



Good Manufacturing Practice Guideline for the Plastic Food Packaging Supply Chain

Food, Drug, and Cosmetic Packaging Materials Committee

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PREAMBLE

This SPI guideline for the plastics industry was prepared by representatives of numerous SPI 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. 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 110), 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; material that is not of 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. Heroic measures are not required; instead, reasonable 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.

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 (include consideration of organoleptic properties).

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.
- 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 to verify manufacturing process conformance with applicable specifications, and to identify and control non-conformant process parameters should be documented. These procedures should address internally generated and recycled materials, as appropriate.
- Procedures should be documented to verify product conformance with applicable specifications, and to identify and control non-conformant products.

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;
- Waste water management;
- Ancillary materials (e.g., machine lubricants, process lubricants, other processing aids).

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.

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, with respect to such examples as ancillary materials, finished products, work in process, and 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 I.D. 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 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 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. An audit is one type of 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 elements included in this GMP guideline.

CATEGORY 11 - MANAGEMENT OF CHANGE

Procedures should be considered 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.

Food: that which is intended for consumption by humans, domesticated pets, and/or livestock.

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 & 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 unintended 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 Information on Plastics-Related Good Manufacturing Practice

Consolidated Standards for Inspection: Food Contact Packaging Manufacturing Facilities
AIB International (2010)

http://www.aibonline.org/Standards/Food_Contact_Pk_Eng_Man_Web.pdf

Global Standard for Packaging and Packaging Materials
British Retail Consortium (2011)

<http://www.brcglobalstandards.com/standards/packaging-and-packaging-materials/>

PAS 223: Prerequisite programmes and design requirements for food safety in the manufacture and provision of food packaging

British Standards Institute (2011)

<http://shop.bsigroup.com/en/SearchResults/?q=PAS223>

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>

Food and Cosmetic Security Preventative Measures Guidance

Department of Health and Human Services, Food and Drug Administration (2007)

<http://www.fda.gov/Food/FoodDefense/FoodSecurity/default.htm>

Grade "A" Pasteurized Milk Ordinance, Appendix J (2009 Revision)

Department of Health and Human Services; Public Health Service;

Food and Drug Administration

<http://www.fda.gov/food/foodsafety/Product-SpecificInformation/MilkSafety/default.htm>

Code for Good Manufacturing Practices for the European Aluminum Industry

European Aluminium Association (2008)

<http://www.alueurope.eu/wp-content/uploads/2011/08/EAA-GMP-Aug081.pdf>

Good Manufacturing Practices for the Production of Packaging Inks formulated for use on the non-food-contact surfaces of food packaging and articles intended to come into contact with food

European Printing Ink Association (2009)

http://www.eupia.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=10008E&eas:dat_im=05048E

Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food

Flexible Packaging Europe, CITPA (2011)

http://www.flexpack-europe.org/upload/Documents/FPE_GMP_Code_6.0.pdf

FSSC (Food Safety System Certification) 22000: Certification scheme for food safety systems in compliance with ISO 22000: 2005 and BSI - PAS 220: 2008, Part I: Requirements for Organizations that Require Certification

Foundation for Food Safety Certification (July 2010)

<http://www.fssc22000.com/downloads/part1.pdf>

Product Safety, Quality and Defense Expectations and Criteria for Manufacturing Facilities of Food Contact Packaging Materials, Food - Related Items, and Personal Care (Contact) Products
NSF Cook & Thurber (2011)

http://www.nsf.org/business/NSF_cook_and_thurber/documents.asp?program=NSFCooThu

Guidelines for Good Manufacturing Practice for Plastic Materials and Articles Intended for Food Contact Applications

Plastics Europe, CEFIC-FCA, and European Plastics Converters
(December 2005, Updated April 2008)

<http://www.plasticseurope.org/Document/guidelines-for-good-manufacturing-practice-for-plastic-materials-and-articles-intended-for-food-contact-applications.aspx?Page=DOCUMENT&fOLid=2>

Guidance for Developing, Documenting and Implementing an SQF 2000 System – General Food Packaging Materials - Manufacture and Distribution

Safe Quality Food Institute (2010)

<http://www.sqfi.com/wp-content/uploads/2000-Guidance-FoodPack.pdf>

