TKPV-Briefing Note 2

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Industrieverband Klebstoffe e.V.

Guideline

Food Legislation Status of Adhesive Raw Materials

for Adhesives used in the Manufacture of Materials and Articles intended to come into Contact with Food

Compiled and revised by the Technical Committee Paper and Packaging Adhesives (TKPV) of the Industrieverband Klebstoffe e.V. (German Adhesives Association), Düsseldorf, Germany.

Legal provisions can change at short notice. This technical briefing note will therefore only be published online.

This briefing note is available for free download at www.klebstoffe.com, Industrieverband Klebstoffe e.V.

General information concerning the series of TKPV Technical Briefing Notes "Conformity work relating to adhesives used in the manufacturing of materials and articles intended to come into contact with food"

A number of special legal requirements and industry standards apply to adhesives used in the manufacturing of materials and articles intended to come into contact with food – e.g. food packaging. This serves consumer protection. By compiling this series of technical briefing notes the Technical Committee Paper and Packaging Adhesives (TKPV) of the Industrieverband Klebstoffe e.V. wants to make these legal requirements and industry standards more transparent. In this series, specific requirements regarding adhesives, their production as well as the selection procedures for appropriate adhesive raw materials will be described. Furthermore, they contain recommendations on the implementation of the Regulation concerning "good manufacturing practice" and hygienic standards during production.

TKPV 1	Guideline – Food legislation status of adhesives used in the manufacturing of materials and articles intended to come into contact with food
TKPV 2	Guideline – Food legislation status of adhesive raw materials for adhesives used in the manufacturing of materials and articles intended to come into contact with food
TKPV 3	Guideline – "Good manufacturing practice" for adhesives used in the manufacturing of materials and articles intended to come into contact with food
TKPV 4	Guideline – Hygiene during production of adhesives used in the manufacturing of materials and articles intended to come into contact with food

Currently, European food legislation does not demand declarations of compliance for adhesive raw materials which ensure that individual components of adhesives comply with food legislation requirements. Nevertheless, the distributor of packaged foodstuffs requires from all partners throughout his packaging material supply chain adequate information on these issues. This information is necessary to enable the partner to fulfil the corresponding rules of the Regulation (EC) No 1935/2004. In order to forward this information in a structured manner, the member companies of the Industrieverband Klebstoffe have voluntarily agreed on an information format. This allows them to describe the food legislation status of raw materials for adhesives which are used in the manufacturing of materials and articles intended to come into contact with food.

This will make the food legislation status of products throughout the supply chain "adhesive raw material manufacturer ⇨ adhesive manufacturer ⇨ converters of adhesives" more transparent.

At the same time, the members of the Industrieverband Klebstoffe document their pronounced sense of responsibility for appropriate consumer information along the supply chain in the food and food-related sector.

This technical guideline provides information on the legal background and describes this information format.

Legal Background

EU Regulation (EC) No 1935/2004 on "materials and articles intended to come into contact with food" of 27 October 2004 applies to all Member States of the European Union. It defines general conditions for materials and articles that, as finished products, are intended to come into contact with food. Of particular interest in this context is Article 3 of this Regulation, which regulates the interactions of these materials and articles with the respective food.

Furthermore, Annex I of this Regulation lists groups of materials and articles for which specific regulations (specific measures) can be adopted.

To date, no such EU specific measure exists for adhesives and the raw materials used in adhesives. Therefore the requirement for a declaration of conformity within the meaning of Article 16 of EU Regulation (EC) No 1935/2004 does not apply to adhesives. Hence, a legally binding declaration of conformity cannot be issued.

Nevertheless, it must still be ensured that materials and articles intended to come into contact with food (e.g. as food packaging) comply with the requirements of Article 3 of Regulation (EC) No 1935/2004. For this purpose, a risk assessment of the finished food packaging is necessary.

Such a risk assessment can be performed at any stage of the supply chain, beginning with the raw material manufacturer.

Ultimately, anyone who distributes packaged foodstuffs must document that the requirements of European Regulation (EC) No 1935/2004 have been fulfilled.

