

GOOD MANUFACTURING PRACTICE

Guideline for the Plastic Food Packaging Supply Chain

FOOD, DRUG, AND COSMETIC PACKAGING MATERIALS COMMITTEE

June 2018



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plasticsindustry.org/projectpass



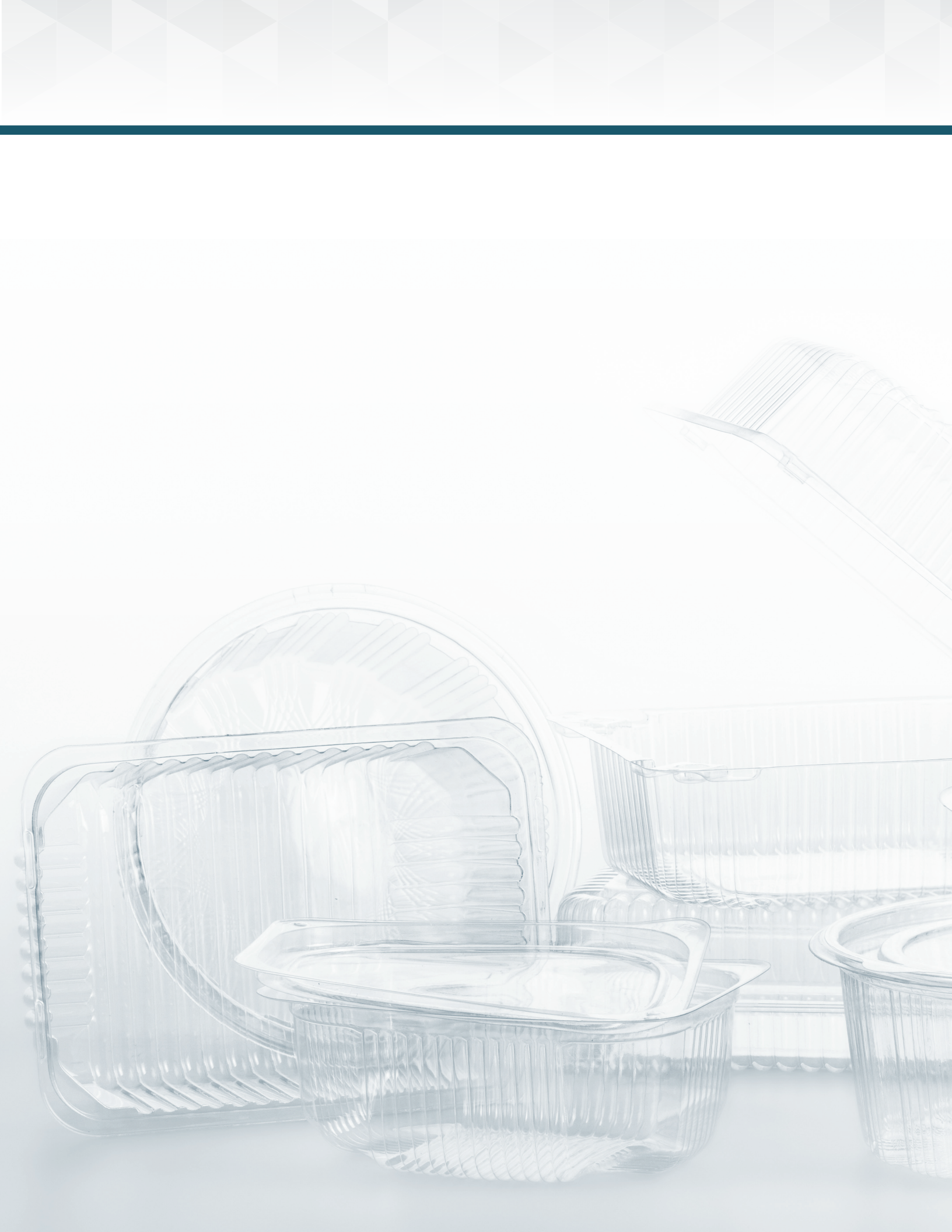
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SUMMARY OF CHANGE

The Introduction has been revised as follows:

- This GMP Guideline applies to facilities that are not required to register with U.S. FDA under Section 415 of the Federal Food, Drug, and Cosmetic Act as facilities that manufacture, process, pack, or hold food for human or animal consumption and are thus not subject to FDA's *Final Rule for Preventive Controls for Human Food*.
- FDA's GMP for direct food additives will transfer from 21 CFR Part 110 to 21 CFR Part 117 upon the effective dates specified in FDA's *Final Rule for Preventive Controls for Human Food* and FDA's *Final Rule: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules*.

