessment; requirements for the use of non-authorised substances in food contact applications and the provision of 'adequate information'

German BfR Recommendations

Despite their recommendation character (no legally binding character), BfR Recommendations are often used as tool to assess compliance. Most relevant for adhesives are:

- Recommendation VI. Styrene Copolymers and Graft Polymers, and Mixtures of Polystyrene with other Polymers*
- Recommendation XIV. Part A. Plasticiser-free dispersions*
- Recommendation XVII. Poly(terephthalic acid diol esters)*
- Recommendation XXII. Polymers Based on Esters of Acrylic and Methacrylic Acids, their Copolymers, and Mixtures of these with other Polymers*
- Recommendation XXV. Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics
- Recommendation XXVIII. Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials
- Recommendation XXXVI. Paper and Board for Food Contact

*Recommendation includes, by reference, the Union List of Regulation (EU) No. 10/2011.

Council of European Resolutions

No Resolutions specific to adhesives exist to date. Certain resolutions for other materials can, however, be referenced when assessing the status of adhesive ingredients that are not present on the Union List or in national legislation:

- Resolution AP (2002)1, Version 4: Paper and board materials and articles intended to come into contact with foodstuffs
- Resolution AP (2004)1, Version 3: Coatings intended to come into contact with foodstuffs
- Resolution AP (2004)2, Version 2: Cork stoppers and other cork materials and articles intended to come into contact with foodstuffs
- Resolution AP (2004)3, Version 3: Ion exchange and adsorbent resins used in the processing of foodstuffs (superseding Resolution AP [97] 1)
- Resolution AP (2004)4: Rubber product products intended to come into contact with foodstuffs
- Resolution AP (2004)5: Silicones used for food contact applications
- Resolution AP (2005)2, Version 2: Packaging inks applied to the non-food contact surface of food packaging
- Technical guides under Council of Europe Resolution CM/Res(2020)9:
 - o 'Paper and Board Used in Food Contact Materials and Articles'. European Directorate for the Quality of Medicines & HealthCare of the Council of Europe, 2021.

2.6. Non-EU Legislation

If a substance is not listed in any EU Regulation, EU member state national legislation or non-binding document in the EU (as described above), non-European legislation might be used for evaluation.

US regulations

The Food and Drug Administration (FDA) is an agency of the US Department of Health and Human Services. Among other tasks, the FDA is responsible for protecting public health through the regulation and supervision of food and its safety. Two sections of the US Code of Federal Regulations Title 21, which is maintained by the FDA, that are directly relevant for adhesives in food contact are:

- 175.105 Indirect food additives: Adhesives and components of coatings -- where *indirect* food contact compliance implies that the material is separated from food by another material (functional barrier)²⁴
- 175.300 Resinous and Polymeric Coatings -- where direct food contact compliance allows direct contact with food

Further sections of Title 21, found in parts 175, 176, 177, 178, 182, 184 and 186 may provide additional relevant information.

Due to the different approach of FDA and EU regulations and the complexity of this subject, compliance with US regulations is not covered in this document.

Swiss regulations

Switzerland, not being part of the European Union nor the European Economic Area, sets its own national regulations for food contact materials. The main regulation for food contact materials in Switzerland is Swiss Ordinance 817.023.21.²⁵

Many similarities can be seen between Swiss Ordinance 817.023.21 and the EU regulations governing food contact, such as the concepts of migration limits, testing conditions, good manufacturing practice, declarations of compliance and lists of authorised materials. As a key distinction from EU regulations, this ordinance does contain specific measures for printing inks. It does not, however, provide specific measures for adhesives.

Despite similarities with EU regulation, a detailed comparison or guidance regarding compliance with Swiss regulations is not covered in this document.

²⁴ 'Functional barrier' in the context of US regulations is defined differently from the functional barrier definition in the context of EU legislation.

²⁵ In addition, Swiss Ordinance 817.02 sets out additional, more generic requirements for food contact articles and articles of everyday use.

3. Requirements placed on adhesive producers

As one part in the supply chain for food contact materials, adhesive producers need to fulfil the applicable regulatory requirements and are obliged to check the general suitability of adhesives for intended food contact applications. An appropriate evaluation of the adhesive is possible if sufficient information is available from raw material suppliers, on the adhesive formulation as well as on the final food contact application.

