

# ASEAN Guidelines for Good Manufacturing Practice for Food Contact Materials

## Forward

The Prepared Foodstuff Product Working Group (PFPWG) under the ASEAN Consultative Committee on Standards and Quality (ACCSQ) established the ASEAN General Guidelines on Food Contact Materials to provide general principles and requirements in relation to safety, composition, and organoleptic integrity of food contact materials<sup>1</sup> (herein after referred to as FCM) placing on the market of ASEAN Member States. To ensure such conformity, the ASEAN General Guidelines on Food Contact Materials requires that all FCM shall be manufactured in compliance with good manufacturing practice (herein after referred to as GMP).

This document provides guidelines for GMP for FCM referred to in the ASEAN General Guidelines on Food Contact Materials and the combinations of those groups of FCM as well as recycled materials used in those groups of FCM.

## SECTION 1 SCOPE

1. This document applies to all sectors responsible for manufacturing of FCM, excluding the production of starting substances.

## SECTION 2 DEFINITIONS

2. For the purposes of this document, the following definitions as well as the relevant definitions stated in the ASEAN General Guidelines on Food Contact Materials shall apply:
  - (a) **'Food-contact side'** means the surface of a material or article that is directly in contact with the food;
  - (b) **'Good Manufacturing Practice (GMP)'** means those aspects of quality assurance which ensure that FCM are consistently produced and controlled to ensure conformity with the guidelines 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;
  - (c) **'Non-food-contact side'** means the surface of a material or article that is not directly in contact with the food;
  - (d) **'Quality assurance system'** means the total sum of the organised and documented arrangements made with the purpose of ensuring that FCM are of the quality required to

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<sup>1</sup> SECTION 3 SCOPE, para 5 of the ASEAN General Guidelines on Food Contact Materials, the term "FCM" covers any types of materials and articles in their finished state that:

- are intended to be brought into contact with food; or
- are already in contact with food and were intended for that purpose; or
- can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable conditions of use.

ensure conformity with the guidelines applicable to them and the quality standards necessary for their intended use;

- (e) **'Quality control system'** means the systematic application of measures established within the quality assurance system that ensure compliance of starting materials, intermediate and finished materials and articles with the specification determined in the quality assurance system;
- (f) **'Suitable purity'** means the quality of a substance of which by-products or impurities are not present at level that would cause an adverse health, safety, and/or organoleptic effect when the finished article is used, as intended, in food contact applications;
- (g) **'Raw materials'** means any substances or materials that take part in or are present during the physical transformation of FCM. These include material recovered from a production process either in house or brought from an external source.

### **SECTION 3 CONFORMITY WITH GMP FOR FCM**

3. Business operators should ensure that manufacturing operations are carried out in accordance with these guidelines.
4. The implementation of these guidelines may vary by the type of FCM being produced and by the position of FCM in the manufacturing process. The guidelines should be applied proportionately to avoid undue burdens for small businesses.
5. To assist business operators implementing this document, an example of these guidelines for plastic materials and articles intended for food contact applications is given in Annex 1. The example is intended as a non-prescriptive generic guidance.

### **SECTION 4 QUALITY ASSURANCE SYSTEM**

6. The business operator should establish and maintain an effective documented quality assurance system. The quality assurance system should be managed via documented evidence and records pertinent to various manufacturing operations. This quality assurance system should ensure:
  - (a) the adequacy of personnel; their knowledge and skill, in particular the role within the GMP system and the respective tasks and responsibilities;
  - (b) the organization of premises in order to be suited to the entire production and logistic system;
  - (c) the adequacy of equipment suited for the production of FCM.
7. The quality assurance system should be appropriate for the size of the business so as not to be excessively burden on small businesses.
8. The business operator may avail himself of internal or external resources to carry out the operations of the same.
9. Starting substances should be selected and complied with pre-established specifications and suitable purity that should ensure compliance of the product with the guidelines applicable to it.

10. Different operations should be carried out in accordance with pre-established instructions and procedures. Business operators should establish such documents covering all operations relevant to the conformity of FCM with the applicable guidelines.
11. The important elements of quality assurance system which should be addressed, but not limited to, are management leadership and personnel involvement; hygiene management; documentation system; production; contracted work; complaint and product recall management; and internal and supplier audits.