Relevant information for the risk assessment to be performed on the raw materials used for adhesives in the manufacturing of materials and articles intended to come into contact with food can be found, if available in the European regulations. One of these regulations is e.g. Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (Plastic Materials Regulation). Furthermore, national regulations of EU Member States may also be consulted for the risk assessments. Examples of this would be the Dutch "Warenwet" and the Italian Decreto Ministeriale 21/3/72". Furthermore, the food legislation risk assessment may also take into consideration national or European recommendations. Examples of these include recommendations of the Federal Institute for Risk Assessment (BfR), the "EFSA opinions" and the "CoE Resolutions".
The applicability of national regulations corresponds to the principle of "mutual recognition".

If substances are used, for which such relevant information is not available, or if limits are listed for substances in the above stated Regulations, then the corresponding substances must be specified, provided that due to their migration potential, they may pose a risk (analogous to Regulation (EU) No 10/2011, Article 19). Only when the raw material manufacturers provide adequate information, the adhesive manufacturer can forward this information to its customers.

Further substances which must be considered for the risk assessment are dual use substances with limitations for use in foodstuffs, provided that, due to their migration potential, they may pose a risk (analogous to Regulation (EU) No 10/2011, Article 19).

Further references on the communication of information in the supply chain can be found in the Union Guideline to Regulation (EU) No 10/2011.

This information helps the adhesive manufacturers and their customers to prepare a risk assessment at the level of the finished product. In doing that, he may also refer to internationally recognized scientific principles and rules, e.g. the US FDA Regulations, or national regulations of non-EU Member States, e.g. Switzerland.

Examples of a document for communicating food legislation information about an adhesive can be found at the end of this technical guideline.

A combination of Regulation (EU) 10/2011, national regulations or recommendations of the EU Member States, such as the BfR and other risk assessment avenues, result in many options for evaluating the food legislation status of adhesive raw materials for adhesives used in the manufacturing of materials and articles intended to come into contact with food.

The term "starting substance" in options A to C below, comprises monomers and other starting substances together with additives, adjuvants and polymerization adjuvants, within the meaning of Regulation (EU) No 10/2011.

In addition to the starting substances, the document must also communicate information about substances that, based on currently available information, are unintentionally contained in the adhesive provided, due to their migration potential, they may pose a risk (analogous to Regulation (EU) No 10/2011, Article 19).

Procedure for creating the document for communicating information:

1. If the starting substances used to produce the adhesive raw material are fully approved according to Regulation (EU) No 10/2011 (Union list) the document can be created in accordance with option A.
2. If the adhesive raw material contains further starting substances that are not approved according to Regulation (EU) No 10/2011 (Union list), but meet the requirements of national (EU Member States) regulations or recommendations, e.g. a BfR recommendation, the document can be generated in accordance with option B.
3. If the adhesive raw material contains further starting substances that are neither approved according to Regulation (EU) No 10/2011 (Union list), nor meet the requirements of national (EU Member States) regulations or recommendations, e.g. a BfR recommendation, the document must be generated in accordance with option C.
4. If the suitability of the adhesive raw material for its intended use has been verified by an appropriate test performed by a specialist department or external testing laboratory, the document can be generated in accordance with option D.
5. If the adhesive raw material meets the requirements of an FDA paragraph, a supplement can be incorporated into the document in accordance with option E.

Option A **The adhesive raw material is listed in the Union list of Regulation (EU) No 10/2011 and/or only starting substances are used in the manufacturing of this adhesive raw material which are listed in the Union list of Regulation (EU) No 10/2011.**

Procedure:

1. Information is provided on the starting substances used, to which legal limitations or specifications apply (e.g. about specific migration limits (SMLs) and dual-use substances).
2. In addition to the starting substances mentioned in point 1, the known substances that are relevant to the risk assessment should be listed. Legal limitations or specifications are to be stated. For non-regulated substances a risk assessment must be performed, e.g. by the adhesive raw material manufacturer. Alternatively, non-listed substances must be stated, so that a corresponding risk assessment can be carried further along the supply chain.

Food legislation product information (example)

The adhesive raw material is itself listed in the Union list of Regulation (EU) No 10/2011 or in the manufacture of this adhesive raw material only such starting substances are used that are approved in accordance with the Union list of Regulation (EU) No 10/2011.