The Glossary has been revised as follows:

- The definition of "food" clarifies that 21 CFR Part 1.227 excludes food contact substances, defined in Section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect

in such food."

The Selected Sources section has been updated as follows:

- The following note has been added for the reader: "The URLs below were active and correct as of publication of this version of the Guideline. They are subject to change or break, however, and linked documents may not necessarily be the latest editions of the sources cited. Please take care to verify."
- Broken URLs were replaced, and references to outdated documents were deleted and/or updated to the latest versions.
- A link was added to FDA's *Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)*.
- The Publically Available Specification (PAS) 220 and 223 documents, which informed the original Guideline published in 2012, have been replaced by the Technical Specifications ISO/TS 22002–1 and ISO/TS 22002–4, the latter for food packaging. Once ISO published the requirements as "Technical Specification" (TS), they were benchmarked for FSSC. These are available at the following **link**: <http://22000-tools.com/fssc-22000-checklist.html>
- All references to FDA's *Food and Cosmetic Security Preventive Measures Guidance* have been removed, because this Guidance has been replaced by FDA's *Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration*, which explicitly exempts food-contact substances from its scope.

PREAMBLE

This guideline for the plastics industry was prepared by representatives of numerous PLASTICS member companies which, themselves, comprise numerous links in the plastic food, drug, and cosmetic packaging materials manufacturing supply chain.

The document is intended as a guide to assist employees whose responsibilities include assurance of their companies' adherence to appropriate Good Manufacturing Practices (GMP). It is intended to serve as a general reference tool for companies and facilities throughout the plastic packaging supply chain, from resin manufacturer through packaging converter.

This document does not establish a GMP program that would be appropriate for any particular facility. Rather, this document serves as a guide for topics and areas that should be considered during development of a GMP program for facilities not required to register with U.S.

FDA under the Food Safety Modernization Act (FSMA) and thus not subject to FDA's *Final Rule for Preventive Controls for Human Food*. Any GMP program must be tailored to a specific facility, its manufacturing conditions, the nature of the product being manufactured, and the product's intended use in the packaging supply chain. It is hoped that the concepts and principles discussed below will be a useful tool to assist practitioners with developing an appropriate GMP program for their own facility.



INTRODUCTION

The concept of good manufacturing practice (**GMP**) underpins the manufacture of all products regulated by the Food and Drug Administration (**FDA**).

Food and food packaging must be manufactured under a GMP program that prevents contamination and ensures products will be safe. The regulatory requirements for a well-designed GMP program vary by the type of product being produced and by the position of the product in the manufacturing process and supply chain. GMP must always be considered with regard to the intended use of the product itself, and it is important for all companies that produce food packaging and other food contact materials to understand the appropriate GMP for their individual products. Manufacturers of food products have different GMP requirements than a company that manufactures, for example, a plastic liner that is used to hold the food product.

Likewise, a manufacturer of an additive or resin that is used in the plastic liner will be subject to different GMP than a company converting those materials into a finished plastic liner. With regard to regulatory requirements, FDA's GMP standards for food contact materials are set forth in Section 174.5 of the food additive regulations (21 C.F.R. § 174.5). Section 174.5 simply states the requirement that the regulations for food contact materials are predicated by the requirements of good manufacturing practice. In comparison to the GMP standards for direct food additives (described in 21 C.F.R. Part 117), FDA's GMP regulations for food packaging provide very little specific guidance. The GMP requirements for direct food additives and finished food are not required or appropriate for food contact materials, and FDA has not prescribed the details of appropriate GMP for packaging and other components of food contact materials.

