Guideline
Hygiene during Production
of Adhesives used in the Manufacturing of Materials and Articles intended to come into Contact with Food

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Legal provisions can change at short notice. For that reason, this technical briefing note will only be published online.

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

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General Information concerning the series of TKPV-Technical Briefing Notes “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 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 “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 material 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

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Preface

European legislation tackles the harmonization of the different requirement systems of Europe with Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (consolidated version of 20 April 2009). It aims at implementing criteria with which to protect the quality of products and thereby the health of its citizens. A purpose inherent to food packaging, because it protects the product from damages and contamination.

To this end, packaging and food industry have always worked closely together. In this, adhesives fulfill an important function without being outwardly visible. They secure the functionality of packaging and support the protection of product and consumer. To fulfill hygiene requirements it is of utmost importance that all parties of 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 ff.

The Technical Committee Paper and Packaging Adhesives (TKPV) has compiled this guideline for members of Industrieverband Klebstoffe as a service partner of the packaging and food industry. It offers factual and legal advice on how 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 mean that necessarily an additional system with external certification has to be installed alongside an already existing quality assurance system. With the aid of this guideline member companies of 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 topic of “Hygiene Management” to which this guideline will refer. This sample letter is appended to this guideline.

The Task

The adhesive manufacturing industry has been supplying the food industry for a long time already either directly or indirectly via the packaging manufacturers with a great variety of products for the manufacturing 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 down to the final consumer.

The high quality of these adhesives is ensured by employing e.g. quality management according to DIN EN ISO 9001.

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

Consequently, far-reaching demands of the food industry on the packaging manufacturers and thereby also on the adhesive manufacturers can arise. The present guideline that was compiled by TKPV on behalf of Industrieverband Klebstoffe and in accordance with existing guidelines of the packaging industry, should inform those manufacturers of adhesives, used in the manufacturing of materials and articles intended to come into contact with food, on how to adapt to this new situation.

Public Health Rule Situation und HACCP-Concept

HACCP (Hazard Analysis and Critical Control Point) is a concept developed for the food industry to carry out self-monitoring in their companies. An internationally binding version of the HACCP-Concept is defined in a body of rules and regulations 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.” (Annex “Hazard Analysis Critical Control Point (HACCP) System and Guidelines for its application” to CAC/RCP 1-1969 (Rev. 4 - 2003) “General Principles of Food Hygiene”)

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:

Implementation of Hazard Analysis:

- Determine Critical Control Points (CCPs)
- Establish one or more Critical Limits
- Establish a Monitoring System
- Establish corrective action in case of control loss of CCPs
- Document all Instructions and Results

Already this brief characterization of the HACCP-Concept 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 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 contaminations of any type affect the quality and hygiene status of the food. This also includes packaging and preliminary products used therein, which ensure the clean and hygienically perfect condition of the food from its completion of production to its consumption by the consumer. Therefore, the packaging material itself must be clean and hygienically faultless, which in turn presupposes the use of hygienically faultless components.

For the food manufacturer packaging can be a CPP (Critical Control Point). In such a case, he will demand information and eventually also measures of the packaging manufacturer and his pre-suppliers, in order to assess the hygiene hazard and minimize the risk. In general, confirmations on risk-free use still are enough, for example

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

Upon customer request it might also become necessary to comply with and confirm special agreements concerning hygienic aspects of the transport- and overpack of the adhesive to be delivered.

How can customer hygiene requirements be ensured?

A company hygiene management system integrated into an existing quality assurance system (e.g. according to DIN ISO 9000) is in most cases usually enough to minimize risks. Therefore we recommend including the recommendations of this guideline and corresponding documentation in this quality assurance system. Such a reference, will assure the food manufacturer, that the adhesive manufacturer adheres to this guideline. He thereby knows 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.

Elements of such a system that cannot be confused with “HACCP” are:

• Employee Hygiene / Contagious Diseases / Infections
• Work Clothes / Head Gear
• Food, Beverages, Smoking at the Workplace
• Prevention of Foreign Matter Invasion (Glass shards, metals and other)
• Protection against Insects, Rodents and so on
• Cleaning of Production and Storage Areas, among others

Ensuring the compliance with all hygiene requirements of the adhesives to be delivered, does not have to be based upon the implementation of an additional elaborate external system. For that the already existing quality assurance system is enough. It can consist of general elements of the company hygiene management and also incorporate adhesive-specific concepts by using the HACCP-Principles like identifying and monitoring so called CCPs.