The following limitations apply:

Starting substances	**Regulation / limitation**	**Concentration in adhesive x (mg/kg)**
Vinyl acetate	*SML (EU No.10/2011)/12 mg/kg*	*Indication recommended (max. value)*
Ascorbic acid	*Dual Use (EU xyz)*	*Indication recommended (max. value)*
Other substances		
Formaldehyde	*SML (EU No.10/2011)*	*Indication recommended (max. value)*

Information about reaction products that can occur during further processing of the adhesive will not be considered here.

Option B **Starting substances that are (also) used in the manufacturing of the adhesive raw material and that are not listed in the Union list of Regulation (EU) No 10/2011. However, these starting substances meet the requirements of national regulations (of the EU Member States) e.g. a BfR recommendation.**

Procedure:

1. Information is provided on the starting substances used, for which legal limitations or specifications exist (e.g. specific migration limits (SMLs) in accordance with Regulation (EU) No 10/2011, or quantity limitations exist in accordance with BfR-recommendation XIV and dual-use substances).
2. In addition to the starting substances mentioned in point 1, the known substances that are relevant to the risk assessment should be listed. Legal limitations or specifications are to be stated. For non-regulated substances a risk assessment must be performed, e.g. by the adhesive raw material manufacturer. Alternatively, non-listed substances must be stated, in order to allow a corresponding risk assessment to be performed further along the supply chain.

Food legislation product information (example)

During the manufacture of the adhesive raw material some starting substances are used that are listed in the Union list of Regulation (EU) No 10/2011. All other starting substances used fulfil the requirements of national regulations (of EU Member States) e.g. BfR-recommendation XIV (plastic dispersions).

The following limitations apply:

Starting substances	Regulation/limitation	Concentration in adhesive x (mg/kg)
e.g. vinylsulfonic acid	*BfR XIV/SML: xx mg/kg*	*Indication recommended (max. value)*
e.g. vinyl acetate	*(EU) No. 10/2011/ SML: xx mg/kg*	*Indication recommended (max. value)*
e.g. emulsifier	*(EU) No. 10/2011/SML: xx mg/kg*	*Indication recommended (max. value)*

Other substances

Other substances can be stated at the discretion of the raw material manufacturer.

Information about reaction products that can occur during further processing of the adhesive will not be considered here.

Option C **The adhesive raw material itself is not listed in the Union list of Regulation (EU) No 10/2011, or during production of this adhesive raw material, starting substances are being exclusively or partially used that are neither listed in Regulation (EU) No 10/2011 nor in a national regulation (of the EU Member States), neither is information available to enable an appropriate risk assessment of these substances to be performed.**

Procedure

1. The procedure in accordance with options A or B applies to the listed starting substances.
2. Non-listed starting substances must first undergo a risk assessment. This can be carried out by the adhesive raw material manufacturer. Alternatively the non-listed starting substances must be specified in order to allow a corresponding risk assessment to be performed.
3. In addition to the starting substances mentioned in points 1 and 2, the known substances that are relevant to the risk assessment should be listed. Legal limitations or specifications are to be stated. For non-regulated substances a risk assessment must be performed, e.g. by the adhesive raw material manufacturer. Alternatively, non-listed substances must be stated, in order to allow a corresponding risk assessment to be performed further along the supply chain.

The application of national non-European assessment regulations (e.g. FDA) should be appropriate for the distributor's risk assessment.

Food legislation product information (example)

During the manufacture of the adhesive raw material some starting substances are used that are neither listed in the Union list of Regulation (EU) No 10/2011 nor in a national regulation (of EU Member States), e.g. a BfR-recommendation.

The following limitations apply:

Starting substances	Regulation/limitation	Concentration in adhesive x (mg/kg)
e.g. vinylsulfonic acid	*BfR XIV/SML: xx mg/kg*	*Indication recommended (max. value)*
e.g. vinyl acetate	*(EU) No. 10/2011/ SML: xx mg/kg*	*Indication recommended (max. value)*
e.g. emulsifier	*(EU) No. 10/2011/SML: xx mg/kg*	*Indication recommended (max. value)*
e.g. monomers	*No assessment*	*Indication recommended (max. value)*

Other substances

Other substances can be stated at the discretion of the raw material manufacturer.

