

TKPV-Briefing Note 4

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Guideline

Hygiene during the Production of 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.

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.

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| 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 |

Contents

Introduction.....	3	6.2	Storage	7
The Task	3	7.	Shipping.....	7
Public Health Rule Situation and HACCP Concept.....	3	7.1	Transport	7
How can Customer Hygiene Requirements be Ensured?.....	4	7.2	Pest Control	7
1. Hygiene Management.....	5	8.	Microbiological Requirements.....	8
1.1 The Hygiene Supervisor	5	9.	Documentation	8
1.2 Hygiene Monitoring.....	5	10.	Summary	8
1.3 Documentation.....	5	11.	Relevant Legal Regulations.....	9
2. Requirements of Employees.....	5	12.	Sample Letter	10
2.1 Personal Hygiene	5			
2.2 Hygiene Training	5			
2.3 Customers and Other Visitors.....	5			
3. Break Rooms and Sanitary Facilities	5			
4. Premises and Machinery	6			
4.1 Cleaning.....	6			
4.2 Ventilation.....	6			
4.3 Lighting	6			
4.4 Maintenance and Repair	6			
4.5 Infrastructure.....	6			
4.6 Spatially Separated Production Areas, Contract Manufacturers, Dealers.....	6			
5. Hazards Arising from Foreign Matter	7			
5.1 General Measures	7			
5.2 Incomplete List of Potential Foreign Matter.....	7			
6. Raw Materials and Products	7			
6.1 Suppliers	7			

Introduction

Regulation (EC) No 852/2004 of the European Parliament and of the Council on the hygiene of foodstuffs deals with European legislation relating to the harmonization of the different requirement systems in Europe. Its aim is to implement criteria for protecting the quality of products and thereby the health of citizens. This is a purpose inherent to food packaging, because it protects the product from damage and contamination.

To this aim, the packaging and food industry have always worked closely together. Adhesives fulfil an important function without being outwardly visible. They ensure the functionality of packaging and support the protection of the product and consumer. To fulfil hygiene requirements, it is of the utmost importance that all parties throughout the supply chain, from risk assessment through process controlling to correct raw material selection, work closely together. This requires a concept that also can be integrated into a QM System according to ISO 9000 et. seq.

The Technical Committee for Paper and Packaging Adhesives (TKPV) has compiled this guideline for members of the Industrieverband Klebstoffe as a service partner of the packaging and food industry. It offers factual and legal advice on how the increasing hygiene requirements for adhesives used in the manufacturing of materials and articles intended to come into contact with food can be fulfilled. This does not necessarily mean that an additional system with external certification must be installed alongside an already existing quality assurance system. With the aid of this guideline, member companies of the Industrieverband Klebstoffe can establish a hygiene management system that ensures the necessary hygiene standards.

This guideline was compiled in accordance with the "Guidelines for Hygienic Production of Plastic Food Packaging" – Edition 2000 – and in close coordination with the Industrievereinigung Kunststoffverpackungen (German Plastics Packaging Industry Association), Bad Homburg (Germany). We would like to express our sincere thanks for this cooperation.

The TKPV has also developed a sample letter on the issue of "Hygiene Management" to which this guideline will refer. The sample letter is appended to this guideline as an Annex.

The Task

The adhesive manufacturing industry has long been supplying the food industry, either directly or indirectly via the packaging manufacturers, with a great variety of products for the manufacture of materials and articles intended to come into contact with food. These adhesives have proven themselves time and again. They make it possible to produce food packaging with impeccable hygiene and to handle it at all processing and distributing stages through to the final consumer.

The high standard of quality of these adhesives is ensured by employing a quality management system, e.g. in accordance with DIN EN ISO 9001.

In the meantime, Regulation (EC) No 852/2004 has harmonized European law in the field of food hygiene legislation. It stipulates that the food industry is obliged to take measures, using the so-called HACCP Concept, to ensure the hygienic manufacturing of food.

This can result in far-reaching demands being made by the food industry on packaging manufacturers and thereby also on adhesive manufacturers. The present guideline, which was compiled by the TKPV on behalf of the Industrieverband Klebstoffe and in accordance with existing packaging industry guidelines, is therefore intended to inform manufacturers of adhesives used in the manufacture of materials and articles intended to come into contact with food, on how to adapt to this new situation.

