ZVEI:
Die Elektroindustrie

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

Zentralverband Elektrotechnik- und Elektronikindustrie

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ZVEI - Zentralverband Elektrotechnik- und Elektronikindustrie e. V.
ZVEI - German Electrical and Electronic Manufacturers' Association
Divisions Small Domestic Electrical Appliances/ Large Domestic Electrical Appliances/Domestical Electrical Heating and Hot-water Appliances
Lyoner Strasse 9
60528 Frankfurt am Main, Germany

Contact:
Kirsten Metz, ZVEI
Phone: +49 69 6302-212
Fax: +49 69 6302-271
E-mail: metz@zvei.org
www.zvei.org

Editorial team of the Food Contact Materials WG:
Nicole Bischof, Eugster/Frismag
Andrea Ehrmann, Liebherr-Hausgeräte Ochsenhausen
Sascha Kappel, BSH Bosch und Siemens Hausgeräte
Kirsten Metz, ZVEI
Rena Schau, Philips
Wolfgang Wäntig, Melitta Europa
Jürgen Wild, Electrolux Hausgeräte

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Content

Preface

The present Guidelines have been developed by members of the ZVEI's Food Contact Materials working group between March 2015 and June 2016.

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 typical examples for the model of responsibility levels presented in chapter 2, as well as 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.

In order 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, as mentioned in the proposed Guidelines on "Materials and Articles Intended to Come into Contact with Food" by the European Committee of Domestic Equipment Manufacturers (CECED). 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

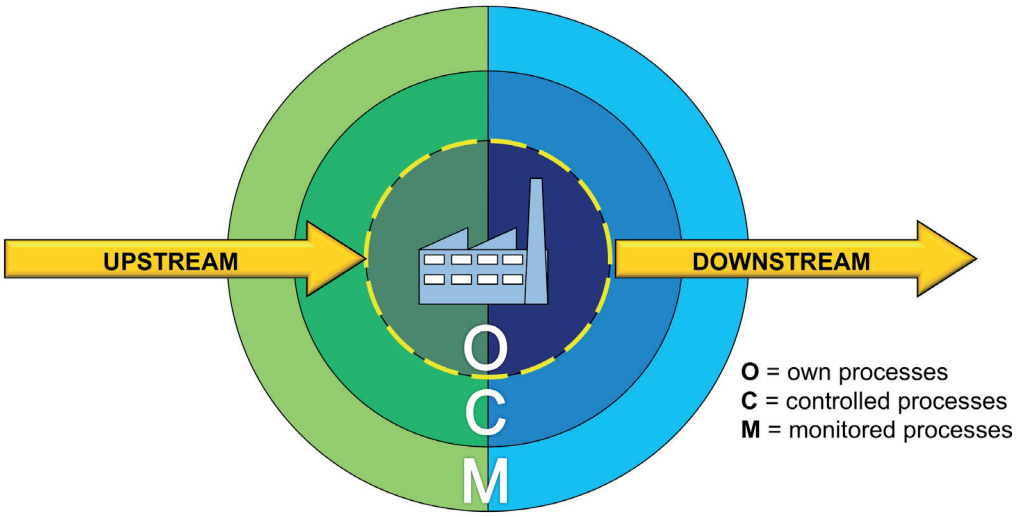
Scope

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.

2.1 Responsibility Levels (Shell Model) for Good Manufacturing Practice

Fig. 1: Model of responsibility levels for good manufacturing practice



The responsibility that arises from GMP Regulation (EC) No. 2023/2006 for those concerned is directed primarily at avoiding any harm to the end user of the product. Consequently, the scope of responsibilities and the resulting measures can be divided into three levels, as shown in fig. 1.

The distinctions between these levels are as follows:

- **O**wn processes
  are processes entirely under one's own control for which one bears full legal liability (examples: own production or distribution).
- **C**ontrolled processes
  are processes partially under one's own control for which one does not bear full legal liability (examples: contract production, supply according to own specifications).
- **M**onitored processes
  are processes which are neither under one's regular control nor within one's responsibility but within one's own sphere of knowledge (examples: purchase of standard parts, processing of one's own products by third parties).

The identification of responsibility levels has to be performed individually for each process.

2.2 Deductions from the Requirements of the Responsibility-Levels Model

The GMP Regulation imposes two principal obligations on those applying it (implementers), which have to be heeded when implementing good manufacturing practice: (1) exercising due diligence in preventing hazards to the end user by applying suitable measures, and (2) maintaining the continuity of this protection over the entire production and supply chain all the way to the consumer.