This chapter describes the process for the gathering of data for raw materials, the evaluation of raw materials and finally the adhesive related evaluation for the intended application (see Figure 1).

Figure 2 presents a decision tree for the adhesive user to evaluate the suitability of an adhesive candidate for the intended food contact application.

3.1. Raw Material Data Gathering

To choose the right raw materials for a new adhesive, adhesive manufacturers should receive from their raw material suppliers not only a technical or a safety data sheet but also up-to-date information covering the chemical identity, purity and food contact compliance aspects of the raw materials. Information on the presence of non-intentionally added substances (NIAS) should also be provided. The raw material information request template in Annex I provides a suggestion on which form such information can be requested.

FEICA has furthermore developed a rejection list that can help to check the status of raw material candidates against critical substances (Annex II). Information on the presence of these substances should be provided by the raw material supplier.

In case the information received from the supplier is not sufficient (e.g. no full chemical identity, no compliance information), the raw material can either be rejected or be checked and characterised by analytical screening methods to supplement the supplier-provided information.

3.2. Raw Material Evaluation

If the raw material does contain substances mentioned in the FEICA rejection list, it should be rejected.

The received information regarding the compliance of food contact regulations should be assessed in detail and checked for completeness (The supplier information request template in Annex I can serve as a guide).

Adhesives are not necessarily composed of the same substances as plastics. In order to accommodate the specific performance requirements of the many types of food contact articles (e.g. bags, pouches, boxes, chopping boards), and the variety of substrates to which adhesives are applied (e.g., plastic, paper, cardboard and wood), different kinds of adhesives, based on a wide range of substances, are necessary.

Plastic materials and articles that are held together by adhesives are consequently allowed to contain in the adhesive (layer) other substances than those authorised at the EU level for plastics (see section 2.3). Adhesive (layers) may be subject to other EU or national rules (see section 2.3 and 2.4)

For all substances listed in the Union List or otherwise authorized by Regulation (EU) No 10/2011, specific restrictions, e.g. specific migration limit (SML), maximum permitted quantity (QM) or specifications (as given 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 in the raw material are not covered by Regulation (EU) No 10/2011, this does not automatically need to result in the rejection of the material for the use in adhesives. As described in section 2.4, 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.

Raw materials may contain substances which are not authorised by any of the above-described sources and possess a molecular weight below 1,000 Dalton. This includes, in particular, non-intentionally added substances (NIAS), which are not subject to the Union List of the Plastics Regulation. For these cases, an extended risk assessment needs to be carried out. Parts of this assessment can employ toxicological data like LD (lethal dose) values, DNEL (derived no effect limit) values, ADI (acceptable daily intake) values or data on toxicodynamic or toxicokinetic behaviour of the substance(s). The risk assessment shall be done in accordance with internationally recognised scientific principles.

This list of options for an extended risk assessment does not aim to be complete and might be modified in future EU Commission guidance for risk assessment. Further guidance on the risk assessment of non-listed substances as well as NIAS is provided by the food contact additives sector group of the European Chemical Industry Council (Cefic).²⁶ The International Life Sciences Institute has published a guidance on the risk assessment of NIAS.²⁷

Regardless of the chemistry and the setting mechanism (physical or chemical), an applied and set adhesive consists principally of polymeric organic substances of high molecular weight. The polymer or polymers in the adhesive as such are typically high molecular weight structures. As substances with a molecular weight above 1,000 Dalton usually cannot be absorbed in the human body, the potential health risk from such polymers themselves is minimal.²⁸ Lower molecular weight polymers as well as the oligomeric fraction with molecular masses below 1,000 Dalton in higher molecular weight polymers should, however, be considered in the risk assessment.

Based on the above-described steps, a raw material may be evaluated as 'suitable for adhesives' or be rejected.

²⁶ Cefic document 'Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under the requirements of Article 3 of the Framework Regulation (EC) 1935/2004'

²⁷ ILSI document 'Guidance on Best Practices on the risk assessment of non-intentionally added substances (NIAS) in food contact materials and articles'

²⁸ Regulation (EU) No 10/2011, Recital 8: '[...] 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. [...]

3.3. Adhesive formulation specific evaluation

When the raw material has been assessed as 'suitable for adhesives', it may be used in a new adhesive formulation.

Focus should be given to potential restrictions laid down on the Union List in Regulation (EU) No 10/2011 (column 8 or 9) and to the specifications (column 10).