From a practical standpoint, GMPs for indirect food additives (including packaging) require the use of sensible measures to assure the products are made under conditions that minimize the possibilities of

contamination that could result in the adulteration of food, and sufficient documentation of these conditions. Such measures also must ensure that the food contact product is of a purity suitable for its intended use; under Section 174.5, material that is not of a suitable purity is unacceptable for use in contact with food, even if the material otherwise complies with the compositional requirements of an applicable food additive regulation. These necessary measures vary depending on the nature of the product and how close it is to the finished product, i.e., whether it is a component of some other product, is subject to further processing and perhaps purification, or is a finished packaging material. For example, a manufacturer of calcium carbonate used as a filler in a polymer may focus more on ensuring the purity of the substance and storing it under appropriate conditions, while a polyethylene terephthalate resin producer may place more emphasis on compliance with the applicable specifications described in the regulations and controlling the levels of residual monomers.

Any manufacturer of a product that may become a component of food has a general obligation to take all reasonable steps necessary to minimize potential impurities and contaminants in the product, and to institute procedures to ensure that the finished product conforms to appropriate specifications. Appropriate care must be taken to assure GMP compliance. This includes considering existing regulatory requirements and industry standards. This guidance does not supplant these sources of GMP requirements, but rather provides general principles to assist with implementation. Factors such as technological limitations, the toxicity of the components at issue, and others may also affect development of the GMP program and must be considered on an individual basis.

CATEGORIES

CATEGORY 1 ↘

GMP PLAN

Many of the essential principles of an appropriate GMP program are incorporated into effective, accountable, documented management systems under any title including, but not limited to, “GMP.” The design of a GMP program can build upon existing quality systems, which may be deemed to be sufficient in and of themselves.

CATEGORY 2 ↘

MANAGEMENT LEADERSHIP AND PERSONNEL

Management should provide appropriate resources for qualified supervisory and involved personnel to perform GMP activities related to finished articles, intermediate materials and food contact substances:

- Management responsibilities for GMP implementation should be assigned, defined and documented.
- Personnel should be adequately trained in a manner that they can understand, observe, and implement the requirements of a company’s GMP plan.

CATEGORY 3 ↘

HYGIENE AND PEST CONTROL

- Hygiene measures, as appropriate to the process and/or position in the supply chain, should be implemented, maintained, and documented for personnel, factories, warehouses, and transportation vehicles/vessels/containers.
- Pest control measures should be maintained and documented as appropriate to the manufacturing process and/or position in the supply chain. Care should be taken that the pest control measures employed are appropriate for use in proximity to food contact materials, considering both the impact on food safety and the impact on the organoleptic properties of the product (e.g., could the pest control measure create an unwanted taste or odor problem).

CATEGORY 4 ↘

DOCUMENTATION

- GMP documents referenced in other sections of this GMP Guideline should be retained and periodically reviewed and updated per individual company policy. Companies should ensure that they are complying with applicable record retention policies.

- Examples may include:
 - » specifications
 - » declarations and assurances
 - » product formulations
 - » batch/lot records
 - » process parameters
 - » control procedures
 - » test methods and analytical records
 - » calibration
 - » standard operating procedures
 - » management of change
 - » maintenance/cleaning protocols
 - » non-conformance investigations

CATEGORY 5 ↘

FLOW OF OPERATIONS

Raw Material Specifications and Acceptance Criteria

- Specifications should be established, reviewed and re-validated on a regular basis, as deemed appropriate.
- Companies should consider a process to specify and approve raw materials based on their conformity with applicable regulations and rules of suitable purity for their intended use.
- A process should be determined for approving suppliers of raw materials.
- A process should be considered to verify raw materials’ conformance, and to identify and control non-conformant materials.
- Resulting documentation—including, for example, supplier declarations and assurances—should be maintained and reviewed as deemed appropriate.

Process and Product Specifications and Evaluation

- Specifications should be established, reviewed and re-validated on a regular basis, as deemed appropriate.
- Procedures should be available to manufacturing personnel so that they may be checked to avoid deviations.
- Procedures to verify manufacturing process conformance with applicable specifications, and to identify and control non-conformant process parameters should be documented.