For fulfilling these obligations, corresponding recommendations may be deduced from the level of responsibility that relates to the implementer's maximum extent of influence and responsibility:

- Own Processes – Control
  On this level, requirements have to be defined for reviewing all processes regularly and for continuously documenting compliance. Own processes also include monitoring the other levels of responsibility.

- Controlled Processes – Monitoring
  For controlled processes, requirements for the processes have to be defined and compliance has to be monitored (e.g. random supplier audits, goods inward inspection). Documentation may be performed by the controlling units, since these processes are their "own processes" in the sense of the responsibility-levels model. As a minimum requirement, it has to be ensured that this documentation is available at all times. Since Commission Regulation (EC) No. 2023/2006 is binding for all links of the supply chain, it is usually possible to restrict monitoring to the direct supplier or buyer ("tier 1").
- Monitored Processes – Reaction
  Since a targeted supervision of requirements is not reasonably possible for processes which can simply be monitored, there is solely an obligation to react as soon as an awareness of potential risks to the end user arises (e.g. when it becomes known that a downstream user uses the products outside the safe field of operation). (N.B.: Any responses initiated in such cases become "own processes" by themselves and are thus subject to their own documentation obligation!)
- General Requirements
  Due to the requirement of pervasiveness, compliance with the requirements of one level of responsibility necessitates that all requirements on all other levels of responsibility in the process chain also have to be complied with.

Good manufacturing practice is relevant to consumer health. The resulting requirements for products and production have the same priority as, for example, electrical or mechanical safety.

For the purpose of simplification, after reviewing the levels of responsibility, an overview should be prepared that shows relationships, permits an easier and safer handling in case of changes, and facilitates reviews, e.g. in the context of audits (cf. case examples in Annex III).

2.3 General Adequacy of Measures within Good Manufacturing Practice

In most cases, it is not possible to completely ignore levels of responsibility and not to define requirements. However, it does not violate Commission Regulation (EC) No. 2023/2006 on good manufacturing practice, if the scope of control cycles is adjusted according to a risk assessment, or if – for individual processes – non-relevant levels are disregarded with adequate justification or considered only to a limited extent ("as deep as necessary, as shallow as possible"). For this reason, it is recommended, as part of the operational implementation of these Guidelines, to perform a risk assessment for one's own primary-use products (i.e. disregarding any unspecified so-called "refurbishment" by third parties, use for purposes not intended, etc.), in order to have a uniform and comprehensible foundation for the definition of measures. To confirm compliance with good manufacturing practice in the sense of Commission Regulation (EC) No. 2023/2006, a risk level should thus be maintained that does not require any follow-up measures. Deviations from this rule are permissible, if the necessary risk minimization is documented and reviewed by third parties in the downstream chain all the way to the consumer (e.g. in the supply of components rather than finished products, in analogy to the product manufacturer's – not the raw material supplier's – obligation to assess substance migration according to Regulation [EU] No. 10/2011 [plastic materials].)

For risk assessment, the application of established and proven methods is recommended, e.g. from the *Corrective Action Guide*, in order to have a (minimum) limit that is as objective as possible ("it is not important *how* the customer is at risk, but *how much*"). Otherwise, it has to be proven that the method used is "state of the art."

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.

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.

In order to avoid errors from oral communication, it is recommended that the documents mentioned herein be kept in paper or electronic format.

The following section describes the quality assurance system at the individual stages of production. To ensure good manufacturing practice, we recommend observing and documenting the following items:

5.1 Materials and Selection of Products (cf. art. 5, para. 2 Commission Regulation [EC] No. 2023/2006)

- **Coordinate and record specifications (e.g. technical information, drawings, stocklists, 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.
- **Check compliance with legal requirements/ substance prohibitions.**
- 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, 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, 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, produce proofs and certification.**
- 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 with regard to cleanliness, undamaged packaging, etc.).**
- If necessary, designate/delineate separate areas within the storage facility.
- **Check whether special hygiene precautions are required.**
- **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 in paper or electronic format.**
- **Check whether documents according to Regulation (EU) No. 10/2011 are available for plastic articles.**
- Define shipping instructions.
- List and implement special requirements for personnel/subcontractors, such as training and briefing, define certification.