Public Health Rule Situation and HACCP Concept

HACCP (Hazard Analysis and Critical Control Point) is a concept developed for the food industry for performing self-monitoring at their own businesses. An internationally binding version of the HACCP Concept is defined in a body of rules and regulations issued by the Codex Agricultural Commission (CAC) of the Food & Agriculture Organization (FAO) and the World Health Organization (WHO) as "A system which identifies, evaluates, and controls hazards which are significant for food safety." (FAO/WHO codex Alimentarius Commission: General Principles of Food Hygiene. Annex: "Hazard Analysis Critical Control Point (HACCP) System and Guidelines for its application"). In order to apply the HACCP Concept to the food industry a HACCP plan must first be established that takes into account the following HACCP principles:

Performing the Hazard Analysis:

- Determine the critical control points (CCPs)
- Establish one or more critical limits
- Establish a monitoring system
- Establish corrective actions in case of CCPs control loss
- Document all instructions and results

This brief characterization of the HACCP concept already clearly shows that, in its international version, it is not directly applicable to the adhesive industry. The requirements of the Hygiene Regulation, respectively of corresponding national laws of the Member States, relate expressly to the permanent establishments, fixtures, machinery, equipment and personnel of food manufacturing companies themselves and not to their supplier companies.

With the HACCP concept, the food manufacturer is supposed to test at which points of the food manufacturing process contamination of any type can affect the quality and hygiene status of the food. This ultimately also includes the packaging and preliminary products used therein, which ensure the clean and hygienically perfect condition of the food from completion of production to its consumption by the consumer. Therefore, the packaging material itself must be clean and hygienically faultless, which in turn pre-supposes the use of hygienically faultless components.

For the food manufacturer, packaging can be a CPP (Critical Control Point). In such a case, the manufacturer will request corresponding information and, where appropriate, also measures to be implemented by the packaging manufacturer and his downstream suppliers, in order to assess the hygiene hazard and minimize the risk. However, in general, verification of "risk-free" use continues to be sufficient. For example:

- Information on the company quality assurance system
- Mandatory product and supplier specifications

Upon request by the customer, it may also become necessary to comply with and verify defined special agreements concerning hygienic aspects of the transportation and secondary packaging of the adhesive to be supplied.

How can Customer Hygiene Requirements be Ensured?

A company hygiene management system integrated into an existing quality assurance system (e.g. in accordance with DIN ISO 9000) is in most cases usually enough to minimize risks. Therefore, we recommend including the recommendations provided in this guideline and corresponding documentation in this quality assurance system. Such a reference will assure the food manufacturer that the adhesive manufacturer is observing this guideline thereby knowing that, during production of adhesives used in the manufacturing of materials and articles intended to come into contact with food, due care is being taken to minimize the risk.

The elements of such a system – which should not be confused with "HACCP" – may include:

- Employee hygiene/contagious diseases/infections
- Working clothes/headgear
- Food, beverages, smoking in the workplace
- Prevention of the ingress of foreign matter (glass shards, metals and others)
- Protection against insects, rodents and so on
- Cleaning of production and storage areas, among others

The basis for ensuring compliance with all of the hygiene requirements relating to the adhesives to be supplied does not have to be the implementation of an additional elaborate external system. Normally, the existing quality assurance system is sufficient. This may comprise general elements of the company hygiene management system and also incorporate adhesive-specific concepts by using the HACCP principles, such as identification and monitoring of the so-called CCPs.

In this regard, it must be considered that adhesives consist of many different components that are produced using very different procedures, and that several intermediate processing stages are frequently involved in their manufacture. This means that the guideline should be applied in a corresponding modified form to all stages: the chain of processing stages through to the user in the food industry should not be broken.

The proposed hygiene system is not only suitable for manufacturing adhesives, but is also applicable to other branches of industry with similar hygiene requirements. It is therefore largely oriented on the guideline of the Industrievereinigung Kunststoffverpackungen, or large parts of the guideline have been adopted.

1. Hygiene Management

Hygiene management should complement and be part of the management system implemented by a company, which includes the quality management system.

1.1 The Hygiene Supervisor

A correspondingly trained middle management employee should be appointed as "hygiene supervisor". The hygiene supervisor is responsible for the function, control and continuous optimization of the hygiene management system. The supervisor ensures regular internal inspections of the hygienic conditions and is the contact person for customers in matters regarding hygiene (e.g. customer enquiries, audits).