- Procedures should address internally generated and recycled materials, as appropriate

Facilities and Equipment

Consideration should be given to the processes used to design, install and maintain facilities and equipment for purposes of protecting product integrity and purity. Some examples may include but are not limited to:

- Water of suitable quality
- Ice, water backflow prevention
- Wastewater management
- Ancillary materials (e.g., machine lubricants, process lubricants, other processing aids)
- Ingress and egress to the facility, with respect to hygiene and security

The following examples may apply to open processes and not to closed processes:

- Lighting (e.g., shatterproof or guarded/ shielded)
- Facilities' condition (e.g., holes in walls, roofs, exterior grounds)
- Employee facilities (e.g., personal storage lockers, cafeteria/break room, restrooms, hand washing facilities)

Laboratories

Internal and external laboratories should possess the qualifications and capabilities deemed necessary to provide accurate and reliable results. Laboratories should have processes in place to ensure the proper handling of samples and results.

Contamination Prevention

Processes should be in place to identify, assess, and control critical hazards, if any, that might otherwise result in contamination of products by unwanted biological, chemical, and/or physical agents.

Considerations include:

- Equipment and set up procedures to control cross-contamination
- Procedures to control cross-contamination when transitioning from one product to another

- Control systems to prevent cross-contamination among raw materials, work in process, auxiliary materials, maintenance and cleaning supplies, finished products, etc., as appropriate
- Procedures to control contamination during materials handling, transfer, packaging and loading operations

Packaging and Labeling

- Processes should be considered to specify and approve product packaging materials in accordance with applicable industry and authoritative standards.
- Companies should adopt procedures to ensure all materials are properly and clearly identified and labeled, as appropriate. Examples may include ancillary materials, finished products, work in progress, recycled materials, and in-use chemicals.
- Containers should be properly closed and adequately secured to prevent contamination.

Storage, Warehousing and Transportation

- Equipment used for storage and transportation of materials should be designed to facilitate sanitation and pest control operations.
- Storage facilities and transportation services should protect the quality of materials (e.g., environmental controls, cross contamination, and off-odors prevention).
- Procedures should be put into place to minimize, identify, and mitigate damage and contamination to containers and their contents.
- Inventory rotation practices should be designed as appropriate (e.g., obsolescence, first in first out).

CATEGORY 6 ↘

DEFENSE AND PRODUCT SECURITY

Security measures should be adequate to defend against adulteration. Preventive practices, as appropriate, may include the following examples:

- Operations evaluated; vulnerabilities to tampering and sabotage identified and mitigated
- Access to facilities limited only to authorized personnel; door keys issued and controlled; employee and visitor ID badges

- Access from facilities' exterior controlled (e.g., locked doors, perimeter fencing, restricted vehicle access, security personnel)
- Secured incoming and outgoing transport vehicles' contents
- Effective electronic information security controls

CATEGORY 7 ↘ **TRACEABILITY**

- Traceability should be established throughout the manufacturing process to facilitate necessary actions. A product lot coding scheme is one example of a traceability-facilitating practice.
- This process should be tested to assess or validate, as appropriate, its accuracy and reliability.

CATEGORY 8 ↘ **INCIDENT AND NON-CONFORMANCE PROTOCOLS**

- A system should be established for recording and investigating incidents and non-conformances and initiating appropriate responses, which may include product recovery if needed.
- Appropriate reactive, corrective and preventive actions should result from this process.
- This process should be tested to assess its effectiveness. The test may include, for example, mock product recovery exercises.