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 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 checks but covers specifications, sampling, inspections, documentation, and clearance. Quality control is implemented across departments and should thus be independent. It ensures that quality-relevant inspections are conducted at a sufficient frequency and to the extent necessary. Personnel in charge of quality control has to have the required experience and qualifications.

Control mechanisms have to be defined and adjusted when necessary.

We recommend observing and documenting the following steps:

6.1 Selection of Materials and Products

- **Safeguard that raw materials, packaging materials, and products are selected and purchased by qualified personnel.**
- **Check whether materials conform to specifications and whether suppliers are able to show required qualifications.**
- **Check suitability of the materials/products selected against the specifications established.**
- **Check criteria for design, construction, and materials selection:**
  - According to which criteria was the design defined?
  - Was the product designed for its 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 for their currentness.**
  - Check supplier requirements regularly.
  - Check for changes in regulations/requirements and revise, if necessary.
  - Possibly find and evaluate new suppliers.

6.2 Receipt of Goods and Stocks

- **Goods inward inspection**
- **Configure stockkeeping in such a way that the organoleptic properties of the starting materials and the products would not be altered.**
- Monitor compliance with specifications.
- **Check starting materials before use.**
- Check for potential damage/contamination of substances during storage.
- **Obtain quality control clearance.**
  - **Conduct a documented risk assessment.**
  - **Define delivery conditions in ways to avoid hazards (e.g. clean, odorless means of transportation; storage temperatures; closed trucks, etc.).**

6.3 Processing/Manufacturing

- **Check production preparation, 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).
- **Re-check in case of changes in the production process.**
- Check auxiliary and operating materials.
- Clean equipment, especially after switching production over from non-food-compliant to food-compliant materials

6.4 Delivery of Goods

- **Comply with transportation regulations.**
- Comply with hygiene requirements.
- **For ceramic articles, a declaration of compliance according to Council Directive 84/500/EEC on ceramic articles at the retail stage has to be on hand, either in paper or electronic format.**
- **For plastic articles, documents according to Regulation (EU) No. 10/2011 have to be on hand.**
- Comply with shipping instructions.

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 IV of the present Guidelines or alternative testing parameters

7.4 Batch Tracing

- **Documentation of preceding and succeeding link in the supply chain**
- Documentation of batch labeling of products (production date, serial number)
- Documentation of the back-tracking process from the customer (product) to the component and of the forward-tracking process from the supplier (component) to the product

7.5 External Checks

If reports from clients (OEM) or consumer (consumer protection organizations) on deviations and/or contaminations exist, appropriate measures must be taken.

The results of these measures have to be documented as follows:

- **Deviations and corrective actions**
- Definition and description of tolerances, control measures, and corrective actions in case of deviation
- Point out options for improvement.

Annex I: Index of Abbreviations and Glossary

Abbreviation	Description/Explanation/Reference
(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
(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
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 15 February 2016, 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"), http://www.bfr.bund.de/en/database_bfr_recommendations_on_food_contact_materials__formerly__plastics_recommendations__-1711.html.
BRC	British Retail Consortium (a hygiene certification)

Abbreviation	Description/Explanation/Reference
CECED	Conseil Européen de la Construction d'Electro-Domestiques (European Committee of Domestic Equipment Manufacturers)
Compliance	behavior in accordance with rules and regulations, compliance in fulfilling official requirements
Corrective Action Guide	"Consumer Product Safety in Europe: Corrective Action Guide – Guidelines for Businesses to Manage Product Recalls & other Corrective Actions" is a legally non-binding guide developed by Orgalime and other European industry and consumer associations in collaboration with authorities of several EU member states, with financial support by the European Commission (DG SANCO, now DG SANTE, Directorate-General for Health and Food Safety). It contains recommendations on actions to be taken after it has been determined that a product is unsafe. The document is available online at: http://ec.europa.eu/consumers/archive/safety/rapex/docs/corrective_action_guide_march2012.pdf
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)
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.
EN 50581:2012 DIN EN 50581 (VDE 0042-12):2013-02 (deutsche Fassung)	European Standard EN 50581:2012 "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: http://www.beuth.de/de/norm/din-en-50581-vde-0042-12-2013-02/168088813

