TKPV-Briefing Note 3

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Industrieverband Klebstoffe e.V.

Guideline

"Good Manufacturing Practice"

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

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Introduction

European legislation has closed another regulatory gap in the European Food and Consumer Goods Act through European Regulation (EC) No 2023/2006 on "good manufacturing practice for materials and articles intended to come into contact with food".

On the basis of European Regulation (EC) No 1935/2004, the production of "materials and articles intended to come into contact with food" must already comply with "good manufacturing practice" (see Article 3 of this Regulation). Regulation (EC) No 2023/2006 now specifies in detail how this concept is to be understood and implemented in terms of these materials and articles. This applies regardless of whether EU specific measures already exist for certain materials and articles – e.g. plastic materials.

Although the Annex to this Regulation is primarily concerned with "good manufacturing practice" relating to printing inks for these materials and articles, it nevertheless applies to all materials and articles intended to come into contact with food (Annex I to Regulation (EC) No 1935/2004), and therefore also to adhesives.

The Technical Committee for Paper and Packaging Adhesives (TKPV) of the Industrieverband Klebstoffe has compiled this guideline as an aid to interpreting the concept of "good manufacturing practice" for adhesives in the production of materials and articles intended to come into contact with food. It is intended to provide affected adhesive manufacturers concerned

with suggestions for installing an appropriate and adequate instrument with which to ensure "good manufacturing practice".

1. Legal Basis

The European Regulation (EC) No 2023/2006 on "good manufacturing practice for materials and articles intended to come into contact with food" essentially states the following regarding this matter:

Article 1 – Subject
This Regulation lays down the rules on good manufacturing practice (GMP) for the groups of materials and articles intended to come into contact with food (hereinafter referred to as "materials and articles") listed in Annex I to Regulation (EC) No 1935/2004 and combinations of those materials and articles or recycled materials and articles used in those materials and articles.

Article 2 – Scope
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.
The detailed rules set out in the Annex shall apply to the relevant individually mentioned processes, as appropriate.

Article 3 – Definitions
For the purpose of this Regulation, the following definitions shall apply:

(a) "good manufacturing practice (GMP)" means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use, without endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof;

(b) "quality assurance system" means the total sum of the organized and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use;

(c) "quality control system" means the systematic application of measures established within the quality assurance system that ensure compliance of starting materials and intermediate and finished materials and articles with the specification determined in the quality assurance system;

(d) ...

(e) ...

Article 4 – Conformity with good manufacturing practice
The business operator shall ensure that manufacturing operations are carried out in accordance with:

(a) the general rules on GMP as provided for in Article 5, 6, and 7,

(b) the detailed rules on GMP as set out in the Annex.

Article 5 – Quality assurance system
1. The business operator shall establish, implement and ensure adherence to an effective and documented quality assurance system. That system shall:

(a) take account of the adequacy of personnel, their knowledge and skills, and the organization of the premises and equipment such as is necessary to ensure that finished materials and articles comply with the rules applicable to them;

(b) be applied taking into account the size of the business run by the operator, so as not to be an excessive burden on the business.

2. 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.

3. The different operations shall be carried out in accordance with pre-established instructions and procedures.

Article 6 – Quality Control System
1. The business operator shall establish and maintain an effective quality control system.

2. The quality control system shall include monitoring of the implementation and achievement of GMP and identify measures to correct any failure to achieve GMP. Such corrective measures shall be implemented without delay and made available to the competent authorities for inspections.

Article 7 – Documentation
1. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to specifications, manufacturing formulae and processing which are relevant to compliance and safety of the finished material or article.

2. The business operator shall establish and maintain appropriate documentation in paper or electronic format with respect to records covering the various

manufacturing operations performed which are relevant to compliance and safety of the finished material or article and with respect to the results of the quality control system.

3. The documentation shall be made available by the business operator to the competent authorities at their request.

2. Topic and Scope

This briefing aid to interpretation of the concept of "good manufacturing practice" compiled by the Technical Committee for Paper and Packaging Adhesives (TKPV) of the Industrieverband Klebstoffe applies exclusively to adhesives used in the production of materials and articles intended to come into contact with food.

In this context, "good manufacturing practice (GMP)" begins with control, approval and admittance of raw materials for manufacturing and ends with the packaging and storage of these adhesives.