CATEGORY 9 ↘ **INTERNAL AND SUPPLIER ASSESSMENTS**

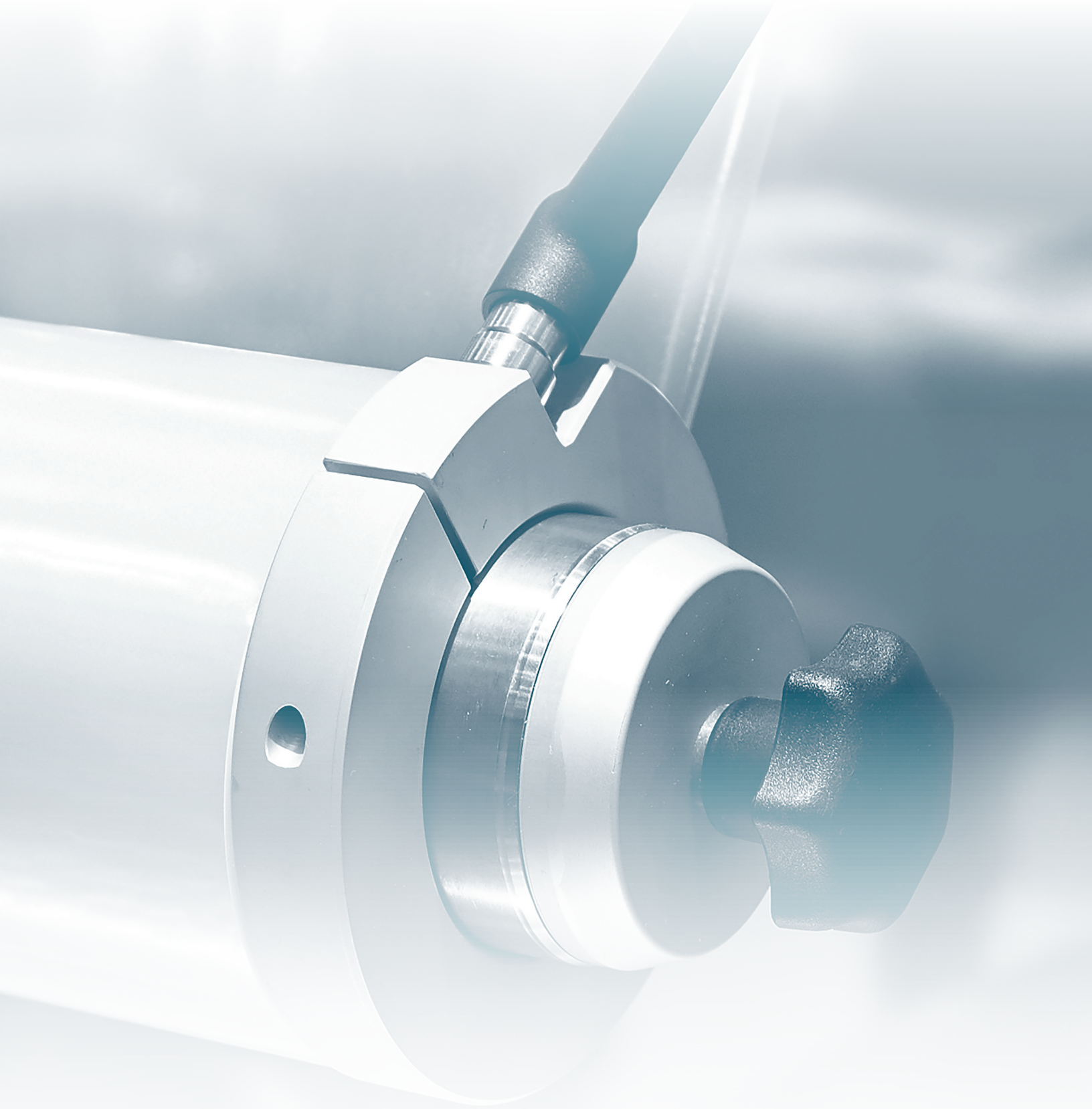
GMP elements should be subjected to assessments to gauge effectiveness. Periodic audits are one option for assessment.

CATEGORY 10 ↘ **CONTRACTED WORK**

Providers of contracted services (e.g., toll manufacturing facilities, storage facilities, sanitation services, transportation services, on-site contractors) should be required to adhere to applicable practices included in this GMP guideline.

CATEGORY 11 ↘ **MANAGEMENT OF CHANGE**

Appropriate procedures should be established to guide employees in the initiation, review, approval and proper communication (internally and/or externally) of changes that impact GMP included in this guideline.



GLOSSARY

These definitions do not supersede or replace legal or regulatory definitions. Rather, these definitions reflect the conventional understanding of practitioners to whom this document is addressed. Practitioners should reference regulatory and guidance documents applicable to their operations while considering their customers' specifications.

Good Manufacturing Practice (GMP): those activities and procedures which reasonably assure finished articles, intermediate materials, or food contact substances are produced and controlled to conform with applicable regulations and standards of suitable purity for their intended use. This GMP Guideline applies to facilities that are not required to register under Section 415 of the Federal Food, Drug, and Cosmetic Act as facilities that manufacture, process, pack, or hold food for human or animal consumption with U.S. FDA and are thus not subject to FDA's *Final Rule for Preventive Controls for Human Food*.

