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Guidelines

Good Manufacturing Practice in accordance with Commission Regulation (EC) No. 2023/2006 on Materials and Electric Home Appliances Intended to Come into Contact with Food

2nd edition

Electro & Digital Industry Association

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Preface

The present Guidelines are a revision of the guide first published by ZVEI in 2016 and was prepared in 2022 by the members of the ZVEI Food Contact Materials Working Group.

They are based on Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food and contain non-binding recommendations by the working group's members, which are relevant for compliance with the aforementioned regulation. There is no warranty whatsoever that these Guidelines may be applicable to other areas with independent regulations or interpretations.

The structure of the chapters was intentionally adapted to the aforementioned regulation. A quote of the regulation, set in italics, precedes each chapter, followed by considerations which the working group deems important and by non-binding recommendations. The **resulting minimum requirements** – in the working group's opinion – **are printed within the individual chapter listings in boldface**. Additional useful and recommended actions are listed in standard typeface. Companies are at liberty to depart from the working group's prioritization at their own discretion.

In addition to a glossary, the Guidelines' annex contains a checklist intended to help verify compliance with GMP Regulation (EC) No. 2023/2006.

To facilitate the implementation of actions recommended in these Guidelines within an existing quality management system according to ISO 9001, the annex also contains a correlation table.

1 Subject Matter and Introduction

Article 1
Subject matter

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 (hereafter 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.

The domestic electrical appliances divisions within the ZVEI represent an industry whose products enrich and inform people's lives in significant ways, in particular through electric appliances used in the kitchen, such as refrigerators, baking ovens, rotisseries, microwave ovens, coffeemakers, toasters, deep fryers, steam cookers, food processors, and water boilers.

Apart from product design, product safety is a key issue for the manufacturers of electric home appliances, especially with articles intended to come into contact with food.

To achieve this objective, which has always had a high priority for our industry, the European Commission has issued numerous regulations for food-related utensils and commodities.

The central framework Regulation (EC) No. 1935/2004 mandates in article 3 that materials and articles intended to come into contact with food "shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could endanger human health or bring about an unacceptable change in the composition of food or bring about a deterioration in the organoleptic characteristics thereof." In addition, article 16 requires that materials and articles that are subject to specific measures must "be accompanied by a written declaration stating that they comply with the rules applicable to them" (declaration of compliance). Moreover, "[a]ppropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand" (cf. chapter 7.2 of the present Guidelines).

More specifically, Commission Regulation (EC) No. 2023/2006 on good manufacturing practice (GMP) for materials and articles intended to come into contact with food specifies the requirements for manufacturers with regard to quality management and control and with regard to documentation.

Some industries (including plastics, packaging, paper, printing inks) have already developed guidelines for the implementation of this regulation. For the application to electric home appliances, member companies of the ZVEI had expressed their desire for a specific interpretation of the requirements for their own industry.

Another driving force for developing the present GMP Guidelines was making the requirements for good manufacturing practice practical for those who do not yet have a comprehensive understanding of GMP. Moreover, the Guidelines are meant to be applicable along the entire home appliances supply chain, thus achieving maximum consumer protection and providing companies concerned with support in legal matters.

We consider the ISO 9001 Quality Management System (QMS) or an equivalent system a suitable foundation for GMP. The main goal is to meet consumer expectations and to comply with legal requirements for our products and services by implementing the QMS. This includes the legal regulations on products intended to come into contact with food.

When a proven QMS is implemented in the production chain, no new work policies are required. The only additional requirement is to implement and integrate the specific requirements for products in contact with food into the existing quality management principles.

2 Scope

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.