If the concentration of a substance with migration potential in the adhesive cannot be determined from supplier-provided raw material information,²⁹ specific analytical testing may be employed to generate the required data.

Under consideration of the recommended adhesive application (adhesive layer thickness, surface to volume ratio), worst case calculation³⁰ can in some cases already help to establish the compliance of the final food contact material with respect to the adhesive. In this case, the recommended conditions of use should be communicated to the downstream user in the Food Contact Status Declaration.

As adhesives are not yet covered by a specific EU legislation, adhesive manufacturers are not subject to the requirement to provide a Declaration of Compliance. The Plastics Regulation (EU) No 10/2011 also does not set out an obligation to issue a Declaration of Compliance for non-plastic constituents of plastic articles.

However, the Plastics Regulation requires that migration of authorised substances and certain other substances not exceed the established migration limits for plastics even in the presence of non-plastic materials. It is therefore necessary that 'adequate Information' be 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. The adequate Information for adhesives is summarised in the Food Contact Status Declaration issued by the adhesive producer (For a template for a Food Contact Status Declaration for adhesives, see section 6).

²⁹ Such as in the case of missing information but also where raw materials react with each other to form the ready-to-use adhesive or if NIAS are formed during the production of the adhesive

³⁰ Assuming a full transfer of the whole quantity of migratable substances into the food

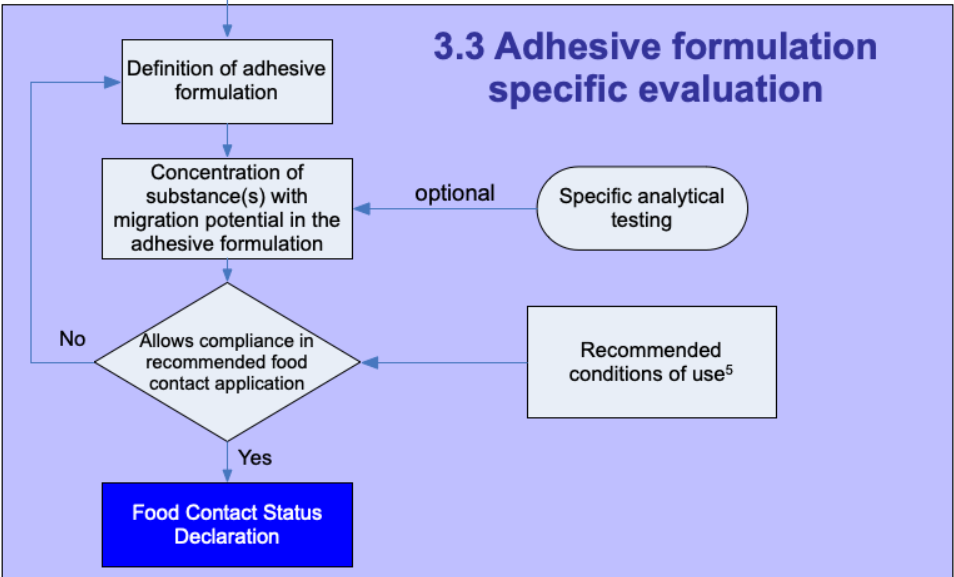
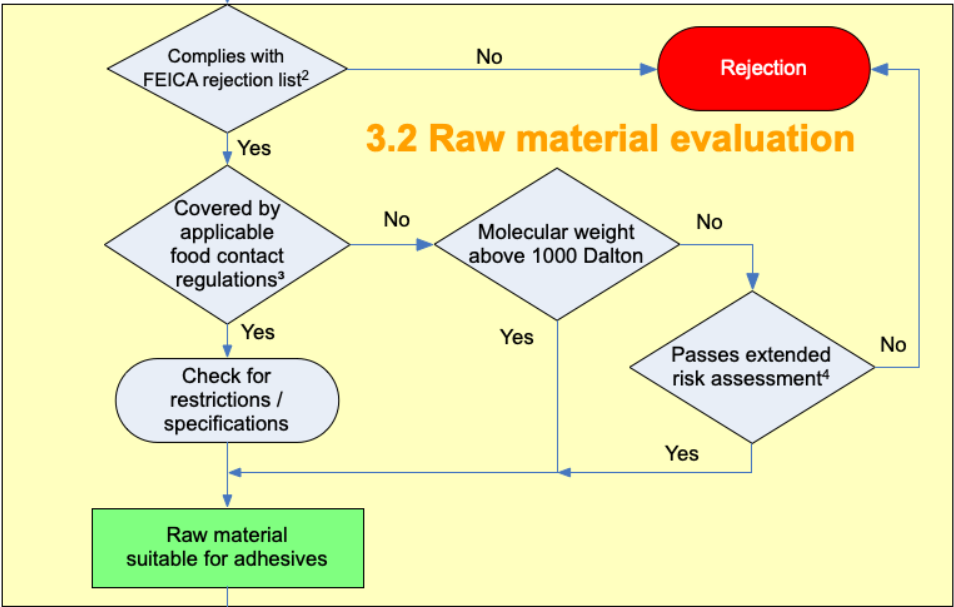
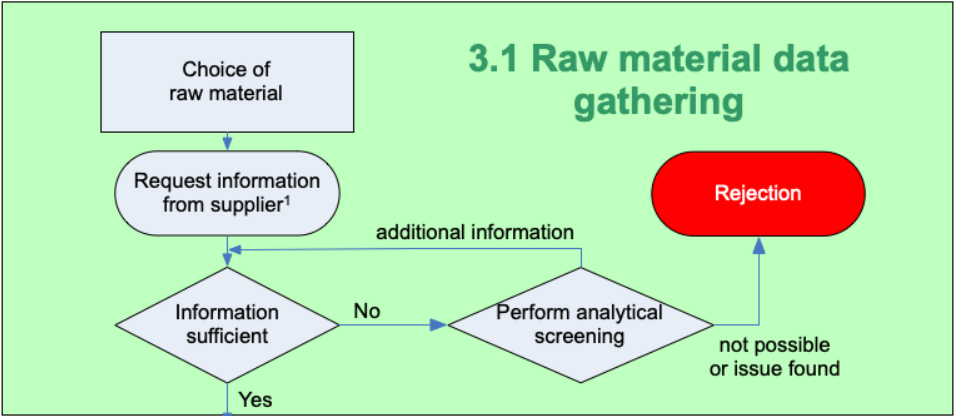