Food: that which is intended for consumption by humans, domesticated pets, and/or livestock. Although the FDA definition of food does include food contact substances, facilities must only register with FDA when they manufacture, process, pack, or hold food for human or animal consumption. This facility registration requirement excludes food contact substances, defined in Section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act as "any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food."

Finished Article: the finished film, bottle, tray, etc., formed from food contact substances and/or intermediate materials, in which food is packaged and/or held.

Intermediate Material: comprised of one or more food contact substances, intermediate material is used to form the finished article. It is not an intermediate process step prior to the formation of a food contact substance.

Food Contact Substance (FCS): One authoritative definition is in Section 409 of the U.S. Federal Food, Drug and Cosmetic Act, which defines an FCS as any

substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food.

Closed Process: a manufacturing process that is self-contained and not exposed to the ambient environment.

Open Process: a manufacturing process that has one or more vessels, feeders, or transfer systems that are not self-contained and therefore exposed to the site's ambient environment.

Contamination: the presence of unwanted biological, chemical, or physical agents in finished articles, intermediate materials, or food contact substances.

Policy: an overall plan articulating general goals and acceptable procedures.

Raw Materials: intentionally added chemicals or mixtures that take part in or are present during the production of food contact substances, intermediate materials, and finished articles.

Suitable purity: a determination that byproducts or impurities are not present at levels that would cause an adverse health, safety and/or organoleptic effect when the finished article is used, as intended, in contact with food. Articles intended for use in contact with food must be compositionally compliant with the applicable food additive regulations and of a purity suitable for their intended use.

Traceability: the ability to trace the history, application, or location of a food contact substance, intermediate material or finished article of interest through production, processing, and distribution, from the supplier (one step back) to the intended customer (one step forward).

SELECTED SOURCES OF INFO ON PLASTICS-RELATED GOOD MANUFACTURING PRACTICE

NOTE: The URLs below were active and correct as of publication of this version of the Guideline. These URLs are subject to change or break, however, and linked documents may not necessarily be the latest editions of the sources cited. Please take care to verify.

Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Seventh Edition)
U.S. Food and Drug Administration (August 2018)

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm>

Consolidated Standards for Inspection: Food Contact Packaging Manufacturing Facilities
AIB International (October 2016)

<https://www.aibonline.org/apac/Schedule-Your-Facility-Visit/Resources/Consolidated-Standards/Food-Contact-Packaging-Manufacturing-Facilities>

Global Standard for Packaging and Packaging Materials
British Retail Consortium (July 2015)

<https://www.brcglobalstandards.com/brc-global-standards/packaging/>

FSSC22000 Food Safety System Certification version 4.1
Foundation FSSC22000 (December 2016)

<http://www.fssc22000.com/documents/standards/downloads.xml?lang=en>

Commission Regulation (EC) 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, Official Journal of the European Union, L384, 29-12-2006, pp.75–78.

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:384:0075:0078:EN:PDF>

Grade “A” Pasteurized Milk Ordinance, Appendix J, Standards for the Fabrication of Single Service Containers and/or Closures for Milk and/or Milk Products (2015 Revision)
U.S. Food and Drug Administration

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/>

UCM513508.pdf

Good Manufacturing Practices for aluminium alloy semi and end products intended to come into contact with foodstuff

European Aluminium Association (April 2012)

www.pac.gr/bcm/uploads/gmp-alum.pdf

Good Manufacturing Practice (GMP) Printing Inks for Food Contact Materials

European Printing Ink Association (March 2016)

http://www.eupia.org/uploads/tx_edm/2016-03-31-EuPIA_GMP_4th_version_final.pdf

Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food Flexible Packaging
Europe, CITPA (July 2011)

http://www.flexpack-europe.org/files/FPE/downloads/FPE_GMP_Code_6.0.pdf

Guidelines for Good Manufacturing Practice for Plastic Materials and Articles Intended for Food Contact Applications
Plastics Europe, CEFIC-FCA, and European Plastics Converters (June 2011)

<https://www.plasticseurope.org/en/resources/publications/114-guidelines-good-manufacturing-practice-plastic-materials-and-articles-intended-food-contact-applications>

SQF Food Safety Code for Manufacture of Food Packaging
Safe Quality Food Institute (March 2017)

<http://www.sqfi.com/documents/>



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