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

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Introduction / Objectives

This guidance aims to help the adhesives industry, customers and other stakeholders to understand how the Regulation (EC) No 2023/2006 “on good manufacturing practice for materials and articles intended to come into contact with food” (GMP Regulation) can be implemented by the adhesive industry. The Guidance paper covers general and detailed rules on good manufacturing practice. Originally, the intention of this Regulation was to cover especially those materials which are not yet regulated through EU regulations, e.g. printing inks, paper and adhesives. However, in reality it forces all actors in the food contact materials supply chain to make sure that the material or article of concern is processed, controlled and evaluated in such a way, that it is suitable for the intended purpose of food contact. The GMP Regulation can be considered as an implementation regulation to the requirements of Article 3 of the Framework Regulation (No 1935/2004).

The GMP Regulation was published to ensure uniformity amongst Member States with regards to GMP for materials and articles intended to come into contact with food and build a frame for the different industry sector guidelines.

Although the regulation does not refer to any standards, the majority of requirements of the GMP regulation can already be covered through an established and implemented Quality Management System (such as ISO 9001 and equivalent procedures). Therefore, this guidance paper will mainly concentrate on requirements which are either adhesive industry specific or additionally needed to comply with the Regulation (EU) No. 2023/2006. The document will often refer to the FEICA food contact guidance for adhesives, which was first published Feb. 2013.

Scope of Regulation (EU) no. 2023/2006

Article 2: *'This Regulation shall apply to all sectors and to all stages of manufacturing, 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.'*

(Whereas no.1) 'Groups of 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 used in those materials and articles should be manufactured in compliance with general and detailed rules on good manufacturing practice (GMP)'

The Regulation is foreseen for all materials and articles which are intended to be brought into contact with food or where migration into the food is possibly expected under the conditions of use.

This would cover both material groups which are already covered by specific measures, such as the plastics regulation (Regulation (EU) no. 10/2011), and material groups which are not yet covered by harmonized European regulations (e.g. print inks, paper, adhesives etc.).

In addition it will also cover cases where an adhesive was not intentionally developed for direct food contact applications, but where migration might take place due to a layer which does not present a sufficient barrier (e.g. paper, board, PE).

The definition of GMP here refers to the aspects of controlled and qualified manufacturing process, which is able to ensure conformity with the rules of Article 3 of Regulation (EC) No 1831/2003 – where it is said that the material or article should not endanger human health, should not cause an unacceptable change in the composition of the food and should not cause a deterioration in the organoleptic characteristics thereof.

Effective Quality Assurance System

Article 5:*'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.'

Quality Assurance (QA) is the maintenance of a defined quality level which is needed to prevent mistakes or defects in manufactured products in order to avoid problems when delivering solutions or services to customers. It comprises planned and systematic activities implemented in a quality system so that quality requirements for a product or service will be fulfilled.

With regards to the GMP regulation FEICA believes that the adhesive intended for food contact material needs to fulfil additional defined criteria in order to be suitable for this purpose.

a. Personnel

To maintain a high quality standard for the food contact adhesives the whole organisation which is involved in the production, quality control and handling of the products must be well trained and continuously educated to raise awareness under consideration of the intended application of the final product. The responsibility of each involved person must be well defined. The operator must be informed about the final application, so that he is aware of the risk for the final consumer caused by his failure. He shall follow the specific defined processes and specifications laid down by the adhesives manufacturer. The company shall provide training in quality assurance requirements to all its personnel and temporary and external staff to a level appropriate to the operations. The effectiveness of the trainings shall be monitored and documented.

b. Premises and Equipment

All premises and equipment shall be tidy, in good condition and organized in such a way that potential sources of physical, chemical and biological contamination and impurities shall be minimized. This should ensure that the adhesives comply with the rules and quality standards appropriate to their intended use. To minimize the risk of contamination it may be necessary to separate products on different production lines. Products as well as raw materials and packaging materialsⁱ to pack and store the final product often need to be separated in different storage areas.

c. Size of the business

All manufacturers of adhesives for food contact material shall follow the requirements of Regulation (EC) 2023/2006. The quality assurance system should be proportionate to the size of the business to avoid undue burdens for small businesses.

d. Specified starting materials

The requirements for starting materials must be specified in such a way, that the final adhesive is able to comply with the requirements for materials and articles intended to come into contact with food, particularly Article 3 of Regulation (EC) No. 1935/2004, which states that possible migration into the food should not endanger human health, should not bring unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof.

A suitable template to request the required information for the raw materials used for all adhesives intended to be used in food contact material can be found in the "FEICA Guidance for a food contact status declaration for adhesives" under the following link: http://www.feica.com/images/stories/library/gup-c002-001_foodcontactstatus_guidance.pdf

For adhesives used in the frame of Regulation (EU) No 10/2011 the EU-Guidance "Information in the Supply Chain" defines clearly which information is necessary for "starting materials for non-plastic-Intermediates".