The procedure for selecting the raw materials and evaluating them on the basis of the information set forth, for instance, in the declarations required according to food legislation, and the assessment of the adhesives in terms of their suitability for the production of food contact materials is described in TKPV-Technical Briefing Notes 1 and 2. Such product specifications and/or declarations required according to food legislation cannot alone necessarily guarantee the control of migration-capable adhesive components, within the meaning of Article 3 of Regulation (EC) 1935/2004 (not to endanger human health, not to bring about change in the composition of the food or a deterioration in its organoleptic properties).

In the following, "good manufacturing practice (GMP)" will be appropriately described, for the purposes of the adhesive manufacturing industry, as the sum of all measures within the meaning of Regulation (EC) No 2023/2006.

Quality assurance systems are intended to ensure that products are manufactured according to documented procedures and descriptions. In contrast to this, rules governing "good manufacturing practice" guarantee the suitability of the product for its intended purpose (in this case, materials and articles intended to come into contact with food). Quality assurance systems complying with ISO can be excellent "carriers" of rules for "good manufacturing practice", but should not be mistaken for "good manufacturing practice" as such.

Systems for ensuring "good manufacturing practice" for adhesives used in the production of materials and articles intended to come into contact with food, encompass the following areas:

1. Quality Assurance System and Quality Policy
2. Corporate Management and Personnel
3. Production
   - Raw material specification and approval
   - Prevention of contamination
   - Change management
   - Storage packaging and warehousing
   - Quality control and specifications
4. Claim management, recall campaigns and incident management
5. Regular internal and supplier audits
6. Documentation, labelling, document archiving
7. Traceability

In addition, the adhesive manufacturer is obliged to take due care during transportation and when choosing a logistics service provider and in terms of his obligations to inform the customer.

3. Definitions

"Good Manufacturing Practice"
"Good manufacturing practice", as part of quality assurance, guarantees a continuous and controlled manufacturing of adhesives that is oriented on their use. In this case, these are the rules governing materials and articles intended to come into contact with food and especially the fulfillment of requirements in Article 3 of Regulation (EC) No 1935/2004.

Raw Materials
In this context, raw materials are all self-produced and/or externally purchased substances or materials, which are to be used in the formulation/manufacturing of these specific adhesives. Within the meaning of Article 2 of Regulation (EC) No 2023/2006, raw materials are starting substances for adhesives. In this case however, only raw materials may be used for which a corresponding specification exists that provides sufficient information.

Food Contact Material
Regulation (EC) No 2023/2006 (Art. 1) refers to the list of materials and articles intended to come into contact with food set forth in Annex I to Regulation (EC) No 1935/2004. It also includes combinations of these materials and articles. According to Article 2 this excludes starting substances.

The stated materials and articles may directly, or following alteration/final treatment, come into contact

with food or they can have an indirect effect on the food (e.g. secondary packaging).

4. Recommendation for "Good Manufacturing Practice"

Certain components/elements are necessary for "good manufacturing practice" in the production of adhesives used in the manufacturing of materials and products intended to come into contact with food. These will be described and explained in the following:

4.1 Quality Assurance System

- Adhesives must be manufactured and inspected consistently. This will ensure that they conform to rules and quality standards applicable to their intended purposes. In this specific instance, this means complying with rules governing the manufacture of materials and articles intended to come into contact with food (and thereby not to endanger human health, not to bring about change in the composition of the food or a deterioration in its organoleptic properties).
- The prerequisite is an efficient quality assurance system (e.g. according to ISO 9001) that actively involves management and personnel.
- An essential part of this is the responsible and independent quality control of the approval and rejection of all materials and processes.
- Raw materials must already comply with predetermined specifications. These specifications ensure that the adhesive will conform to existing rules governing materials and articles intended to come into contact with food. Suitable specification samples are described in the Annex to the technical briefing note 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".

4.2 Corporate Management and Personnel

- The implementation of "good manufacturing practice" requires the clear definition of responsibilities, their assignment to personnel and their documentation.
- In order to fulfil all relevant requirements reliably, the production and quality control staff involved in the manufacture of these adhesives should be appropriately trained or experienced and should receive continuous further training.

4.3 Production

4.3.1 Raw Material Specification and Approval

- A process of approval and continuous assessment of raw material suppliers exists (see 4.4).
- A process exists for the approval of raw materials. For this purpose, each supplier must provide a specification that has been agreed on with the adhesive manufacturer. This specification describes the suitability of the corresponding raw material for the production of adhesives used in the manufacturing of materials and articles intended to come into contact with food. The information required in such a specification is described in technical briefing note 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". Among others, they contain details of material-specific limitations which can be communicated within the supply chain, in line with the delegation of tasks. Only raw materials that have been documented in this manner and comply with specifications will be approved (see 4.4). Approval must be given before use in production.
- Raw materials must be stored in such a manner, that they can neither be mixed nor adulterated.
- Materials that fail to meet the agreed acceptance criteria will be clearly identified and labelled and blocked in order to prevent incorrect use.