1.2 Hygiene Monitoring

Depending upon the size of the company, the hygiene supervisor is assisted by a hygiene team consisting of suitable employees. They are also trained for this task and have the necessary overview of the different parts of the company in which this guideline is to be applied.

This team and the hygiene supervisor meet regularly to review their results and to determine any new measures which may have become necessary. The hygiene supervisor is responsible for the implementation of these measures and must report to the hygiene team on their progress.

The hygiene management system must be regularly reviewed and further developed by the hygiene team, as necessary.

1.3 Documentation

The application of the hygiene management system, including all its activities and monitoring measures, must be documented in an appropriate manner in order to make meaningful audits possible (see also section 9).

2. Requirements of Employees

2.1 Personal Hygiene

- a) Every employee working in the production of adhesives used in the manufacture of materials and articles intended to come into contact with food must pay particular attention to hygiene. This does not only include people who come into contact with the finished product. This refers to all who, through direct or indirect contact with raw materials, machine parts, intermediate products etc., that can transfer contamination and germs

into adhesives and thereby into the packaging or even the food itself.

- b) Each employee is primarily responsible for his personal hygiene. If necessary, management must instruct employees accordingly (see 2.2).
- c) The hygiene supervisor makes sure that, in designated areas, all company personnel wear appropriate and clean protective clothing. In-house safety regulations must be adhered to at all times.
- d) If an employee is assumed to, or suffers from a contagious disease, then he must inform his superior who will then take appropriate measures in consultation with a doctor.
- e) Employees who have wounds, skin infections, or other injuries to hands and arms, must wear appropriate bandages approved by a doctor that cover these affected parts. These must be changed regularly.

2.2 Hygiene Training

- a) Upon the introduction of a hygiene management system, all employees must be sufficiently informed about the basics of hygiene principles at their company while paying special attention to their respective workplace. An integral part of the induction of new employees must therefore include a brief introduction to this issue. Hygiene training should be provided and carried out at adequate intervals.
- b) The content of such training is determined by the hygiene team and must be continuously adapted to changing circumstances and requirements. Continuous and further training of employees can be integrated into already established training measures, e.g. general safety instructions or quality training. Additional supportive measures can include the posting of hygiene regulations at suitable locations.

2.3 Customers and Other Visitors

The managers in charge are responsible for appropriately informing customers, outside staff and other visitors to the company about the hygiene requirements and that these must be adhered to, e.g. by wearing prescribed protective clothing.

3. Break Rooms and Sanitary Facilities

The national statutory regulations of EU Member States concerning break room and sanitary facilities for employees should largely satisfy the requirements of hygienic working. Particular attention should be paid to the following measures:

- Lockers should be provided for employees, outside the production rooms, in which they can store their personal effects and street wear. Protective clothing is to be stored separately.
- Eating and drinking is only permitted in designated rooms, which are spatially separated from the production areas. Care must be taken to ensure that clothing and shoes are not contaminated by food and beverages. If necessary, these must be cleaned or changed before returning to the workplace.
- Smoking and chewing gum is also only permitted in designated rooms. These can be identical to the rooms mentioned above.
- Toilet facilities must at the very least comply with general regulations.
- Hand washing facilities must be located in every break room or room connected with these, as well as in all toilet facilities. Hands should be washed before returning to the workplace. Where necessary, hand washing facilities should be installed in close proximity to the workplace.
- All break rooms and toilet facilities must be cleaned and aired regularly in accordance with prescribed guidelines. Air should be ventilated outside the building.

4. Premises and Machinery

4.1 Cleaning

- a) Rooms and installations must be cleaned according to specified cleaning regulations which contain the following:
 - Specification of all areas and machine parts that are to be cleaned according to a scheduled plan
 - Cleaning method and frequency
 - Designation of those responsible for cleaning a certain area
 - Type and concentration of cleaning agent, measures in case of spills
 - Precautions to prevent the contamination of the product
 - Documentation of cleaning (see also section 9)
- b) Buildings should be constructed in such a manner that they can be cleaned effectively. Everything should be maintained in good condition. All inner components of the production rooms should be constructed in such a manner as to prevent product contamination through foreign matter. All installations and machinery must be kept in a clean and functional state.
- c) All waste is to be removed immediately and to be disposed of in the appropriate collection

containers. Discarded and inoperable machinery or machine parts should be removed from the production rooms and stored separately from the raw materials and products.