1.1. Involvement of the entire supply chain

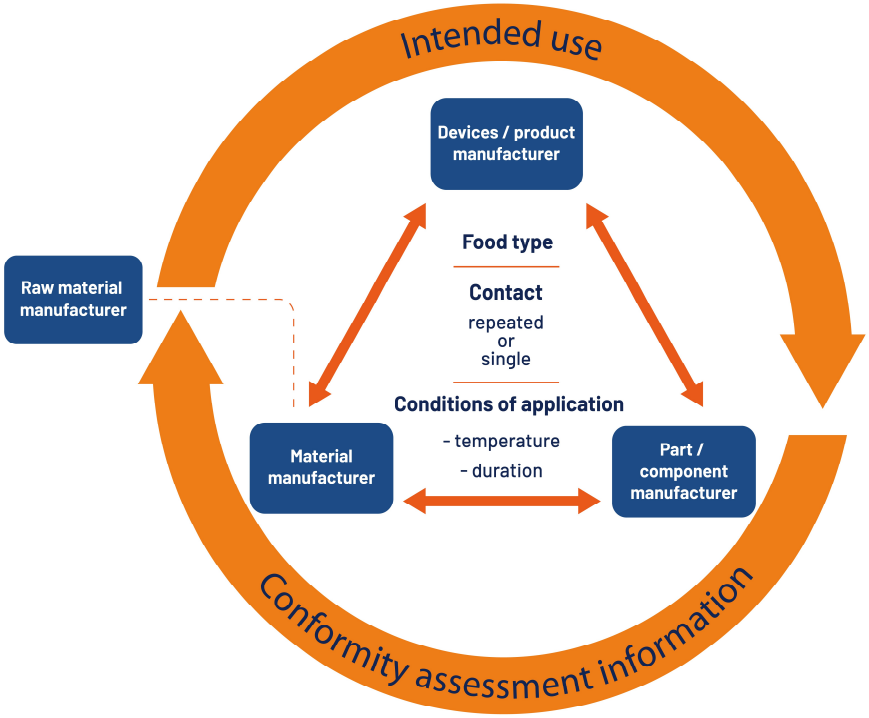

Fig. 1: Model of concerned actors for good manufacturing practice[1]

All participants in the supply chain are affected by GMP measures. The responsibility arising from the GMP Regulation (EC) No. 2023/2006 for the respective parties concerned is primarily directed at avoiding possible hazards to the end customer. The aim of GMP is therefore to assist process control along the entire supply chain. The different actors have to inform each other about the used materials, testing and application conditions. This process runs in both directions, from the material manufacturer to the device manufacturer and back. Conformity assessment must be known and implemented throughout the supply chain. All parties involved benefit from the exchange of information, as a legally compliant product is achieved. For this, there are clear, documentable requirements that can be checked and provided at any time. Participants in the supply chain must therefore actively inform each other of the need to comply with GMP.

Exempt from GMP compliance are manufacturers and processors/handlers of starting materials. Starting materials are understood to be raw materials, e.g. sand, crude oil, ores, but also monomers. All further processing stages, e.g. polymerization, which lead to the production of food contact polymers (polymer, additives, such as stabilizers, glass fibers, dyes, crosslinkers) are GMP-relevant.

[1] Manufacturing must take place under GMP conditions at all points in the supply chain and prevent contamination. All necessary information must be passed on to the other actors in the supply chain via the DoC.

2.2 Derivation of requirements - examples of application

The GMP Regulation imposes two main obligations on the user that must be observed in the implementation of Good Manufacturing Practice:

- The appropriate duty of care (“due diligence”) to avoid end-user hazards.
- Continuity of this protection throughout the entire production and supply chain up to the end user

Requirements for all participants in the supply chain are derived from Article 2 GMP. Since Good Manufacturing Practice is crucial for the safety of products and thus for the protection of the end user, it has the same priority as, for example, the electrical or mechanical safety of end products. The requirements can be divided into eight areas: Basics, Hygiene, Substances and Product Selection, Incoming Goods, Processing, Outgoing Goods, Monitoring and Corrective Action. Examples of the relevant areas are explained in more detail below. A detailed checklist can be found in Appendix III.

In the area of **fundamentals**, the prerequisites are established. There, for example, it is important to ensure that a system is in place to continuously monitor the implementation and control of GMP. Through continuous controls, deviations or changes are noticed more quickly and the responsible actor can react quickly.
Another important aspect of GMP is **hygiene** in manufacturing and in the workplace. Actors must ensure that hygiene concepts at the workplace exist and are adhered to for all GMP-relevant areas. Contamination with other substances must be avoided at all costs to ensure the purity of materials or the cleanliness of components.

This is followed by the area of **substance and product selection**. Participants in the supply chain must ensure that GMP concerns are considered when selecting their suppliers. As shown in Figure 1, all stages of the supply chain must adhere to GMP.

Good manufacturing practice also applies to **incoming goods**. Intermediate products intended for food contact must be stored appropriately before further processing. For example, it may be necessary for the products concerned to be specially labeled, for storage rooms to be locked at all times, or for the products concerned to be specially climate controlled.

Furthermore, the **processing of the substances** is also affected by GMP. In addition to the materials for the product, auxiliary and operating materials must also be checked for their suitability for food contact. Otherwise, there is a risk of contamination of the material that is suitable for food contact.
However, GMP compliance does not end with production and storage. Certain requirements must also be considered when **transporting** finished products/devices. Forwarders, for example, must be informed about the specific nature of the goods and how to handle them properly.

Changes in materials or finished products may impact GMP compliance and thus require **corrective action**. To comply with GMP, it is therefore essential to continuously check whether changes to the existing quality assurance measures are necessary, e.g., renewed migration measurements in the case of changed surfaces.

2.3 Measures and due diligence within the scope of Good Manufacturing Practice

Compliance with Good Manufacturing Practice must be checked regularly. In most cases, the manufacturing steps cannot be considered separately. Instead, information must be obtained from other players to assess one's own situation. Examples of compliance with due diligence include self-monitoring, GMP audits of suppliers, and/or regularly obtaining confirmation of food contact compliance.