Abbreviation	Description/Explanation/Reference
EN ISO 22716	Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices (ISO 22716:2007) Art. 8, para. 2 of Regulation (EC) Nr. 1223/2009 on cosmetic products states: "Compliance with good manufacturing practice shall be presumed where the manufacture is in accordance with the relevant harmonised standards, the references of which have been published in the Official Journal of the European Union." The Official Journal of the European Union (2011/C 123/04) references international standard DIN EN ISO 22716 "Cosmetics – Good Manufacturing Practices (GMP) – Guidelines on Good Manufacturing Practices," published in December 2008. It contains guidelines on the quality aspects of cosmetics as they relate to manufacture, monitoring, storage, and shipping. The German-language version and the English translation of the DIN EN ISO 22716:2008-12 standard may be obtained from the publisher, Beuth Verlag: http://www.beuth.de/de/norm/din-en-iso-22716/112877654
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 (source: Wikipedia). Hazard analysis is the first of seven principles of an HACCP plan. Cf. also (in German): http://www.bfr.bund.de/cm/350/fragen_und_antworten_zum_hazard_analysis_and_critical_control_point_haccp_konzept.pdf.
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)

Abbreviation	Bezeichnung/Erklärung/Verweis
ISO	International Organization for Standardization http://www.iso.org/iso/home.html
ISO 19600	International standard for the implementation of compliance management systems to prevent non-compliant conduct by management or workforce. It allows verification whether those in charge have conducted themselves in compliance with regulation and have adequately fulfilled their obligations. Additional goals of this standard are the evaluation of the effectiveness of compliance measures and pertinent communication as well as continual process improvement. As an ISO standard, it is internationally consistent and intended to offer transnational organizations and businesses a reliable and practicable system for compliant conduct. The German-language version of the standard may be obtained from the publisher, Beuth Verlag: http://www.beuth.de/de/norm/iso-19600/228104966
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 26 January 2016, http://www.gesetze-im-internet.de/lfgb/index.html
Guidelines "Material Declarations within the Supply Chain"(ZVEI 2014)	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: http://www.zvei.org/Themen/GesellschaftlundUmwelt/Seiten/ZVEI-Leitfaden-zu-Materialdeklarationen-innerhalb-der-Lieferkette.aspx
OEM	Original Equipment Manufacturer
Orgalime	European Engineering Industries Association, representing interests of mechanical, electrical, and electronic, metalworking and metal articles industries, http://www.orgalime.org
QMS	Quality Management System
ZVEI	Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (German Electrical and Electronic Manufacturers' Association) http://www.zvei.org/en/Pages/default.aspx

Annex II: Correlations between GMP and ISO 9001

Reference in the present Guidelines or in Commission Regulation (EC) 2023/2006	ISO 9001:2015
5. 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

Reference in the present Guidelines or in Commission Regulation (EC) 2023/2006	ISO 9001:2015
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
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 *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.*	7.1.5 Monitoring and measuring resources 7.1.5.2 Measurement traceability 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: Typical Examples for the Model of Responsibility Levels

Fig. 1: Model of responsibility levels for good manufacturing practice

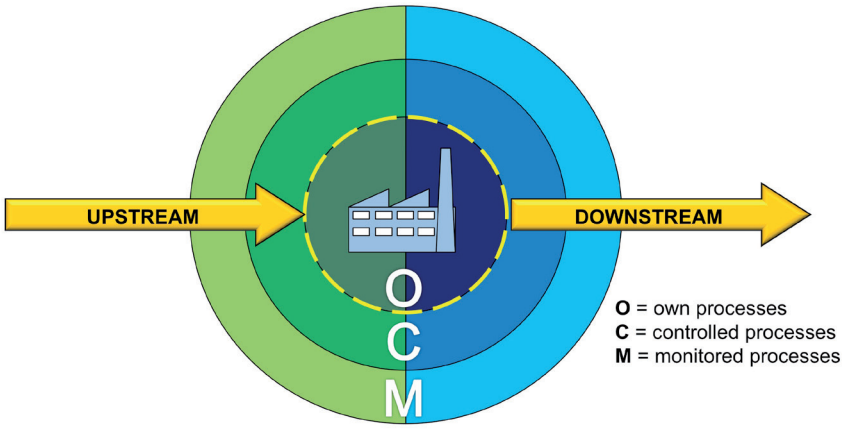
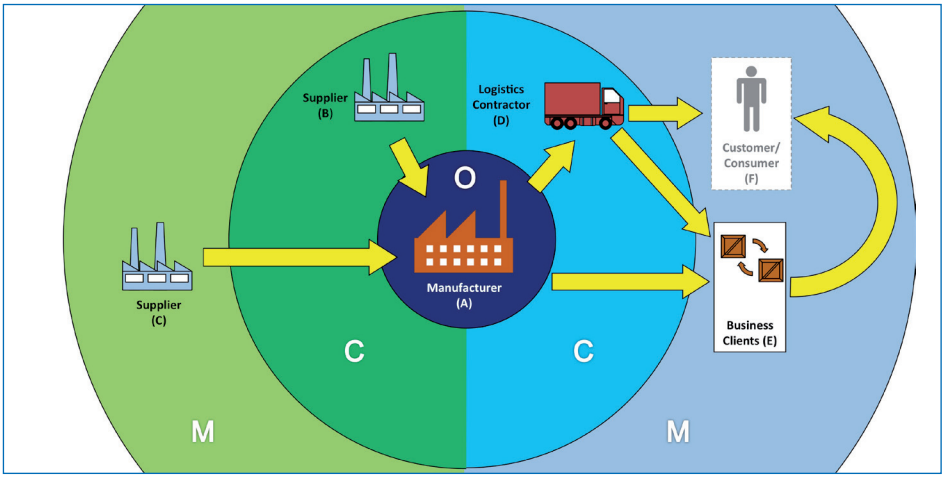