4.3.2 Prevention of Contamination

- A contamination prevention procedure exists based upon risk assessment.
- Cross-contaminations between adhesives used in the manufacturing of materials and articles intended to come into contact with food, along with those that cannot be used for this application are actively avoided.
- Efficient procedures exist, including during adhesive production batch changeovers, in order to prevent such cross-contamination (e.g. buffer or cleaning requirements).
- Special processes ensure that transport, packaging and loading are carried out in such a manner that contamination of the adhesive is prevented.
- If necessary, appropriate and adequate hygienic measures for personnel, production sites, storage facilities and transport will be taken (see TKPV technical briefing note 4 "Guideline – Hygiene during production of adhesives used in the manufacturing of materials and articles intended to come into contact with food").
- If necessary, a pest control program will be introduced and implemented.

4.3.3 Change Management

- Work processes and their corresponding timeframes will be established and documented. Change management will apply in the event that changes have to be made to work processes. This ensures that any possible change in composition or an increased risk of contamination of adhesives used in the manufacturing of materials and articles intended to come into contact with food will be identified.
- Changes to adhesive formulations or raw materials (change in specification) are subject to change management.
- Processes exist that document and verify the influence of such changes on the final quality of the adhesive, its performance, composition and its compliance with legal requirements.

4.3.4 Storage, Packaging, Warehousing and Transport

- The storage capacity for raw materials and adhesives is sufficient and well managed.
- Storage conditions must reliably guarantee that any unacceptable changes to raw materials and adhesives used in the manufacturing of materials and articles intended to come into contact with food are prevented.
- Silos and bulk containers are used exclusively to store raw materials and adhesives used in the manufacturing of materials and articles intended to come into contact with food. Where this is not possible, effective measures will be implemented for preventing unacceptable contamination (e.g. cleaning or change processes).
- Processes exist to ensure the correct labelling of all packaging units.

4.3.5 Quality Control and Specifications

- Documented specifications for raw materials and finished products exist.
- Raw materials and finished products are monitored to ensure their compliance with specifications.
- In line with his quality control procedures, the adhesive manufacturer must perform random checks of the specified values, thereby inspecting the raw material suppliers.

4.4 Claim Management, Recall Campaigns for Adhesives and Incident Management

- A system exists that not only registers and examines claims, but also enables the recall of "off-spec" products (traceability). The examination of claims should lead to recommendations for the improvement of processes.
- Special measures ensure that "off-spec" products or recalled adhesivesfor the manufacturing of materials and articles intended to come into contact with food, will not be used. Exempt are those adhesives, which have been extensively examined, modified and approved according to their corresponding requirement profile.

4.5 Regular Internal and Supplier Audits

- A process for establishing and implementing regular internal audits exists. This self-regulation ensures that "good manufacturing practice" is observed and implemented.
- A process for performing regular supplier audits exists. These will evaluate the supplier's measures for ensuring compliance with the agreed specifications of raw materials for the production of adhesives used in the manufacturing of materials and articles intended to come into contact with food.

4.6 Documentation, Labelling, Document Archiving

- A documentation system for raw material specifications, adhesive formulations, work processes, time frames, product approval specifications, quality control results and other relevant information (e.g. calibration documents, customer information) exists.
- If different adhesives are produced in a single plant – i.e. adhesives both for materials and articles intended to come into contact with food as well as adhesives intended for other purposes – cross-contamination must be prevented. Appropriate measures must be implemented for this purpose. Plants, pipe systems, containers and tanks for processing, filling and storing raw materials and adhesives for materials and articles intended to come into contact with food, are to be clearly marked. This can be achieved, for example, by labelling or through the use of electronic control systems. This ensures that information about the content, the batch description, status control and other relevant facts are accessible.
- These quality criteria will be supplemented as necessary.

4.7 Traceability

A system exists that ensures, e.g. in the event of claims or if a product recall becomes necessary, seamless traceability of the adhesive batches supplied to customers – right back to the raw material batches used in their production.

5. 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 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

All available leaflets of the

Technical Committee Paper and Packaging Adhesives (TKPV)

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The information platform on the internet.