Information about reaction products that can occur during further processing of the adhesive will not be considered here.

Option D **The suitability of the adhesive raw material for its intended purpose has been verified by an appropriate test performed by a specialist department or external testing laboratory**

Procedure:

1. Testing of the adhesive raw material by an appropriate specialist department or corresponding external testing laboratory in terms of its suitability for its intended purpose.
2. Verification of suitability is provided by a test report in which potential limitations (e.g. in terms of the volumes to Food legislation product information (example)

Food legislation product information (example)

The suitability of the adhesive raw material for its intended purpose has been verified by an appropriate test performed by a specialist department or external testing laboratory/institute. Please find a copy of the test report enclosed. Any limitations listed there must be observed.

Option E **The adhesive raw material meets the requirements of one or more FDA paragraphs (e.g. 21 CFR 175.105 "Adhesives") and may be used in the manufacture of adhesives/food packaging in compliance with the Federal Food, Drug and Cosmetic Act.**

Procedure:

1. Testing of the adhesive raw material to establish if the requirements of one or more FDA paragraphs are met.

Additional food legislation product information (example)

The adhesive raw material meets the requirements FDA paragraphs xyz (e.g. 21 CFR 175.105 "Adhesives"), which are not valid in Europe, and may be used in the manufacture of adhesives/food packaging in compliance with the Federal Food, Drug and Cosmetic Act.

Information about reaction products that can occur during further processing of the adhesive will not be considered here.

Example of an Information Sheet Describing the Food Legislation Status of an Adhesive Raw Material

Raw Material XYZ

Food legislation product information for the assessment of the finished product according to (EC) No 1935/2004:			
Regulation /Specific Measures	**Starting Substances*)**	**listed**	**non-listed**
Regulation (EU) No 10/2011		☒	☐
Not listed		☒	☐
Nicht gelistet		☒	☐

Starting Substances with Limitations			
Starting Substances	**%**)**	**Regulation /Limitation**	
		(EU) Nr. 10/2011	**BfR, Recommendation XIV**
A	< 0.1000	SML***) XY mg/kg	no limitation
B		SML***) XY mg/kg	SML***) XY mg/kg
C	< 0.0100	not listed	max. XY µg / dm² in the dispersion film
D	< 0.0100	not listed	max. XY µg / dm² in the dispersion film

Non-listed starting substances and/unintentionally introduced substances with limitations			
	%)**	**Regulation /Limitation**	
		(EU) No. 10/2011	**BfR, Recommendation XIV**
E (Starting Substance)	< 0.0100	not listed	not listed
F	< 0.050	SML***) XY mg/kg	no limitation
G	< 0.01	SML***) XY mg/kg	SML***) XY mg/kg

*) The term "starting substance" comprises, within the meaning of Regulation (EU) No 10/2011, monomers and other starting substances, additives, adjuvants and polymerization adjuvants.
**) Indication optional (maximum value)
***) SML Specific Migration Limit

Note: This information sheet serves only as an example. Depending upon option A – C being described, the raw material and the raw material manufacturer, the format and content of the information sheet may vary.

Relevant Legal Regulations

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and on repealing Directives 80/590/EEC and 89/109/EEC

Commission Regulation (EU) No 10/2011 and subsequent Directives of 14 January 2011 on plastic materials and articles intended to come into contact with food

Union Guidance on Regulation (EU) No. 10/2011 on materials and articles intended to come into contact with food, in relation to the communication of information throughout the supply chain

Commission Regulation (EU) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food

The recommendations and data given in this technical guideline are to the best of our knowledge in keeping with the present state-of-the-art. They are intended purely for information and as non-committal guidelines. Therefore, no warranty claims can be derived from them.

All available leaflets of the

Technical Committee Paper and Packaging Adhesives (TKPV)

of the Industrieverband Klebstoffe e.V.

can be found in the currently valid version at

www.klebstoffe.com

The information platform on the internet.