Fig. 2: Case example 1 – all parties are autonomous



Manufacturing company A produces a food processor, for which it obtains modules and components from company B, as shown in the diagram, and standard parts from company C. The finished food processors are then sold either to consumers (F) or to business clients (E). The goods are delivered by a shipping company D hired by company A. All of the companies are autonomous and work independently of each other. Company A does not serve consumers directly.

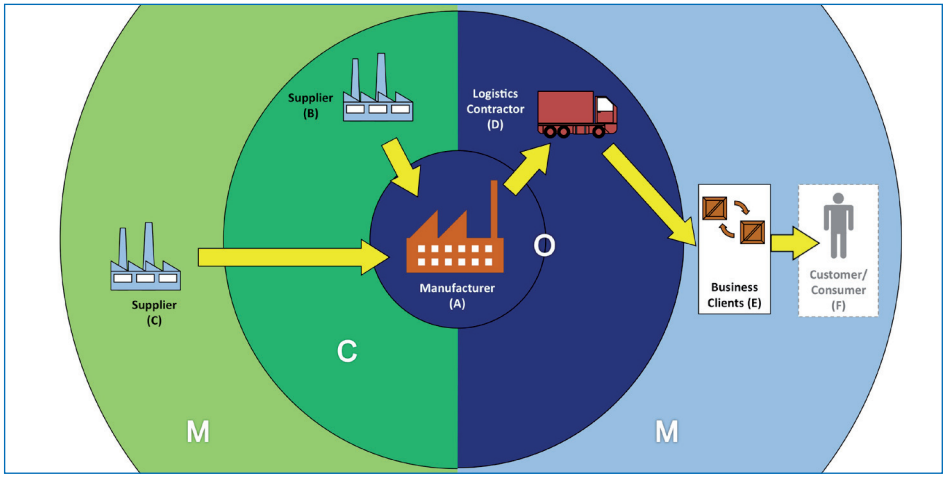
For deducing on which level of responsibility each of the companies operates, their relationship to each other has to be examined. Differentiation has to be based on the questions who establishes the definition/specification and who has to comply with it:

- **relationship entirely within a single company → company's own processes**
- **contractee defines/specifies the products/services → controlled processes**
- **contractor defines/specifies the products/services → monitored processes**
- **no direct relationship → monitored processes**

In our example, the results will be as follows:

- **Relationship A–B:** Company A defines/specifies the modules and components to be supplied by company B, since it has them manufactured according to its own design drawings (technical specifications). → Company B is on level C.
- **Relationship A–C:** Company A does not define/specify the components supplied by company C, since company C has technically specified them according to their own terms or according to third-party terms (standards). → Company C is on level M.
- **Relationship A–D:** Company A defines the services to be provided by company D, which is thus on level C.
- **Relationship A–E:** Company A defines the products, yet is not contractee but contractor in this case. → Business clients E are on level M.
- **Relationship A–F:** Since company A has no direct relationship to consumers F, the end customer is on level M.