At the same time, the principle of “as deep as necessary, as shallow as possible” applies. This means that control cycles can be adapted, or parts of the supply chain need not be considered for individual processes. This approach is compliant with Regulation (EC) No. 2023/2006 on Good Manufacturing Practice.

It is therefore advisable to carry out a risk assessment of one's own products (as part of the operational implementation of the GMP Regulation) to have a uniform and comprehensible basis for the definition of measures

3 Definitions

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 compliance with the rules applicable to them and with the quality standards appropriate to their intended use by not 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 organised and documented arrangements made with the purpose of ensuring that materials and articles are of the quality required to ensure compliance 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) 'non-food-contact side' means the surface of the material or article that is not directly in contact with food;

(e) 'food-contact side' means the surface of a material or article that is directly in contact with the food.

4 Conformity with Good Manufacturing Practice

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.*

The regulation describes a quality assurance system, a quality control system and the documentation to ensure Good Manufacturing Practice. These points will be explained in more detail in the next chapters.

5 Quality Assurance System

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 organisation 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.

To avoid errors from verbal communication, written or electronic documentation of the documents mentioned here is recommended.

The quality assurance system at the individual stages of production is described below. We recommend that the following points be observed and documented to ensure Good Manufacturing Practice:

5.1 Materials and Selection of Products

Information on substance and product selection can be found in § 5 para. 2 Regulation (EC) No. 2023/2006.

- **Coordinate and record specifications (e.g., technical information, drawings, stock lists, list of materials) of starting materials/products and equipment with the supplier/client.**
- Define and document criteria for design.
- **Perform and document risk assessment of production processes and products (food contact materials**), e.g., by applying FMEA (Failure Mode and Effects Analysis), or in analogy to the hazard analysis according to the HACCP concept, or by using alternative or own procedures. (See annex III for critical control points)
- **Check compliance with legal requirements/substance prohibitions. (Especially for Food Contact Materials and end products made from them, the intended and foreseeable conditions of use (types of food, maximum temperature, maximum contact duration, repeated or single use) of the end product must be observed!)**
- Check whether the intended use was adequately considered in construction.
- **Select materials with regard to the intended use.**
- Select suppliers.
- **Check whether all declarations – e.g., according to Regulation (EU) No. 10/2011 – are on hand and whether products have been duly declared (cf. documentation),** e.g., documented risk assessment in case of specific product issues, re-evaluation of ingredients, potential misuse, declaration of conformity, supplier declaration, raw material specifications, component specifications, safety data sheets, etc.
  - Conduct and document internal process audits according to ISO 9001, IFS, BRC, HACCP, or alternative systems.
- Monitor future developments, apply for exemptions, take account of changing customer demands.
- Regularly review substitution options.
- Possibly find and evaluate new suppliers.

5.2 Receipt of Goods/Stocks

- **Check for regulations regarding storage and, if required, take special precautions** (e.g., cleanness, appropriate packaging, no storage near poisonous or volatile substances, pest control etc.)
- **Conduct/verify identification.**
- **Define protective packaging for storage** (e.g. closed box).

- **List and implement special requirements for employees/subcontractors**, such as training and briefing, define verifications.
- If necessary, designate/delineate separate areas within the storage facility.
- **Check whether special hygiene precautions are required.**

5.3 Processing and Manufacturing

- **Check whether all relevant specifications and documents are on hand.**
- **List and implement special requirements for personnel/subcontractors, such as training and briefing, produce proofs and certification.**
- **Define product packaging/labeling.**
- Check production clearance.
- Determine (batch) labeling/identification.
- Define and implement maintenance/cleaning cycles.
- **Check whether special hygiene precautions are required.**

5.4 Delivery of Goods

- **Ascertain regulations regarding transportation and verify compliance** (e.g., visual inspection of truck regarding cleanliness, undamaged packaging, etc.).
- If necessary, designate/delineate separate areas within the storage facility.
- **Check whether special hygiene precautions are required** (e.g., wearing gloves when handling the products).
- Check in the case of ceramic articles, whether a declaration of compliance according to Council Directive 84/500/EEC on ceramic articles at the retail stage is on hand.
- Define shipping instructions.
- According to 1935/2004, a DoC must be supplied with each part; in particular for ceramics and plastics, the requirements of the individual measures of the Ceramics Directive 84/500/EEC and Regulation (EU) No. 10/2011 must be complied with and stated.

5.5 Monitoring, Measurement, Analyses, and Evaluations

- Service/repair management (exchange of experiences)
  - Define core processes in front and back office.
  - Train personnel (integrate suggestions for improvements into the process).
  - **Define process operations and responsibilities.**
- Distribution
- Customers
- Continual improvement
  - Define structured methods and processes for continual improvement.
  - Take into account improvement resulting from the introduction of innovations and from employee suggestions.
  - Lay down plans for checking the effectiveness of the improvement options.