Figure 1. Flow chart for the assessment of raw materials and adhesive formulations. (1. see Annex I for an information request template; 2. see Annex II; 3. see sections 2 and 3.2; 4. see explanations under 3.2; 5. see explanations under 3.3)

3.4. Evaluation of the adhesive by the downstream user

In general, the adhesive is applied on a substrate, which may form a part of the packaging or any other food contact material or article. This substrate typically separates the adhesive from the food³¹ and can represent either

- a total barrier (no migration into the food is possible)
- a functional barrier (ensures that the final material or article complies with Article 3 of Regulation [EC] No 1935/2004 and any material-specific measures such as Regulation [EU] No 10/2011)³²
- almost no barrier – as is the case, for example, for paper and some thin polymer films (possible migrants can easily migrate through the substrate into the food)

A functional barrier ensures that all possible migrating substances do migrate only in amounts that comply with Article 3 of Regulation (EC) No 1935/2004, that is, migration does not exceed relevant migration limits (e.g., SML, SML[T], non-detection limit).

If the substrate does not present a functional barrier to the possible migrating substances of the adhesive, and if the concentrations of migrating substances in the adhesive are known, a worst-case calculation³³ can be carried out, where the amount of adhesive in packaging and the surface to volume ratio of packaging and food are taken into account.

The needed concentration data for migrating substances can be provided by the adhesive supplier to the adhesive user. Alternatively, the adhesive supplier can calculate the worst case and provide the maximum possible application weights³⁴ up to which relevant migration limits will be respected. This approach is consistent with EU guidance that compliance work shall be concluded as high up the manufacturing chain as possible.³⁵

In the case that concentration information is available for migrating substances, but a worst-case calculation does *not* prove compliance with relevant migration limits, either a migration modelling or a migration test can be performed to confirm whether the adhesive can be considered as safe for the intended application.

It is the nature of worst-case calculation that it may strongly overstate migration; migration modelling in software may therefore provide migration values substantially closer to reality and is an approach recognized in Regulation (EU) No 10/2011. The Joint Research Centre of the European Commission has published a technical guideline on the application of migration modelling to the verification of specific migration limits.³⁶

³¹ Exceptions to this rule comprise cold seal and heat seal coatings which perform an adhesive function in the closing of packaging.