In this regard it must be taken into account, that adhesives consist of many different components with very different procedures and additionally often are produced and used in several intermediate processing stages. Therefore, the guideline can be applied in a corresponding modified form to all stages: The chain of processing stages down to the user of the food industry should not be broken.

The proposed hygiene system is not only suitable for the manufacturing of adhesives, but also applicable to other industry branches with similar hygiene requirements. For that reason, it mainly follows, respectively largely adopted the guideline of the Industrievereinigung Kunststoffverpackungen.

1. Hygiene Management

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

1.1 The Hygiene Supervisor

An employee of the middle management, trained accordingly, should be appointed as “Hygiene Supervisor”. In smaller companies this task can be assigned to the e.g. Quality Management Representative (Head of QA).

The hygiene supervisor is responsible for the functioning, controlling and continuous optimization of the hygiene management system. The supervisor ensures regular internal inspections of hygienic conditions and is the contact person in matters regarding hygiene for customers (e.g. customer inquiries, audits).

1.2 Hygiene Supervision

Depending on company size, 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 company parts in which this guideline is implemented.

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

The hygiene management system has to be verified regularly and as required developed further by the hygiene team.

1.3 Documentation

The application of the hygiene management system including all its activities and monitoring measures has to be documented in an appropriate manner to make meaningful audits possible (also see chapter 9).
2. Requirements for Employees

2.1 Personal Hygiene

a) Every employee working in the production of adhesives used in the manufacturing of materials and articles intended to come into contact with food, has to pay particular attention to hygiene. This not only includes 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. can transfer contamination and germs unto adhesives and thereby unto the packaging respectively the food itself.

b) Each employee is primarily responsible for his personal hygiene. If necessary however management will ask employees to exercise particular sensitivity (see 2.2).

c) The Hygiene Supervisor makes sure that in designated areas all company personnel wears clean protective clothing. The clothing also includes, if required, appropriate shoes and head gear. In any case, in-house safety regulations must be adhered to.

d) If an employee suffers from a contagious disease or if this has to be assumed, then he has to inform the superior, who will then in consultation with a physician take appropriate measures.

e) Employees, who have wounds, skin infections, or other injuries to hands and arms, must wear appropriate and physician approved bandages covering these affected parts and change them regularly.

2.2 Hygiene Training

a) Upon the introduction of a hygiene management system, all employees have to be sufficiently informed about the basics of hygiene principles of their company paying special attention to their respective workplace. Hence an integral part of hiring is the briefing of new employees. Hygiene trainings should be provided and carried out at adequate intervals.

b) The contents of such trainings are determined by the hygiene team and continuously adapted to changing circumstances and requirements. Continuous further training of employees can be integrated into already established trainings about e.g. general safety instructions or quality trainings. Additional supportive measures include the posting of hygiene regulations at suitable locations.

2.3 Customers and other Visitors

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

3. Break Rooms and sanitary Facilities

The national 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:

- Outside of the production rooms, lockers should be provided for employees, in which they can store their personal effects and street wear. Protective clothing is to be stored separately.
- Eating and drinking is generally permitted only in designated rooms, which are spatially separated from the production. Care must be taken to ensure that clothing and shoes are not contaminated by food and beverages, and if so they have to 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 beforehand.
- Bathrooms must at the very least comply with general regulations.
- Installations for hand washing must be in every break room or room connected with these, as well as in all bathrooms. Before returning to the workplace hands should be washed. Where necessary, installations for hand washing in close proximity to the workplace should be installed.
- All break rooms and bathrooms are to be cleaned and aired regularly in accordance with given guidelines, in which case ventilation should go to the outside.

4. Premises and Machinery

4.1 Cleaning

a) Rooms and installations must be cleaned according to specified cleaning regulations, that contain the following:
- Specification of all premises and machine parts that are cleaned according to 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 chapter 9)

b) Buildings should be constructed in such a manner, that they can be cleaned effectively. Everything should be maintained in a good condition. All inner components of the production rooms should be constructed in such a manner as to prevent product contaminations through foreign matter. All installations and machinery must be kept in a clean and functioning state.

c) Any kind of waste is to be removed immediately and to be thrown into 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 air particles like smoke or steam or excess heat in a safe manner.

b) The ventilation should be enough to prevent water condensation. If filter systems are being used, they should be accessible for inspections, cleaning and exchange. The outside air-supply of the ventilation system should be installed far from any sewage pipes, exhaust gas- and air systems, and 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 an ongoing production must be controlled to prevent contaminations. Prior to this, the workmen should be made familiar with the hygiene concept.