## **SECTION 5 QUALITY CONTROL SYSTEM**

12. The business operator should establish and maintain an effective quality control system that guided by documented activities for monitoring and maintaining the quality assurance system.
13. The quality control system should monitor key parameters determining the fitness-of-use of starting substances, raw materials, semi-finished products, and finished products.
14. The quality control system should monitor key parameters determining safety, composition, and organoleptic integrity of the finished products.

## **SECTION 6 DOCUMENTATION**

15. The business operator should 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.
16. The business operator should 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.
17. The documentation should be made available by the business operator to the competent authorities at their request.

## **SECTION 7 THE APPLICATION OF PRINTING INK**

18. Printing inks should only be applied to the non-food-contact side of FCM and the printed surfaces should not come into direct contact with food.
19. The formulating of printing inks and the handling of printed FCM should be in such a manner that substances from printed surface are not transferred to the food-contact side:
  - (a) through the substrate or;
  - (b) by set-off in the stack or reel,

in concentrations that lead to levels of the substance in the food which do not transfer their constituents to food in quantities which could:

  - (a) endanger human health;
  - (b) bring about an unacceptable change in the food;

(c) bring about unacceptable changes in the organoleptic characteristics thereof.

## **ANNEX 1**

# **GMP for Plastic Materials and Articles Intended for Food Contact Applications**

### **1. OBJECTIVE**

This document aims to assist business operators dealing with the production of plastic materials and articles intended for food contact applications in effectively implementing the ASEAN Guidelines for Good Manufacturing Practice for Food Contact Materials.

### **2. SCOPE**

This annex provides guidance for GMP for plastic materials and articles intended for food contact applications.

The details may vary depending on the position in the supply chain beginning at the approval and acceptance of the starting substances for polymer production and ending when the materials and articles come into contact with food.

The production of starting substances (e.g. monomers, catalysts) as well as the manufacture of multi-layer multi-material packaging which does not consist exclusively of plastics is excluded from the scope of this Annex.

### **3. GENERAL**

The document provided below is designed to fulfill the requirements of GMP for FCM. However, they can vary depending on the nature of the product and the position in the supply chain.

#### **3.1 Quality assurance system**

Business operators dealing with the production of plastic materials and articles intended for food contact applications should take account of:

- (a) the establishment of a quality policy which is adequate to consistently produce plastic materials and articles for food contact applications in compliance with the applicable guidelines;
- (b) the establishment of an effective quality assurance system with the active participation of management and personnel;
- (c) the establishment of a quality control department to take responsibility and authority to independently approve/reject all materials in the process.

The quality assurance system should address the following key elements

##### **3.1.1 Management leadership and personnel involvement**

- (a) Management responsibilities for GMP implementation are assigned, defined, and documented.
- (b) The personnel supervising or performing the manufacture or control of plastics intended for food contact applications should be adequately trained in a manner that they can understand and perform the assigned functions.

- (c) Training of personnel should include training on GMP for FCM.

### **3.1.2 Hygiene management**

- (a) 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 containers/vehicles/vessels.
- (b) Pest control measures, as appropriate to the process and/or position in the supply chain, should be maintained and documented or the justification for lack of one should be documented.

### **3.1.3 Documentation system**

- (a) There is a system in which product formulations, operating procedures, process parameters, control procedures, product specifications, batch/lot records, test methods, analytical records, management of change, maintenance protocols, non-conformance investigation, and other important information should be documented, retained, and periodically reviewed and updated.
- (b) In a factory where plastics are produced for food contact use as well as for non-food contact use, and when there is a risk of cross contamination that the quality of FCM will be compromised, the production of plastics intended for food contact applications should be clearly marked.
- (c) Procedures covering traceability from incoming starting substances to outgoing food contact plastics are in place. These procedures also take into account the use of raw material recovered from a production process and the recording and traceability of their use.
- (d) Major equipment, transfer lines, containers, and tanks that are used for processing, filling or holding food contact plastics should be identified by either labelling or electronic control systems to indicate contents, batch designation, control status, and other pertinent information.