³² Commission Regulation (EU) No 10/2011: '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 Article 3 of Regulation (EC) No 1935/2004 and with the provisions of this Regulation

³³ Assuming a full transfer of the full quantities of migratable substances into the food

³⁴ Specified relative to packaging geometry or amount of food

³⁵ EC Document 'Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain'

³⁶ JRC Document 'Practical Guidelines on the Application of Migration Modelling for the Estimation of Specific Migration'

Where the concentrations of migrating substances are *not* available or where migration modelling is not sufficient to demonstrate compliance, migration testing can be performed on the finished food contact material or article, following the relevant provisions, such as for plastics those laid down in Regulation (EU) No 10/2011. Migration testing is the approach for verification of compliance that is closest to the real food contact situation.³⁷

In addition to assessing migration, the possibility of substance transfer by set-off (for example in a reel or stack where the outer layer of packaging is in direct contact with the inner layer) should be considered by the adhesive user.

³⁷ See also FEICA Guidance Paper 'Migration testing of adhesives intended for food contact materials'

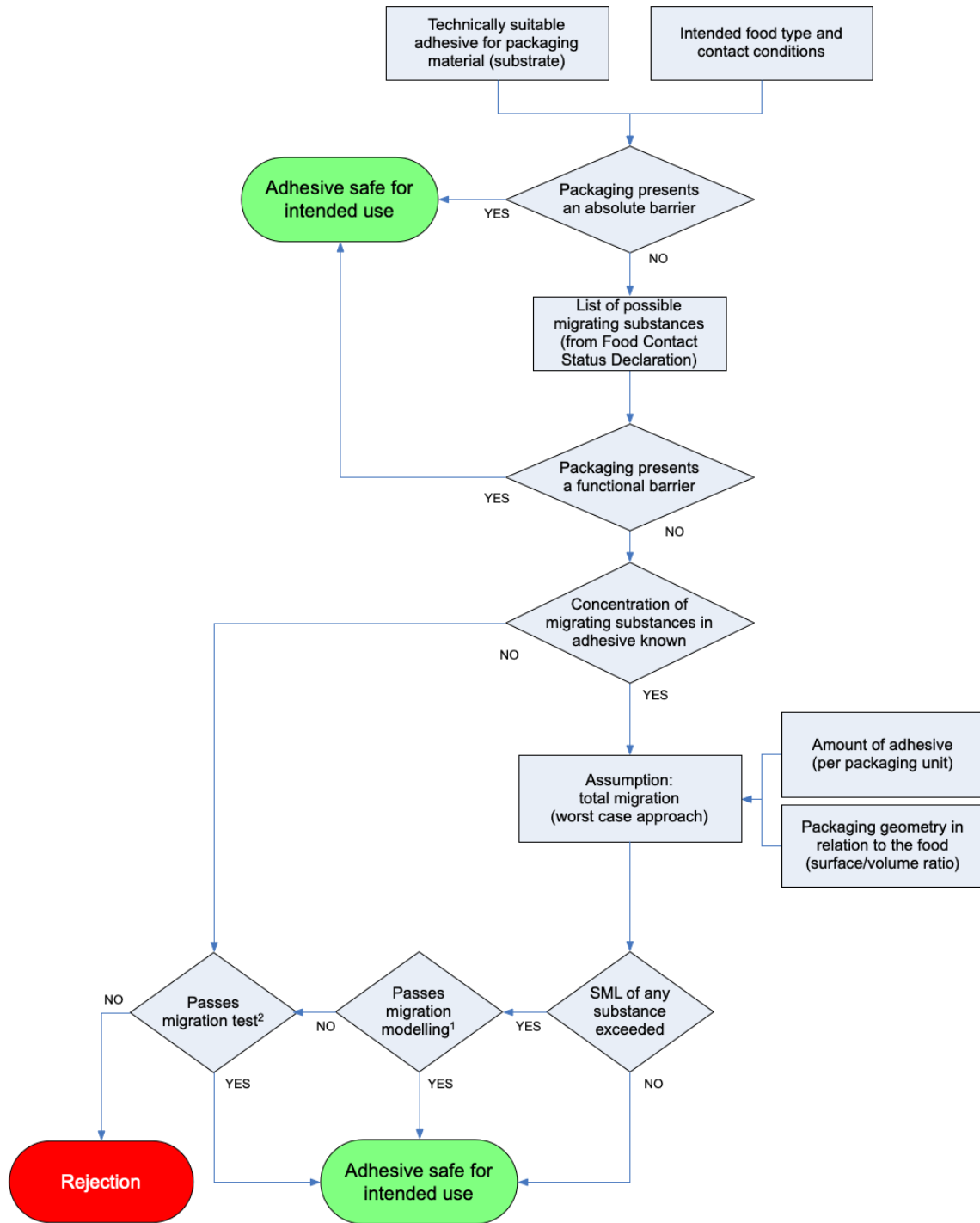


Figure 2. Flow chart for the assessment of the safe use of adhesives by the downstream user. (1. For example, using INRA ['Migresives' project], FABES MIGRATEST, SML Advanced of AKTS AG; 2. Internal or external testing, preferably at an accredited laboratory).

4. Template for a Food Contact Status Declaration for adhesives

1. Identity and address of the adhesive manufacturer
2. Product name
3. Date
4. Product Compliance Status with EU and non-EU regulations
 - a. (EC) No 1935/2004 – GMP and traceability, Article 3 as applicable
 - b. (EC) No 2023/2006 – GMP regulation
 - c. (EU) No 10/2011 – Plastics regulation
 - i. Are all substances present in the adhesive listed in the Union List?
(If not all substances are listed see point d. for further options for risk assessment)
 - ii. Information on substances with restrictions (SML, SML[T]), specification, etc. in accordance with Annex I and Annex II (e.g. metals, primary aromatic amines)³⁸ of the regulation and information on intentionally used substances for which genotoxicity has not been ruled out
 - iii. Information on dual use additives, if the food additive or flavouring substance has a restriction in food (identity of substance as listed in the European legislation on additives [Regulation (EC) No 1333/2008] or flavourings [Regulation (EC) No 1334/2008] in the form of substance name and E-number or FL number)
 - iv. Information on non-authorized substances if evaluated as relevant (e.g. NIAS, that is, impurities, reaction products, reaction by-products or decomposition products)
 - d. Compliance status with other legislation and measures