6 Quality and Control System

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.

The quality control system does not start with product quality control. It covers the entire product development process from specifications, sampling, testing, documentation to approvals. Quality control is interdepartmental and should therefore be independent. It ensures that the quality-relevant tests are carried out in sufficient numbers and to the required extent. The personnel required for quality control must have appropriate qualifications and experience.

Control mechanisms must be defined and adapted as necessary.

In the case of existing quality control systems, e.g., ISO 14000 or 9000/9001, to comply with GMP, explicitly GMP-specific points must be integrated and checked for effectiveness.

We recommend that the following steps be observed and documented:

6.1 Selection of Materials and Products

- **Safeguard that raw materials, packaging materials, and products are selected and purchased by qualified personnel** (pay particular attention to food contact suitability of materials and training of personnel).
- **Ensure that feedstocks/materials/products meet specifications and that suppliers can demonstrate necessary qualifications**
- **Check suitability of selected substances/products according to the established specifications (e.g., by comparing the intended conditions of use of the product with the information from the declaration of conformity or the test report)**
- **Check criteria for design, construction, and materials selection:**
  - According to which standard was the design defined?
  - Was the design based on the intended use?
  - Was the material chosen according to the intended use?
  - Are design, construction, and material suitable for the intended use?
- Supplier audits:
  - **Check all required certificates/proofs for up-to-dateness.**
  - Check supplier requirements regularly.
  - Check for changes in regulations/requirements and revise, if necessary.
  - Search for and evaluate new suppliers if necessary.

6.2 Receipt of Goods and Stocks

- **Goods inward inspection** (integrity of packaging, comparison of designation between ordered and delivered material, cleanliness, etc.).
- **Configure stockkeeping in such a way that products intended for food contact are not adversely affected** (e.g., odor, taste, dusting, moisture/UV radiation/corrosion).
- **Do not store FCMs next to hazardous/odorous materials (e.g., oils, paints, fumigants)**
- Monitor compliance with specifications.
- **Inspect materials and components/assemblies upon removal from storage** (check for damage and/or contamination during storage), obtain quality control clearance
  - Carry out documented risk assessment of the logistics chain (e.g., following HACCP)

  - Define delivery conditions in such a way that risks are avoided (e.g., clean, odor-free means of transport, storage temperatures, closed truck ...)

6.3 Processing/Manufacturing

- **Check production preparation (e.g., check material & component designation for correctness), check production facilities for cleanness.**
- Document production conditions and process parameters.
- **Conduct sampling during production** (e.g. visual inspection and laboratory follow-up according to sampling plan).
- Check auxiliary and operating materials (e.g., use lubricants classified according to NSF H1 or H2 where necessary; check whereabouts of auxiliary and operating materials on product, integrate cleaning process if necessary).
- Clean equipment, especially after switching production over from non-food-compliant to food-compliant materials

6.4 Delivery of Goods

- **Comply with transportation regulations** (cf. 6.2 Receipt of goods).
- Comply with shipping instructions.
- For materials or articles, the corresponding documents (declaration of conformity) must be available electronically or in paper form.

6.5 Monitoring, Measurement, Analysis, and Evaluation

- Validate inspection methods and intervals.
- **Check raw materials/materials/goods inward inspections at goods receipt/store.**
- **Define sampling (how/by whom/record), including sample identification (batch, production date, or other unambiguous identifiers).**
- **Define clearance (by whom and when required).**
- Define and describe tolerances, control measures, and corrective actions in case of deviation.
- Check compliance with specifications during production.
- Document and evaluate deviations.
- **Take reference samples, if required.**
- Conduct clearance/final inspection before roll-out.
- Check whether shipping documents/safety data sheets are on hand and up to date.
- Observe special transportation or shipping instructions.
- Conduct internal audits (process operations, risk management).
- Conduct external audits (supplier evaluation, terms of delivery, transportation, production processes/facilities).
- Document results of audits, supplier evaluations, customer ratings as well as deviations, corrections, and improvement measures.
- **Supplier surveys/statements with GMP confirmation**
  - Deviations and corrective actions
- Record options for improvement.
- Management review

6.6 Corrective Actions

- **Document and evaluate complaint cases – deduce measures within the scope of the product monitoring obligation, where required.**
- **Conduct, document, and evaluate incoming goods controls – deduce measures, where required.**

7 Documentation

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.

Appropriate documentation includes declarations of compliance or confirmations of:

- **Compliance with Framework Regulation (EC) No. 1935/2004**
- **Compliance with Regulation (EC) No. 2023/2006**
- **Compliance with Regulation (EU) No. 10/2011 (for FC plastic materials only)**
- Compliance with Regulation (EC) No. 282/2008 (for FC recycled plastic materials only)
- Compliance with Directive 84/500/EEC and Directive 2005/31/EC (for FC ceramic articles only)
- Compliance with Regulation (EC) No. 1895/2005 (for FC epoxy derivatives)
- Compliance with Directive 2007/42/EC (for FC cellulose film)

For all other food contact materials for which no European regulation has been established, we recommend naming relevant national regulations and recommendations.

