

ASEAN General Guidelines on Food Contact Materials

The ASEAN Secretariat
Jakarta



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ASEAN General Guidelines on Food Contact Materials

Foreword

The development of the ASEAN General Guidelines on Food Contact Materials (FCM) has been undertaken by the Prepared Foodstuffs Product Working Group (PFPWG) established by the ASEAN Consultative Committee on Standards and Quality (ACCSQ). It is intended that this document serves as a reference to ASEAN Member States as a means of enhancing food safety across the region through the establishment of harmonised requirements. This document provides general guidelines for Food Contact Materials while specific requirements will be developed in separate documents.

The PFPWG intends to prioritise and establish the schedule for the development of specific measures for 17 groups of Food Contact Materials as listed in Annex.

To support the implementation of ASEAN General Guidelines for Food Contact Materials, PFPWG has also developed an ASEAN Guidelines for Good Manufacturing Practice for Food Contact Materials.

ASEAN General Guidelines on Food Contact Materials

SECTION 1 INTRODUCTION

1. Food Contact Materials play an important role in food supply chain by protecting food against contamination during storage and transportation. However, they have potential to transfer a number of harmful chemicals into food. Therefore, an effective control system for FCM is critical to ensure safety of food products throughout their shelf-life.
2. This ASEAN General Guidelines on Food Contact Materials provides ASEAN Member States (AMS) with a common set of guidelines for the establishment of control systems for FCM. The Guidelines should be used in conjunction with the ASEAN Guidelines for Good Manufacturing Practice for Food Contact Materials and where appropriate with applicable specific measures.

SECTION 2 OBJECTIVE

3. This document is intended primarily to provide general guidelines for use by competent authorities and food industries to ensure the use of safe food packaging. This document also provides guidance on traceability system to assist food industries to be able to identify the compliance of FCM with the relevant requirements, thereby protecting consumers and facilitating trade in foodstuffs among AMS.
4. This document also provides general guidance in relation to the placing, on the market of AMS, of FCM intended to come into contact with food.

SECTION 3 SCOPE

5. This document provides general guidelines for the safety and safe use of FCM FCM, which 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.
6. These Guidelines shall not apply to:
 - (a) FCM which are naturally occurring, such as banana leaves, bamboo leaves, bamboo stalks, molluscs shells, and have not been subjected to chemical treatment or modification;
 - (b) covering or coating materials which form part of the food and may be consumed together with this food such as edible casings, for sausage or cheese, [materials derived from inner walls of bamboo culm covering glutinous rice sticks]; and
 - (c) fixed public or private water supply equipment.

SECTION 4 DEFINITIONS

7. For the purposes of these Guidelines, the following definitions shall apply:
- (a) '**Business**' means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of manufacturing, processing and distribution of FCM;
 - (b) '**Business operator**' means the natural or legal persons responsible for ensuring that the requirements of these Guidelines are met within the business under their control;
 - (c) '**Declaration of Compliance**' (**DoC**) is a written declaration by a business operator that a FCM complies with all the relevant requirements applicable to the particular FCM;

Note:

This document is to confirm to the customer the compliance of the FCM with the relevant requirements and to provide the customer with relevant information necessary to establish or check the compliance of the FCM with relevant requirements.

- (e) '**Placing on the market**' means the holding of FCM for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution and other forms of transfer themselves;
- (f) '**Starting substances**' are substances that are intentionally added or are present during the production of materials;
- (g) '**Traceability**' means the ability to follow the movement of FCM through all stages of manufacture, processing and distribution.

SECTION 5 GENERAL PRINCIPLES AND REQUIREMENTS

8. To ensure the use of safe food packaging, food industries should be able to identify the compliance of FCM with this guideline.
9. All FCM shall be manufactured in compliance with good manufacturing practice (GMP)¹ so that under normal or foreseeable conditions of use, the FCM 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.
10. The safety of FCM should be determined by risk assessment of substances. For FCM authorised by national/regional authority may be considered to be safe upon review of relevant risk assessment result and/or of approvals granted by the relevant national/regional authority.

Substances used in the manufacture of FCM and FCM in its finished state shall comply with the requirements applicable in the AMS in which it is placed in the market.

¹ The ASEAN Guidelines for Good Manufacturing Practice for Food Contact Materials(GMP) refer.

11. The release of constituents from FCM into food shall be as low as reasonably practicable in accordance with Good Manufacturing Practice (GMP) to avoid contamination of food and to preserve the characteristics thereof. Overall migration limits and specific migration limits, when appropriate, shall be established.
12. The release of constituents from FCM into food shall not change the organoleptic characteristics of food so as to render the food unfit for human consumption.