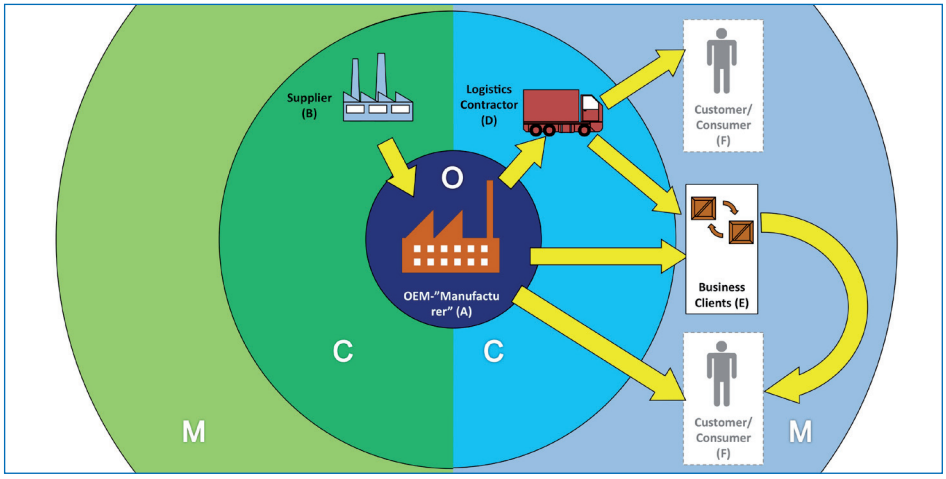
Fig. 3: Case example 2 – in-house service provider



This case is based on example 1, but in this case, the manufacturer decides to take over the logistics contractor, so that all deliveries are handled by the shipping company.

- Due to the change in the **Relationship A–D**, this now becomes an internal relationship and thus transitions from level C to level O!
- If the logistics contractor remains independent/autonomous in legal terms (independent company, not only a department), the relationship does not change (→ case example 1).

Fig. 4: Case example 3 – OEM business



This case is again based on example 1, but the difference is now that manufacturer A decides not to maintain an in-house production and instead become an OEM "manufacturer" who sells modified products from other manufacturers (supplier B) under his own brands. In addition to the sale to business clients (E), he also takes up direct marketing to consumers (F).

- **Supplier B** remains on level C, even though he manufactures products according to his own specifications, since these products are being modified by **manufacturer A** according to the requirements of his brands = final specification by **manufacturer A.**
- Since **manufacturer A** exclusively purchases finished products manufactured according to his own specifications, he does not purchase any standard parts. For this reason, **supplier C** is removed from the diagram, and level M remains empty in the upstream direction.
- In addition to the B2B relationship with **business clients (E)**, there is a new, direct B2C relationship with **end customers (F)**. Even though the consumer is provided with an instruction manual and thus with some sort of "specification" how to use the product as intended, he will remain on level M, as long as there is (as in this example) no contractual obligation on the part of the end customer vis-à-vis the manufacturer, which would allow compliance actually to be verified.

Annex IV: 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

	Priority	Confirmed?		Comment
		Yes	No	
1. Basics				
1.1 Is there a person primarily in charge of GMP?	1			
1.2 Are all applicable laws and regulations known, and are they being documented and communicated?	1			
1.3 Has ISO 9001 or an equivalent quality management system been implemented?	1			
1.4 Is there a system in place for the continual monitoring of good manufacturing practice and its documented results?	1			
1.4.1 Is the system adequate for identifying weaknesses?	1			
1.5 Does quality control fully cover the minimum requirements of GMP Regulation (EC) No. 2023/2006, and is this verified by the QMS?	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			

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

	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 Were special hygiene and cleaning requirements communicated to contracting parties (e.g. logistics contractors, cleaning contractors, suppliers, clients)?	1			
2.4 Is a risk assessment regarding the necessity of pest control conducted regularly and adapted to local conditions?	1			
2.4.1 If necessary, is pest control conducted and documented?	1			
2.5 Have rules been defined for the conduct of potential visitors?	2			
2.5.1 If so, are visitors instructed accordingly before entering GMP areas?	2			
2.5.2 If required, is necessary and suitable protective equipment (e.g. bonnets, overshoes) provided to visitors?	2			