### **3.1.4 Production**

#### ***Starting substances and/or raw materials specifications and acceptance:***

- (a) There is a procedure to select and approve suppliers of starting substances and/or raw materials.
- (b) There is a procedure to specify and approve starting substances and/or raw materials. Only approved substances or materials are used.
- (c) There is a procedure to verify the conformance and suitable purity of starting substances and/or raw materials before use.
- (d) Non-conformant starting substances and/or raw materials should be identified and controlled to prevent misuse.
- (e) There is a procedure to prevent the contamination of starting substances and/or raw materials during storage, handling, and transportation.

***Contamination prevention:***

- (a) There are adequate procedures based on risk assessment to prevent and response to contamination. These procedures are in place to assure that the relevant operations are conducted in such a way to avoid product contamination.
- (b) The equipment and set up are adequate to preclude cross-contamination between products for food contact and those for non-food contact.
- (c) There are effective transition procedures such as cleaning to avoid cross-contamination when transitioning from non-food contact to food contact products.
- (d) There is a separation procedure or control system to segregate starting substances and/or raw materials as well as products that are non-conformant.
- (e) There are procedures in place to assure that transfer, packaging or loading operations are conducted in such a way to avoid product contamination.

***Facilities and equipment:***

- (a) The design of process, installation, and maintenance of facilities and equipment for purposes of protecting product integrity and purity should be taken into account.
- (b) Examples include, but not limited to, water of suitable quality, waste water management, lighting, and employee facilities (e.g. hand washing facilities, lockers).

***Process and product specifications and evaluation:***

- (a) There are procedures to establish specifications of process and products.
- (b) These specifications should be documented, reviewed, and revalidated on a regular basis.
- (c) There are documented procedures to verify manufacturing process conformance with established specifications and to identify and control non-conformant process parameters.
- (d) There are documented procedures to verify product conformance with established specifications and to identify and control non-conformant products.

***Incident reporting and corrective actions:***

- (a) There is a system to record and investigate incidents and non-conformances and initiate appropriate responses, which may include product recovery.
- (b) Appropriate preventive actions should be established to avoid those incidents and non-conformances.
- (c) The effectiveness of the preventive actions should be tested.

***Management of change:***

- (a) There is a management of change procedure in case manufacturing process has been changed. The management of change procedure is capable of detecting and indicating potential changes in the composition or increases risk of contamination.
- (b) Changes in product formulations, starting substances and/or raw materials or suppliers of these materials are subject to a management of change.
- (c) There are documented procedures to evaluate the impact of such changes on the final product quality, performance, composition, and compliance with applicable guidelines.

***Storage, packaging, warehousing, and transportation:***

- (a) Equipment used for storage and transportation of starting substances and/or raw materials should be designed to facilitate sanitation and pest control operation and to prevent contamination.
- (b) Storage and transportation facilities (e.g. silo, truck) can either be dedicated equipment receiving only food contact materials or alternatively there are effective measures (such as cleaning) to ensure that the containers do not contain any products or contaminants that are not compatible with the intended use of food contact.
- (c) Inventory rotation practices should be designed (e.g. first in, first out).
- (d) Packaging of products should be specified and approved in accordance with applicable standards.
- (e) There are procedures in place to ensure all materials are properly and clearly identified and labelled.

**3.1.5 Contracted work**

- (a) Any contracted work (e.g. manufacturing facilities, transportation services) should be subject to written contracts.
- (b) Providers of those contracted services are required to perform according to this GMP guidelines comparable to the one assured by the own operation.

**3.1.6 Complaint and product recall management**

- (a) There is a system in place for recording and investigating incidents and complaints, including product recall if needed. The investigation should result in recommendations for corrective and preventive actions.
- (b) There are measures in place to ensure that non-conforming or recalled products are not released for food contact use without extensive investigation and proper authorisation.

**3.1.7 Internal and supplier audits**

- (a) There is a procedure in place to ensure regular internal audits or self-assessments and supplier audits in order to monitor the implementation and respect of GMP.

### **3.2 Quality control system and Specifications**

Business operators dealing with the production of plastic materials and articles intended for food contact applications should take account of the following issues:

- (a) Specifications for starting substances and/or raw materials and finished products are documented.
- (b) Starting substances and/or raw materials and finished products should be monitored to verify their compliance and conformance with specifications.
- (c) Testing to verify such compliance and conformance are conducted either internal or external laboratories which should possess the qualifications and capabilities deemed necessary to provide accurate and reliable results.
- (d) Every food contact material product code has one unique specification.

Bibliography:

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