7.1 Documentation of the Quality Assurance System

For documenting the quality assurance system, documentation of the following items, among others, is required:

- **Manufacturing method according to the predefined parameters**
- **Auxiliary and operating materials used**
- **Change of materials and potential cross-contamination**
- **Selection of materials and products**
- **Supplier selection and evaluation**
- Formulae (e.g., analysis certificates)
- Cleaning and maintenance of factory equipment and facilities
- Personnel knowledge and skills (e.g., training documents)
- Packaging and storage
- Internal and external audits
- Risk assessment at the development stage of production processes and products
- Specifications/tolerances for products and materials
- Risk assessment in case of specific product issues, re-evaluation of ingredients, potential misuse, etc. (e.g., full product FMEA)

7.2 Declaration of Compliance

In addition to the declarations of compliance required on the European level for specific individual measures, suitable documents have to be made available that prove compliance with pertinent regulations (so-called background documents, such as test results, analysis reports, risk assessments, worst-case studies, GMP documentation). These documents have to be made available to the competent authorities at their request. They include:

- **Materials and Selection of Products**
  Are declarations available furnished by

  - **granulate manufacturers?**
  - **raw-material suppliers?**
  - **component suppliers?**
  - **batch suppliers?**
  - **printing-ink suppliers?**
  - **suppliers of hot stamping foils?**
- **Transportation and Storage**
  Are these documents available:
  - GMP declarations by logistics providers?
  - documentation of audits, their execution, deviations, corrections, and improvement measures?
  - documentation on FIFO (first in – first out)?
  - documentation of storage conditions?
  - documentation of storage processes?
- **Processing and Manufacturing**
  - **Cleaning agents, auxiliary and operating materials**
    - certification (NSF H1 or equivalent) of auxiliary and operating materials
    - certification (NSF H1 or equivalent) of cleaning agents
  - Employees
    - documentation of personnel training conducted
  - Production facilities
    - certification of production facilities (conveyor belts and the like)
  - Processes and parameters
    - **documentation of the manufacturing process**
    - **documentation of formulae**
    - **documentation of process parameters**
    - **documentation of production stages**
    - **process documentation on the cleaning of production facilities**
    - **documentation of change of material (non-food-compliant to food-compliant materials/conversion of production facilities)**
  - **documentation of who performed change of material/conversion of production facilities**
  - documentation of audits, their execution, deviations, corrections, and improvement measures
  - Flow of material
    - **documentation of barred materials or finished products**
    - **documentation of the management of out-of-spec parts**
    - documentation of packaging regulations
    - documentation of material flow
- **Monitoring, Measurement, Analyses and Evaluations**
  - **analyses of articles inspected**
  - documentation of execution of and deviations, corrections, and improvement measures following
    - internal audits
    - client audits

7.3 Supplier Audits

- **Creation and maintenance of documents by suppliers and manufacturers of food contact articles, containing information on to specifications, manufacturing formulae and processing to the extent that they are relevant to compliance and safety of the finished material or article**
- Documentation of individual manufacturing stages
- **Manufacturers providing background documentation to competent authorities at their request**
- Supplier audit, e.g., according to checklist in Annex III of the present Guidelines

7.4 Batch Training

- Documentation of batch labelling of products (production date, serial number)
- Documentation of the traceability process from raw material to final article along the supply chain

7.5 External Checks

In the event of complaints, errors or deviations, appropriate countermeasures shall be taken to ensure conformity.

The results and measures shall be documented as follows:

- **Deviations and corrective actions**
- Definition and description of tolerances, control measures, and corrective actions in case of deviation
- Identify, implement, and check improvement possibilities (internal CIP measures)