 - i. National legislation of EU-member states, as applicable (see section 2.4)
 - ii. Recommendations (see section 2.5)
 - iii. Non-EU Legislation (see section 2.6)
 1. FDA (e.g., Code of Federal Regulations Title 21, part/section 175.105, 175.300, 176.170, 176.180, 177.1390 and 177.1395)
 2. Swiss Ordinance 817.023.21
 3. Other (as applicable/requested)
 - e. Demonstration of compliance by other measures
If none of the above listed options can be applied to demonstrate the suitability of the product or one or more 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 simulated conditions of the intended food contact application.
5. If the information given under 4 is not sufficient to demonstrate compliance, the adhesive supplier may need to recommend the application of a (functional) barrier.
6. 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 (e.g. time, temperature, food simulants). The downstream user also needs to evaluate the possible influence on the organoleptic properties of the food.

³⁸ See also FEICA Guidance paper 'FEICA recommendation to adhesive suppliers and users on the assessment of PAAs in polyurethane adhesives intended to be used in food packaging'

Disclaimer:

Please add your company's legal disclaimer.

5. Contact

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Annex I: Request template for information from raw material suppliers

1. Date
2. Identity and address of the raw material supplier
3. Chemical identification of the raw material (e.g. CAS number, PM Ref, FCM, EINECS and typical molecular weight)
4. Information about purity and the presence of non-intentionally added substances (NIAS)
5. 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. Regulation (EC) No 2023/2006 – GMP regulation (as far as applicable)
 - c. Regulation (EU) No 10/2011 – Plastics regulation:
 - i. Substances on the Union List with restriction, including maximum concentration in the raw material
 - ii. Substances subject to restriction by Annex II of the Regulation
 - iii. Non-authorised substances for which genotoxicity cannot be ruled out
 - iv. Non-authorised substances including NIAS³⁹ if they can be reasonably expected to migrate, including maximum (residual) concentration and risk assessment (e.g., other food contact legislations/toxicological evaluations/CMR studies)
 - v. Dual use additives,⁴⁰ including maximum concentration and identity of the substances as listed in the European legislation on additives, Regulation (EC) No 1333/2008, or flavourings, Regulation (EC) No 1334/2008 (Substance name, E-number or FL number)
 - d. Other regulations and recommendations (EU member states legislation, Swiss Ordinance, BfR etc.), FDA (e.g. 21 CFR 175.105), including applicable restrictions
6. Compliance with the FEICA rejection list (Annex II of this document)
7. Confirmation by the raw material supplier that the adhesive producer will be notified without delay in case any of the information provided relative to points 1-6 changes or ceases to be correct.