The specifications agreed with the raw material suppliers enable the adhesive producers to manage the risk of their products and to create detailed food contact statements for the downstream user.

e. Pre-established instructions and procedures

To maintain a consistent product quality and to ensure that Article 3 of the Framework Regulation is respected by all operations which concern the production, quality control and handling of the products must be pre-established with a well-defined procedure with detailed instructions and parameters. This includes the approval and assessment of raw material suppliers, the approval of raw materials according to pre-established specifications, the cleaning procedures [e.g. cleaning of vessels and pipes or containers for multiple use], the production procedures and the approval of the final product as well as the management of change up to the approval of the freight services and all outsourced activities. A recall process should be established, documented and tested on a regular basis.

Effective Quality Control System

Article 6: '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'

Quality control (QC) is a procedure or a set of procedures which make sure that a manufactured product or performed service comply to a pre-defined set of quality criteria or meets the requirements of the customer.

Following the intention of the GMP regulation FEICA affirms that the quality of the products and processes need to be controlled in a way that ensures that the adhesives comply with the requirements of Article 3 of Regulation (EC) 1935/2004.

a. Raw Materials and Finished Products specification

The authors of this guidance presume that an appropriate Quality Management System is in place and that the demand of Article 5 of the GMP regulation which requires pre-established raw material specifications is fulfilled. Following these rules the defined specifications for raw materials as well as for finished products need to be constantly controlled.

b. Processes

All processes (e.g. cleaning processes, processes to avoid physical, chemical and biological contamination, off-spec control and outsourced activities) which are established to ensure a quality of the adhesive for safe food contact needs to be controlled so that there is no risk for the final consumer.

c. Monitoring of Implementation and achievement of GMP

Internal Audits need to be conducted on a regular basis to verify the correct implementation and application of the described GMP requirements. The management team shall review the implementation status on a regular basis (e.g. customer complaints, recalls, pest control, management of change).

d. Corrective Measures

Findings (e.g. customer complaints) have to be considered as input to review the quality assurance system. A documented root cause analysis methodology has to be in place. Corrective measures should be implemented and their effectiveness measured and recorded. The information needs to be available to the competent authorities upon request.

Documentation

Article 7: '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.'

Documentation: A set of documents and records in paper or digital form.

In relation to the GMP Regulation the aim of documentation is to store important information for easier retrieval within the company as well as for authorities in order to be able to demonstrate compliance to article 3 of regulation (EC) 1935/2004.

Although it is assumed that companies have a quality management system in place, the existing documentation needs special adaptation to fulfil GMP requirements e.g. design input of new products, manufacturing procedures, cleaning procedures.

Examples of documents additional to those required by general quality management systems. (Some of these documents are explained in more detail in the FEICA guidance for a food contact status declaration for adhesives, they are marked with an '*'):

a. Relating to raw materials

- Raw material suppliers' food contact status declaration, including Raw material specification *
- Reports of extraction or migration testing on Raw Materials (if relevant)

b. Relating to the adhesive product

- Adhesive's Food Contact Status Paper*
- Documentation of the contamination risk assessment (e.g. HACCP (Hazard Analysis Critical Control Point)
- Reports on extraction or migration testing on adhesive product (if relevant)*
- Results of worst case scenario calculations (if relevant)*
- Reports of migration simulations (if relevant)*

It should be noted that any additional documentation specific to GMP needs to be controlled and retained in the same manner as ordinary quality documentation.

Conclusion

The objective of the above guideline is to assist the adhesives industry, with the implementation of the Regulation (EC) No 2023/2006 'on good manufacturing practice for materials and articles intended to come into contact with food'. The guidance might also help customers and other stakeholder (to) understand better what they can expect from an adhesive intended for food contact material.

Beyond the requirements expected to be already implemented through a Quality Management System (such as 9001), the guideline recommends procedures to assure a safe adhesive for food contact applications. It particularly touches the personnel, premises and equipment, the size of the business and pre-established instructions and procedures under the umbrella of "Quality Assurance". However the chapter "specified starting materials" represents the heart of this guideline and is strongly connected with the separate "FEICA guidance on establishing a food contact status for adhesives".

The "Quality Control" should ensure that pre-defined quality criteria are controlled with respect to a safe adhesive for food contact applications. At the same time the material specifications, the processes, the corrective measures and the GMP implementation should be monitored.

Finally the "Documentation" is the tool which confirms and shows the implemented measures for the requirements defined through the GMP Regulation (2023/2006).

Contact

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