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APPENDIX

Annex I – Index of Abbreviations and Glossary

Abbreviation	Description/Explanation/Reference
(EC) No. 1935/2004	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, http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32004R1935
(EC) No 2023/2006	Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R2023
(EU) No. 10/2011	Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02011R0010-20140324
84/500/EEC	Council Directive of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs, http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31984L0500
2005/31/EC	Commission Directive of 29 April 2005 amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:110:0036:0039:en:PDF
(EC) No. 282/2008	Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006, http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32008R0282
(EC) No. 1895/2005	Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food, http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005R1895
2007/42/EC	Commission Directive of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs, http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32007L0042
BedGgstV	German Commodities Regulation of 10 April 1992, revised by public notice on 23 December 1997, last revised on 02 December 2021, http://www.gesetze-im-internet.de/bundesrecht/bedggstv/gesamt.pdf
BfR	Bundesinstitut für Risikobewertung (Federal Institute for Risk Assessment), http://www.bfr.bund.de/en/home.html
BfR Recommendations	Database BfR Recommendations on Food Contact Materials (formerly “Plastics Recommendations”), https://bfr.ble.de/kse/faces/DBEmpfehlung.jsp.
BRC	British Retail Consortium (a hygiene certification)
CIP	CIP (= Continuous Improvement Process) is the constant evaluation of existing processes and their improvement. The aim is to improve the quality of substances, materials, components, and products.
Compliance	behavior in accordance with rules and regulations, compliance in fulfilling official requirements
DIN	Deutsches Institut für Normung (German Institute for Standardization) http://www.din.de/en
DIN 10528	German “Guideline for the selection of materials used in contact with foodstuffs,” in order to prevent a harmful influence on foodstuffs. The German-language version of the standard may be obtained from the publisher, Beuth Verlag: http://www.beuth.de/de/norm/din-10528/115835757

DoC	Declaration of Compliance (in contact with food). A declaration of conformity is the written confirmation by a manufacturer that a product has certain properties.
EN	European standards, ratified by one of three committees for standardization (European Committee for Standardization CEN, European Committee for Electrotechnical Standardization CENELEC, and European Telecommunications Standards Institute ETSI). All European standards are the result of a public standardization process.
DIN EN IEC 63000 VDE 0042-12:2019-05 (German version)	European Standard EN 63000:2018 “Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances” was published in the *Official Journal of the European Union* (2012/C 363/05). The purpose of this European standard is to specify the technical documentation a manufacturer has to produce in order to confirm compliance with relevant restrictions of substances. Link to the *Official Journal of the European Union* 2012/C 363/05: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:363:0006:0007:EN:PDF The German-language version of the standard may be obtained from the publisher, Beuth Verlag: https://www.beuth.de/de/norm/din-en-iec-63000/302205544
FC	Food Contact
FCM	Food Contact Material(s)
FIFO	First In – First Out: Method of managing inventory, used (among other fields) in commodities management and production engineering
FMEA	Failure Mode and Effects Analysis
GMP	Good Manufacturing Practice
HACCP	Hazard Analysis and Critical Control Points is a systematic preventive approach to food safety from biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe, and designs measurements to reduce these risks to a safe level. Hazard analysis is the first of seven principles of an HACCP plan. Cf. also (in German): https://www.bfr.bund.de/de/a-z_index/hazard_analysis_and_critical_control_point__haccp_-4550.html
IEC	International Electrotechnical Commission, the international standards organization for electrical, electronic and related technologies http://www.iec.ch/
IEC 62474	Standard for “Material declaration for products of and for the electrotechnical industry.” This standard specifies the procedure, content, and form of data exchange for material declaration within the supply chain. Even though this international standard was developed for the electrotechnical industry, requirements and form of the data exchange may be applied to other industries as well. http://std.iec.ch/iec62474 The German-language version of the standard may be obtained from the publisher, Beuth Verlag: http://www.beuth.de/de/norm/din-en-62474-vde-0042-4-2013-05/171905309
IFS	International Feature Standard (a hygiene certification)
ISO	International Organization for Standardization http://www.iso.org/iso/home.html
ISO 9000 ISO 9001	The ISO 9000 family is a series of standards that define, establish, and maintain an effective quality assurance system for manufacturing and service industries. It intends to facilitate mutual understanding on both the national and international level. Evidence is provided through a certification process, followed by independent certification bodies issuing a certificate valid for a limited period of time. While ISO 9000 covers the basic concepts and language of quality management systems, ISO 9001 sets out the requirements of a quality management system. The German-language version of both standards may be obtained from the publisher, Beuth Verlag: http://www.beuth.de/de/norm/din-en-iso-9000-2015/235671064 http://www.beuth.de/de/norm/din-en-iso-9001-2015-11/235671251

LFGB	German Food, Commodities and Feedstuff Code (LFGB) of 1 September 2005, revised by public notice on 3 June 2013, last revised on 27 September 2021, http://www.gesetze-im-internet.de/bundesrecht/lfgb/gesamt.pdf
Guidelines “Material Declarations within the Supply Chain”	The ZVEI brochure intends to inform specifically about aspects of material declarations within the supply chain as they relate to the exchange of product-specific material and substance information for the purpose of ensuring product compliance. It focuses in particular on explaining international standard IEC 62474 on material declaration for products of and for the electrotechnical industry. The Guidelines (available in English and German) may be downloaded from the ZVEI website.
OEM	Original Equipment Manufacturer
QMS	Quality Management System
ZVEI	Verband der Elektro- und Digitalindustrie e. V. (Electro and Digital Industry Association) https://www.zvei.org/en/