³⁹ 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 1,000 Da)

⁴⁰ 'Dual use additive' means additives as listed in Annex I to Regulation (EU) No 10/2011 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

The 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 for adhesives should confirm the compliance with the following provisions:⁴¹

1. Substances and preparations should not be classified as carcinogens, mutagens and reprotoxic chemicals (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 Union List of Regulation (EU) No 10/2011
2. Article 11 of European Parliament and Council Directive 94/62/EC of 20 December 1994 (as amended) 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. Alkanes, C10-C13, chloro (Short Chain Chlorinated Paraffins) (CAS 85535-84-8) should not exceed concentrations above 0.1% (REACH candidate list of substances of very high concern for authorisation)
4. Neither phthalates nor azo colorants should exceed concentrations of 0.1% according to Annex XVII of Regulation [EC] 1907/2006
5. Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
6. 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
7. Restrictions to nonylphenol (REACH candidate list of substances of very high concern for authorisation)
8. Regulation (EU) No 412/2012, related to dimethylfumarate
9. Directive 2011/65/EU (ROHS), as amended, complying with restrictions to polybrominated biphenyls (PBBs) and polybrominated diphenyl ethers (PBDEs)

⁴¹ This document cites the initial EU legal acts (regulations, directives). Many of these acts have been revised or amended since their original publication. The citations shall therefore be understood as referring to the respective regulations/directives in their current form, as amended.

Annex III: Useful Links

Europe

- European Food Safety Authority/EFSA: <https://www.efsa.europa.eu/>
(EFSA opinions: <https://www.efsa.europa.eu/en/publications.htm>)
- Council of Europe resolutions: <https://www.edqm.eu/en/resolutions-policy-statements> and <https://www.edqm.eu/en/food-contact-materials-and-articles>
- EU food contact material database: https://webgate.ec.europa.eu/foods_system/
- Overview of European Food Contact legislation: https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation_en
- EU Guidance on Regulation (EU) No. 10/2011 and EU Guidance on information in the plastics supply chain: https://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/related-docs_en

European Member State regulations

- German Bundesinstitut für Risikobewertung, Database BfR Recommendations on Food Contact Materials: https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp
- Warenwet (Netherlands):
 - <https://wetten.overheid.nl/BWBR0034991/2020-07-01>
(for packaging and articles that come in contact with food)
 - <https://wetten.overheid.nl/BWBR0001969/2021-07-01>
(overall 'warenwet' dealing with all articles - law originating from 1935)

Other countries

- US Government Printing Office, texts of regulations: <https://www.govinfo.gov/app/collection/cfr>
- Online version of Title 21 of the Code of Federal regulations: <https://www.ecfr.gov/current/title-21>
- US Food and Drug Administration website, in particular
 - Food contact notifications: <https://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/Notifications/default.htm>
 - Threshold of regulation exemptions: <https://www.fda.gov/food/ingredientpackaginglabeling/packagingfcs/thresholdregulationexemptions/default.htm>
 - Generally Recognised as Safe (GRAS) notices inventory: <https://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/default.htm>
 - List of indirect food additives: <https://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=iaListing&displayAll=true>
 - Everything added to food in the USA: <https://www.accessdata.fda.gov/scripts/fdcc/?set=FoodSubstances>

- Swiss Ordinances (full texts available in French, German and Italian, no translations into English)
 - Ordinance 817.02 ('framework regulation'):
<https://www.admin.ch/opc/de/classified-compilation/20143388/index.html>
 - Ordinance 817.023.21 on food contact materials: <https://www.admin.ch/opc/de/classified-compilation/20143393/index.html>
 - Annex 2 (Plastics): <https://www.blv.admin.ch/verpackungen>
 - Annex 9 (Silicones): <https://www.blv.admin.ch/verpackungen>
 - Annex 10 (Printing inks): <https://www.blv.admin.ch/verpackungen>