- d) Strong smelling disinfectants and cleaning agents should not be used for cleaning.

4.2 Ventilation

- a) Effective and suitable ventilation systems should exist to remove particles in the air, such as smoke, steam or excess heat, in a safe manner.
- b) The ventilation should be sufficient to prevent water condensation. If filter systems are in use, they should be accessible for inspections, cleaning and exchange. The outside air supply for the ventilation system should be installed far from any sewage pipes, exhaust gas and air systems plus dust enriched areas, to prevent contamination.

4.3 Lighting

All production, control and storage rooms should be illuminated well to ensure adequate conditions of visibility. All lamps should have unbreakable diffusers or coverings.

4.4 Maintenance and Repair

Repair and maintenance work on the building and machinery during ongoing production must be controlled to prevent contamination. Prior to this, the workforce should be made familiar with the hygiene concept.

4.5 Infrastructure

Paths, access roads as well as indoor and outdoor facilities at the production site must be included in the hygiene concept in such a manner that they pose no contamination risk. Particular care should be taken that no waste is lying around. Fixed walkways in the production area should be marked accordingly.

4.6 Spatially Separated Production Areas, Contract Manufacturers, Dealers

If production takes place at different production sites or if the product is processed further, decanted or stored by an intermediary before delivery to customers, this hygiene guideline should be implemented at all of the corresponding premises.

5. Hazards Arising from Foreign Matter

5.1 General Measures

Possible reasons for contamination by any type of foreign matter must be listed in a hazard analysis. Employees must be encouraged to find and remove foreign matter and contamination and endeavour to prevent them from occurring by taking appropriate measures. The hygiene regulations must set forth when the manager or the hygiene supervisor is to be notified. Production areas are to be thoroughly examined for foreign matter at regular intervals. Foreign matter that is capable of contaminating a product also includes parts of the production plant and machinery and items that are needed for other reasons.

5.2 Incomplete List of Potential Foreign Matter

The following are just some examples:

- Glass shards
- Cutting blades
- Loose nuts and screws
- Loose, small machine parts
- Pieces of adhesive tape, paper, cardboard, wood splinters, labels
- Oil, lubricants and other chemicals
- Loose bag seals
- Staples
- Hair
- Earplugs
- Crumbling paint
- Pencils, pens
- Pallet slivers and possibly also contamination by pallets
- Ripped or cut-off small packaging parts
- Strongly smelling cleaning agents
- Insects, birds and rodent faeces etc.

6. Raw Materials and Products

6.1 Suppliers

All suppliers of raw materials, intermediate products and commodities should be duly informed of the hygienic regulations. Depending on the product, the supplier must ensure that the corresponding hygiene measures are implemented and he will then be included in the list of approved suppliers.

6.2 Storage

- a) To enable proper cleaning, inspection and pest control, all materials should be stored at a sufficient distance from the walls.
- b) All raw materials, adjuvants, intermediate products and finished products should be stored in such a manner to prevent contamination and pest infestations. All goods should be packaged and covered except during the manufacturing process itself. In particular, this applies to the finished products which should be sealed tightly. Raw materials in damaged packaging that may have become contaminated during transport or storage should be subjected to thorough cleaning or, if necessary, be rejected.
- c) Raw materials, intermediate products and finished products should be stored separately from other substances, particularly from sub-standard products and waste.
- d) Pallets must be intact and made from suitable material. They must also be kept clean, dry and odourless.

7. Shipping

7.1 Transport

- a) Transport vehicles must be suitable for the transportation of materials for the food industry. They are to be cleaned and inspected on a regular basis.
- b) When dealing with rental vehicles, the hygiene requirements should be included in the rental contract.
- c) All vehicles, no matter of which origin, are to be inspected before loading.
- d) Meticulous selection and cleaning of the vehicles also applies to in-house transportation, e.g. to transportation between different company sites of one company.