Annex II: Correlations between GMP and ISO 9001

Reference in the present Guidelines or in Commission Regulation (EC) 2023/2006	ISO 9001:2015
5. Quality Assurance System	
Art. 5, para. 1 (a), GMP Regulation No. 2023/2006 *take account of the adequacy of personnel, their knowledge and skills, and the organisation of the premises and equipment such as is necessary to ensure that finished materials and articles comply with the rules applicable to them*	6.1.2 The organization shall plan (cf. n. 1 and 2) 7.1 Resources 7.1.2 People 7.2 Competence 7.1.6 Organizational knowledge 7.1.3 Infrastructure 7.1.4 Environment for the operation of processes 8.1 Operational planning and control 8.2 Requirements for products and services
Art. 5, para. 2, GMP Regulation No. 2023/2006 *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.*	8.2 Requirements for products and services 8.2.1 Customer communication 8.2.2 Determining the requirements for products and services 8.2.3 Review of the requirements for products and services 8.4 Control of externally provided processes, products and services 8.4.3 Information for external providers
Art. 5, para. 3, GMP Regulation No. 2023/2006 *The different operations shall be carried out in accordance with pre-established instructions and procedures.*	8.2.3 Review of the requirements for products and services
5.1 Materials and Selection of Products	6.1.2 The organization shall plan (cf. n. 1 and 2) 7.1 Resources 7.1.2 People 7.1.6 Organizational knowledge 7.1.3 Infrastructure 8.1 Operational planning and control 8.2 Requirements for products and services 8.4 Control of externally provided processes, products and services 8.3 Design and development of products and services 8.2.4 Changes to requirements for products and services
Selection of Suppliers	8.4.3 Information for external providers
Documented Internal Process Audits	9.2 Internal audit
5.2 Receipt of Goods/Stocks	7.1.3 Infrastructure 7.1.4 Environment for the operation of processes 8.5.3 Property belonging to customers or external providers
5.3 Processing and Manufacturing	8.5 Production and service provision 8.5.1 Control of production and service provision 8.6 Release of products and services 8.5.2 Identification and traceability
5.4 Delivery of Goods	8.5.5 Post-delivery activities
5.5 *Monitoring, Measurement, Analysis, and Evaluation*	7.1.5 Monitoring and measuring resources 7.1.5.2 Measurement traceability
Reference in the present Guidelines or in Commission Regulation (EC) 2023/2006	**ISO 9001:2015**
Customers	9.1.2 Customer satisfaction
Continual Improvement	10 Improvement 10.3 Continual improvement 8.5.6 Control of changes
6. Quality Control System	
Art. 6, para. 2, GMP Regulation No. 2023/2006	7.1.5 Monitoring and measuring resources 7.1.5.2 Measurement traceability

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.	8.3.5 Design and development outputs 8.3.6 Design and development changes 8.2.4 Changes to requirements for products and services
6.3 Processing/Manufacturing	
In Case of Production Process Changes	8.5.6 Control of changes
6.5 Monitoring, Measurement, Analysis, and Evaluation	9.1 Monitoring, measurement, analysis and evaluation 9.1.3 Analysis and evaluation
Internal Audits	9.2 Internal audit
Management Review	9.3 Management review 9.3.2 Management review inputs 9.3.3 Management review outputs
6.6 Corrective Actions	8.7 Control of nonconforming outputs 10.2 Noncompliance and corrective action
7. Documentation	
7.1 Documentation of the Quality Assurance System	7.5 Documented information 7.5.2 Creating and updating 7.5.3 Control of documented information

Annex III - Checklist for Self-Checking Compliance with Commission Regulation (EC) No. 2023/2006 (GMP Regulation) Good manufacturing practice for materials and articles intended to come into contact with food

1 = minimum GMP requirement, has to be implemented in each and every case
2 = recommended
3 = only required if mentioned in risk assessment

Part of the GMP-System	Priority	Confirmed?		Comment
		yes	no	
1. Basics				
1.1 Is there a person primarily in charge of GMP?	1			
1.2 Are the applicable laws and regulations known and are they documented and communicated internally?	1			
1.3 Is ISO 9001 or an equivalent quality management system and appropriate quality assurance documentation implemented?	1			
1.4 Is there a system in place to continuously monitor the implementation and control of Good Manufacturing Practice (GMP) and its documented results?	1			
1.5 Does the quality control fully include the minimum requirements of the GMP Regulation EC 2023/2006 and is this verified by management?	1			
1.6 Does an adequate documentation of the quality assurance system exist?	1			
1.7 Is there a GMP training or briefing of personnel/subcontractors, and is it documented?	1			