SECTION 6 SPECIFIC MEASURES FOR GROUPS OF FCM

13. For the groups of FCM listed in Annex and, where appropriate, combinations of those FCM or recycled² FCM used in the manufacture of those FCM, specific measures may be adopted by AMS. Those specific measures may include:
 - (a) a list of starting substances authorised for use in the manufacturing of FCM hereinafter referred to as positive list;
 - (b) purity standards for starting substances referred to point (a) of this paragraph;
 - (c) special conditions of use for starting substances referred to point (a) of this paragraph and/or the FCM in which they are used;
 - (d) specific limits on the migration of certain constituents or groups of constituents, if appropriate into or on to food, taking into account of other possible sources of exposure to those constituents;
 - (e) an overall limit on the migration of constituents into food, or on to food;
 - (f) other rules to ensure compliance with Section 5;
 - (g) basic rules for checking compliance with points (a) to (f) of this paragraph;
 - (h) rules concerning inspection, collection of samples and the methods of analysis to check compliance with points (a) to (f);
 - (i) specific provisions for ensuring the traceability of FCM including provisions regarding the duration for retention of records;
 - (j) provisions requiring the AMS to establish and maintain a publicly available register of authorised substances, processes, or materials or articles.

SECTION 7 LABELLING

14. The labelling, advertising and presentation of FCM shall not mislead the customers.
15. FCM, which are not yet in contact with food when placed on the market, should be accompanied by:
 - (a) the words 'for food contact' and/or symbol³ or a specific indication as to their use;

² The use of recycled materials shall only be allowed when proof of safety are provided and demonstrated and subject to AMS' regulations.

³ Member States may specify the symbol and rules for use of the specified symbol to identify FCM that comply with requirements.

- (b) if necessary, special instructions to be observed for safe and appropriate use;
 - (c) the name or trade name and, in either case, the address or registered office of the manufacturer, processor, or seller responsible for placing on the market of the Member State; and
 - (d) adequate labelling or identification to ensure traceability of the FCM, as described in Section 9;
16. The information referred to in paragraph 15(a) shall not, however, be obligatory for any articles which, because of their characteristics, are clearly intended to come into contact with food;
17. The information required by paragraph 15 shall be conspicuous, clearly legible and indelible;
18. The language of the label under paragraph 15(a), 15(b), and 15(c) should be the language required by national regulations. A supplementary label containing the mandatory information in the required language may be used instead of relabelling in cases where the language of the original label is not appropriate.

SECTION 8 DECLARATION OF COMPLIANCE (DoC)

19. FCM supplied in accordance with these Guidelines shall be accompanied by a Declaration of Compliance stating compliance with the applicable requirements. The Declaration shall be made available by business operators to the competent authorities and customers on demand. Retailers⁴ of FCM not yet in contact with food are not required to make DoC available to their customers.
20. Supporting documentation that substantiates the Declaration of Compliance shall be made available to competent authorities on demand. This supporting documentation shall comply with applicable regulatory requirements.

Supporting document should be renewed when substantial change in the composition occurs that bring about changes in the migration or when new scientific data becomes available.

This supporting documentation may include, but not limited to:

- (a) information for the manufacturing step under responsibility of the relevant business operator;
- (b) documents received from suppliers; documents released to customers;
- (c) production recipes, analytical results, migration test results.

⁴ Retailer is a business operator selling final FCM only to the final consumer. It includes distribution terminals of supermarket and wholesale outlets. If the operator is selling to a business operator, then he has the role of a distributor instead.

SECTION 9 TRACEABILITY

21. The traceability of FCM should be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.
22. With due regard to technological feasibility, business operators should have in place systems and procedures to allow identification of the businesses from which and to which FCM and, where appropriate, substances or products covered by this Guidelines and its implementing measures used in their manufacture are supplied. That information should be made available to the competent authorities on demand.
23. The FCM which are placed on the market in Member States should be identifiable by an appropriate system which allows their traceability by means of labelling or relevant documentation or information.

SECTION 10 INSPECTION AND CONTROL MEASURES

24. Member States should carry out official controls in order to enforce compliance with this Guidelines in accordance with provisions of relevant laws.

The compliance testing of FCM may include, as appropriate:

- (a) material tests to verify compositions, identify type of materials or determine purity;
- (b) overall migration tests; and
- (c) specific migration tests.



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List of groups of FCM which may be covered by specific measures

1. Active and intelligent materials and articles
2. Adhesives
3. Ceramics
4. Cork
5. Rubbers
6. Glass
7. Ion-exchange resins
8. Metals and alloys
9. Paper and board
10. Plastics
11. Printing inks
12. Regenerated cellulose
13. Silicones
14. Textiles
15. Varnishes and coatings
16. Waxes
17. Wood

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