7.2 Pest Control

- a) Measures are to be taken to keep animals (insects, birds, rodents etc.) out of the factory, especially out of those areas that have been classified as critical areas by the hazard analysis.
- b) If necessary, a recognized pest control company should be engaged to provide pest control services, unless in-house employees have been trained for this purpose. Said pest control must be contractually obliged to compile a written report after each visit and to forward this to the hygiene supervisor.

- c) If there is an infestation, appropriate measures must be immediately taken and ongoing controls implemented until the hazard has been remedied.
- d) Electric insect exterminators should be installed to combat insects in all areas identified as necessary by the hazard analysis. Their operation should be tested regularly.
- e) Every employee is obligated to notify the hygiene supervisor if there is an infestation of pests in the buildings and of any other animals on the premises.

8. Microbiological Requirements

- a) Generally, a routine microbiological assessment of adhesives is not necessary, because it is neither an appropriate control nor is it suitable for identifying contamination. However, under certain circumstances, microbiological control can be employed as a quality control instrument to document that the product is sufficiently protected against microbial contamination. The hygiene management system should be used as a preventive measure. On no account, should microbiological tests replace a hygiene management system.
- b) Microbiological specifications are only useful in situations where adhesives are used in particularly critical applications. In such cases, threshold values for specifically named micro-organisms, a plan for taking samples and the test method to be used should be determined together with the customer. Furthermore, point 8.a) should also be considered here.

9. Documentation

- a) All regulations, measures and controls of the hygiene management system, including recall campaigns should be fully documented.
- b) All records must be continuously maintained in order to verify that hygiene measures have been properly implemented. These include, for example:
 - Instructions
 - Cleaning measures
 - Contamination caused by foreign matter or similar
 - Independent monitoring and audits
 - Customer complaints
 - Internal audits
 - Inspections and audits by customers, authorities or other commissioned independent auditors

- Pest control measures
 - Maintenance, repair and general engineering work.
- c) A list of all preventive measures carried out and all changes to the hygiene management system should be brought to the attention of all employees.

10. Summary

For a long time, the adhesive industry has supplied a variety of adhesive products for manufacturing materials and articles intended to come into contact with food.

These adhesives have proven themselves at all stages of the process – from production through to the customer. They are reliable components in the manufacture of packaging as a means of protection for food.

The high quality of these adhesives can be ensured by applying quality management systems such as DIN ISO 9000 et. seq.

Regulation (EC) No 853/2004 establishes new quality criteria for the food industry. This regulation harmonizes European legislation concerning food hygiene. It imposes the introduction of measures ensuring the faultless production of food, with the use of Hazard Analysis and Critical Control Point Concept (HACCP).

For this reason, the corresponding requirements placed on the food industry can be passed onto the packaging manufacturer and downstream supplier. This guideline was developed by TKPV to:

- inform adhesive manufacturers of the new situation,
- offer assistance in adapting to the new requirements,
- define new procedural rules that have been recognized and approved by the members of the Industrieverband Klebstoffe.

11. Relevant Legal Regulations

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (consolidated version of 20 April 2009)

Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 27 October 2003 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 1831/2003 of 22 December 2003 on good manufacturing practice for materials and articles intended to come into contact with food

12. Sample Letter

Letterhead of IVK member xyz

To customer A, B, C
Sample Street
Sample City

....., date

Self-Declaration on the Hygiene Management System (of IVK member xyz)

Dear Sir or Madam,

As a manufacturer and distributor of adhesives used in the manufacture of materials and articles intended to come into contact with food, we are aware of our relevant responsibilities. We therefore herewith declare that we have developed and put into practice a hygiene management system based on Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (consolidated version of).

This encompasses, for example:

- Regular hygiene instruction for employees, visitors and external contractors
- Suitable work clothes and protective clothing
- Strict ban on smoking and consumption of food and beverages in production facilities
- Regular cleaning and maintenance of production, storage and transport facilities as well as of staff- and sanitary rooms
- Regular pest control
- Hygiene factors are also taken into consideration in the selection of suppliers

All of these measures and results are documented and their effectiveness regularly verified through internal audits and management reviews.

This enables us to ensure that all adhesives placed on the market by our company intended for use in the food industry are procured, manufactured, stored and transported in accordance with recognized procedures.

We draw your attention to the fact that it is incumbent upon the end-user to test the delivered products for their suitability relative to the intended end-use.

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All available leaflets of the
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