4.5 Infrastructure

Paths, access roads as well as indoor and outdoor facilities of the production site have to be included into 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 footpaths should be marked accordingly.

4.6 Spatially separated production areas, Toll Manufacturer, Dealers

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

5. Dangers emitted by Foreign Matter

5.1 General Measures

Possible reasons of contamination by any type of foreign matter have to be listed in a hazard analysis. The staff are obliged to find and remove foreign matter and contaminations, respectively to prevent them from occurring. The hygiene regulations are to determine 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 can contaminate a product include, items belonging to production facilities or are needed for other reasons.

5.2 Incomplete List of possible 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 eventually also contaminations by pallets
- Ripped-off or cut-off small packaging parts
- Strong smelling cleaning agents
- Insects, faeces of birds and rodents, 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 has to ensure certain hygienic measures and will then be included in the list of approved suppliers.

6.2 Storage

a) To enable proper cleaning, control and pest control all materials should be stored with enough distance from the walls.

b) All raw materials, adjuvants, intermediate products and finished products should be stored in such a manner that contaminations or pest infestations can be avoided. Except during the manufacturing process itself, all goods should be packaged and covered. This applies in particular to the finished products which should be sealed tightly. Raw materials in damaged packaging that may have been contaminated during transport or storage should be subjected to a thorough cleaning or if necessary to be rejected.

c) Raw materials, intermediate products and finished products should be stored separately from other substances, particularly from deficient products and waste.

d) Palettes must be intact and made from suitable material. They are to be kept clean, dry and odorless.

7. Shipping

7.1 Transport

a) Transport vehicles must be suitable for the transport 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 loan 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 transports, e.g. to the transport between different company sites of one company.

7.2 Pest Control

a) Measures are to be taken to keep animals (insects, birds, rodents,...) out of the factories, 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 authorized, unless a company-owned employees have been trained for this purpose. The authorized company has to be contractually obliged to compile a written report after each visit and forward this to the hygiene supervisor.

c) If there is an infestation, appropriate measures have to be taken immediately and ongoing controls implemented until the hazard has been remediated.

d) Electrical insect exterminators should be installed against insects in all areas that the hazard analysis considered necessary. Their functionality should to be tested regularly.

e) Every employee is obligated to notify the hygiene supervisor, if there is an occurrence of pests in the buildings and of animals on the premises.

8. Microbiological Requirements

a) Generally a routine microbiological assessment of adhesives is not necessary, because it neither is an appropriate control nor suitable for identifying contaminations. However under certain circumstances microbiological control can be employed as a quality control instrument, to document the sufficient protection of the product from 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) Only where adhesives are used in particularly critical applications, microbiological specification values can be useful. In such cases, limit values for specifically named micro-organisms, a plan for the drawing of samples and the test method should be determined together with the customer. Furthermore, 8.a) is also to be taken into account 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, to prove, that hygiene measures have been properly implemented. These include e.g.:
   - Instructions
   - Cleaning Measures
   - Contaminations caused by foreign matter or something else
   - 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 carried out preventive measures and all changes of the hygiene management system should be brought to the attention of all employees.

10. Summary

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

These adhesives have proven themselves in all stages, from production through trade to the customer. They are reliable system components for the manufacturing of packaging as protection of food.

The high quality of adhesives is ensured by applying quality management systems like DIN ISO 9000.

The Regulation (EC) No 852/2004 establishes new quality criteria for the food industry. This regulation harmonizes European legislation concerning food hygiene. It imposes the introduction of measures ensuring a faultless production of food, with the use of Hazard Analysis and Critical Control Point Concept (HACCP), on the food industry.

For that reason, such requirements of the food industry can be passed on to the packaging manufacturer and pre-supplier. The present guideline was developed by TKPV to

- inform the adhesive manufacturers about 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 Industrieverband Klebstoffe.

11. Relevant Legal Regulations


12. Sample Letter

Letterhead of the Association-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 manufacturer and distributor of adhesives used in the manufacturing of materials and articles intended to come into contact with food, we are aware of our special responsibility. We therefore herewith declare that we have developed and put into practice a hygiene management system based on the Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (consolidated version of 20 April 2009).

This contains e.g.

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

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

Hereby we ensure that all adhesives placed on the market by our company and used in the food industry are procured, manufactured, stored and transported according to the generally accepted rules of technology.

Please be advised, that it is incumbent upon the end-user to test the suitability of the delivered products.

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