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

	Priority	Confirmed?		Comment
		Yes	No	
3. Materials and Selection of Products				
3.1 Have contracting parties (e.g. suppliers) been informed about the requirements for the manufacture of food contact articles and GMP through suitable documents (e.g. drawings, guidelines, operating instructions, etc.)?	1			
3.2 Are all starting substances and additives used in the manufacture of food contact material checked for compliance with applicable legal requirements[1]?	1			
3.3 Were materials selected according to their intended use and documented accordingly?	1			
3.4 Were all certificates required from suppliers checked for currentness and validity?	1			
3.5 Have supplier audits been performed and documented?	2			
3.6 Were the criteria for design, construction, and materials selection defined, reviewed, and documented?	2			
3.7 Were GMP requirements taken into consideration in the choice of suppliers?	2			
3.8 Are there any documented internal audits, e.g. according to ISO 9001, IFS, BRC, or alternative systems?	2			

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

[1] 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 .

	Priority	Confirmed?		Comment
		Yes	No	
4. Receipt of Goods and Stocks				
4.1 Were materials selected, used, and stored in such a way that they would/could cause no harm to products intended to come into contact with food?	1			
4.2 Were employees/ subcontractors trained on special requirements and certified?	1			
4.3 Was a documented risk assessment of the logistics chain conducted?	1			
4.4 Were delivery terms framed in a way to avoid risks?	1			
4.5 Are incoming goods inspections conducted, documented, and evaluated?	1			
4.6 Are there any special requirements for storage facilities used for storing food contact articles?	2			
4.6.1 If so, is compliance with these requirements checked and documented?	2			

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3 = only required if mentioned in risk assessment

	Priority	Confirmed?		Comment
		Yes	No	
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 Were manufacturing conditions and process parameters documented?	1			
5.6 Are all relevant specifications and documents on hand?	1			
5.7 In case of deviations from specifications in the ongoing production, have pertinent countermeasures been documented?	1			
5.8 Has product packaging/ labeling been defined?	1			
5.9 Was production clearance checked?	2			
5.10 Was batch labeling defined?	2			
5.11 Was the approval of auxiliary and operating materials verified?	2			

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2 = recommended
3 = only required if mentioned in risk assessment

	Priority	Confirmed?		Comment
		Yes	No	
6. Delivery of Goods				
6.1 Were the required declarations of compliance for foodstuffs produced for the customer?	1			
6.2 Were the special GMP requirements during transportation of finished products communicated to personnel/carrier/ subcontractor, and was verification defined?	2			
6.3 If necessary, were separate storage facilities provided?	2			
6.4 Have shipping instructions been defined?	2			
7. Monitoring, Measurement, Analysis and Evaluation				
7.1 In case of changes relevant to food contact, was the declaration of compliance updated accordingly?	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 Were process operations and responsibilities defined?	1			

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2 = recommended
3 = only required if mentioned in risk assessment

	Priority	Confirmed?		Comment
		Yes	No	
7. Monitoring, Measurement, Analysis and Evaluation				
7.5 Were starting materials inspected?	1			
7.6 Was sampling defined?	1			
7.7 Were reference samples taken, if necessary?	1			
7.9 Was it defined by whom and when clearance is required?	1			
7.10 Were the preceding and succeeding links in the supply chain documented?	1			
7.11 Were internal audits performed?	2			
7.12 Were external audits (suppliers, shippers) performed and documented?	2			
7.13 Has a final inspection been conducted before dispatch?	2			

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2 = recommended
3 = only required if mentioned in risk assessment

	Priority	Confirmed?		Comment
		Yes	No	
7. Monitoring, Measurement, Analysis and Evaluation				
7.14 Were special transportation or packaging instructions implemented?	2			
7.15 Have structured methods and processes for continual improvement been defined?	2			
7.16 Were the inspection methods and intervals validated?	2			
7.17 In case of deviations, were tolerances, control measures, and corrective actions defined?	2			
8. Corrective Actions				
8.1 Have corrective actions to eliminate detected weaknesses been defined?	1			
8.2 Is the execution of corrective actions being monitored?	1			
8.3 Are complaint cases documented and evaluated?	1			
8.4 If necessary, are corrective actions deduced from the results of goods inward inspections and documented?	1			

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

Die Elektroindustrie

ZVEI - German Electrical and Electronic
Manufacturers' Association
Lyoner Strasse 9
60528 Frankfurt am Main, Germany

Phone: +49 69 6302-0
Fax: +49 69 6302-317
E-mail: zvei@zvei.org
www.zvei.org