Part of the GMP-System	Priority	Confirmed?		Comment
		yes	no	
2. Hygiene				
2.1 Is there a concept for hygiene at the workplace in all GMP-relevant areas?	1			
2.2 Is there a training for hygiene at the workplace, and is it being documented?	1			
2.3 Are special hygiene and cleaning requirements communicated to contracting parties (e.g., logistics contractors, cleaning contractors, suppliers, clients)?	1			
2.4 Is a regular risk assessment on the need for pest control carried out, adapted to local conditions and requirements?	1			
2.4.1 If necessary, is pest control conducted and documented?	1			
2.5 Are rules defined for the conduct of potential visitors?	2			
2.5.1 If rules are in place, are visitors briefed on these rules before entering GMP areas?	2			
2.5.2 Is - in case of need - necessary and suitable protective equipment (e.g., hoods, overshoes, etc.) kept available for visitors?	2			
3. Materials and Selection of Products				
3.1 Are the requirements for the manufacture of food contact components and GMP communicated to the contractual partners (e.g., suppliers) by means of suitable documents (e.g., drawings, guidelines, work instructions, etc.)?	1			

Components of the GMP System	Priority	Confirmed?		Comment
		yes	no	
3.2 Are all starting substances and additives used in the manufacture of food contact material checked for compliance with applicable legal requirements[2]?	1			
3.3 Are all required certificates/evidence from suppliers checked for timeliness?	1			
3.4 Are supplier audits conducted and documented?	2			
3.5 Were the criteria for design, construction, and materials selection defined, reviewed, and documented?	1			
3.6 Were GMP requirements taken into consideration in the choice of suppliers?	1			
3.7 Are there any documented internal audits, e.g., according to ISO 9001, IFS, BRC, or alternative systems?	2			
4. Receipt of Goods and Stocks				
4.1 Are materials used and stored in such a way that they do not (cannot) adversely affect products intended for food contact?	1			
4.2 Are employees/subcontractors trained on special requirements and certified?	1			
4.3 Is a documented risk assessment of the logistics chain carried out with regard to GMP?	1			
4.4 If delivery terms are agreed, is attention paid to avoiding GMP risks?	1			
4.5 Are incoming goods inspections conducted, documented, and evaluated?	1			

[2] Health & Consumers Directorate-General, E. C. (2014). Summary of the national Legislation http://ec.europa.eu/food/safety/docs/cs_fcm_non-harmonised.pdf Health and Consumers Directorate-General, E. C. (2015). References of the European and National Legislations – Working Document http://ec.europa.eu/food/safety/docs/cs_fcm_non-harmonised.pdf .

Components of the GMP System	Priority	Confirmed?		Comment
		yes	no	
4.6.1 If so, is compliance with these requirements checked and documented?	2			
5. Processing and Manufacturing				
5.1 Is there a maintenance and inspection plan for facilities?	1			
5.2 Are there any instructions and corresponding documentation on the cleaning of production facilities in case of a switchover from non-compliant to food-compliant material?	1			
5.3 Is there a cleaning plan for buildings, machines, conveyor belts, transportation facilities, etc.?	1			
5.4 Is cleaning equipment selected, used, and stored in such a way that it may (or could) not harm product intended to come into contact with food?	1			
5.5 Are manufacturing conditions and process parameters documented?	1			
5.6 Are all relevant specifications and documents on hand?	1			
5.7 Are appropriate countermeasures documented in the event of specification deviations in ongoing production?	1			
5.8 Is product packaging/labeling defined?	1			
5.9 Are food contact components suitably stored/intermediately stored/packaged throughout the production process?	1			
5.10 Does a final inspection take place?	2			
5.11 Is batch management / parts labeling in place to ensure traceability?	1			

Components of the GMP System	Priority	Confirmed?		Comment
		yes	no	
6. Delivery of Goods				
6.1 Are the required declarations of conformity provided?	1			
6.2 Are the special GMP requirements for transport communicated to employees/forwarding agents/subcontractors of products and has evidence been defined?	2			
6.3 If necessary, are separate storage facilities provided?	2			
6.4 Are shipping instructions defined?	2			
7. Monitoring, Measurement, Analysis and Evaluation				
7.1 If changes are made (e.g., design or regulatory) that are relevant to food contact, is the declaration of compliance updated?	1			
7.2 Are there any review mechanisms in place to check whether changes, regulations, and customer demands affect food contact requirements?	1			
7.3 Are there any confirmations of GMP compliance from the suppliers' side?	1			
7.4 Are process operations and responsibilities defined?	1			
7.5 Are the raw materials/materials regularly tested for their suitability for food contact?	1			
7.6 Is the process of sampling defined?	1			
7.7 Are reference samples taken?	2			
7.8 Is it defined by whom and when a release is required?	1			

Components of the GMP System	Priority	Confirmed?		Comment
		yes	no	
7.10 Are the test methods and intervals validated?	2			
7.11 Are tolerances and control measures or, in the event of a deviation, corrective measures defined?	2			
8. Corrective Actions				
8.1 Are corrective actions defined to address detected vulnerabilities?	1			
8.2 Is the processing of corrective actions monitored?	1			
8.3 Are complaint cases documented and evaluated?	1			

Date: Signature: