Republic of the Philippines
Department of Health
**FOOD AND DRUG ADMINISTRATION**

**FDA CIRCULAR**
**No. 2022-011**

29 NOV 2022

**SUBJECT:** **Guidelines on the Application and Issuance of Voluntary Certification of Food Contact Articles (FCA) Used for Prepackaged Processed Food Products**

## I. RATIONALE

Pursuant to Section 2 Article II Book I of the Implementing Rules and Regulation (IRR) of Republic Act 9711 otherwise known as "The Food and Drug Administration Act of 2009", the Food and Drug Administration (FDA) is mandated to develop and issue policies, standards, regulations, and guidelines that would cover establishments, facilities, and health products. Health products as defined in the said Act refer to the products that may have an effect on health that requires regulation as determined by the FDA. Food Contact Articles (FCA) are health products constituting chemicals that can migrate from the materials into food. As these chemicals migrate, they may alter the characteristics of the food unacceptably or have adverse effects on the taste and/or odor of foods (Linssen, 1992).

Regulation of FCA is specified in R.A. 10611 also known as the Food Safety Act of 2013 which states that food is adulterated if it is in a container having in whole or in part any poisonous or deleterious substance. Moreover, any food packaging material which results or may reasonably be expected to result, or indirectly in it becoming a component or otherwise affecting the characteristics of any food is considered a food additive according to the Bureau Circular 2006-016 or the Updated List of Food Additives.

Hence, the determination of the suitability of the Food Contact Articles for use in the packing, packaging, transporting, or holding of food shall be conducted by the FDA Common Services Laboratory (CSL) to carry out the foregoing laws.

## II. OBJECTIVES

To provide guidelines on the procedure for the voluntary certification of Food Contact Articles. Specific Objectives of this are as follows:

1. To establish the guidelines on the conduct of voluntary certification of food contact articles used for prepackaged processed food products.

2. To provide information on the process of application for the voluntary certification to the stakeholders involved.

## III. SCOPE

This Circular shall cover both locally manufactured and imported food contact articles, in finished or final form, with or without applied adhesives and/or printing inks, limited to:

A. Direct Food Contact Articles which include all primary packaging materials of pre-packaged processed food products having the following materials:
   1. Metal
   2. Glass
   3. Ceramic
   4. Enameled
   5. Synthetic Resin
   6. Phenolic Resin
   7. Melamine Resin
   8. Urea Resin
   9. Synthetic Resin made from Formaldehyde
   10. Polyvinyl Chloride
   11. Polyethylene
   12. Polypropylene
   13. Polystyrene
   14. Polyvinylidene Chloride
   15. Polyethylene Terephthalate
   16. Polymethyl Methacrylate
   17. Nylon
   18. Polymethyl Pentene
   19. Polycarbonate
   20. Polyvinyl Alcohol
   21. Rubber
   22. Paper and paperboard

B. Articles with incidental contact to processed food products having the materials listed under Direct Food Contact Articles.

## IV. DEFINITION OF TERMS

For the purpose of this Circular, the following terms shall mean:

A. **Adhesives** – refer to the naturally derived materials such as paste, glue etc. used for sealing of folding cartons, laminating paper to paperboard and labeling of food containers. This may also include starch and casein-based adhesives, natural rubber latex, polyvinyl alcohol emulsion, petroleum wax in combination with polymers and tackifying resin. Glued-on, self-adhesive (pressure sensitive), in-mold and

and tackifying resin. Glued-on, self-adhesive (pressure sensitive), in-mold and sleeve labels are most commonly used for any type of food container including bottles and metal cans.

B. **Establishment** - means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization involved in the manufacture, importation, and distribution of food contact articles.

C. **Food Contact Substance/Materials**– any substance that is intended for use as a component of materials used in packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food.

D. **Food Contact Articles** - are the finished or final form made up of one or multiple different food contact substances/materials and food contact chemicals such as adhesives and printing inks.

E. **Migration** - is defined as the partitioning of chemical compounds by diffusion or absorption from the packaging into the food.

F. **Prepackaged** - means packaged or made up in advance in a container, ready for sale to the consumer, or for catering purposes.

G. **Primary Packaging** – the term used to designate the layer of packaging in immediate contact with the product, thus, it is the first packaging layer in which the product is contained. It is constructed considering the product itself and any existing secondary layers of packaging.

H. **Printing Inks** - Mixtures of colourants with other substances which are applied on materials to form a graphic or decorative design together with or without other coloured or uncoloured overprint varnishes/ coatings or primers which are normally applied in combination with a) in order to enable the printed design to achieve specific functions such as ink adhesion, rub resistance, gloss, slip/friction, durability, etc.

I. **Processed Food** - refers to food that has been subjected to some degree of processing like milling, drying, concentrating, canning, or addition of some ingredients which changes partially or completely the physico-chemical and/or sensory characteristics of the food's raw material.

J. **Voluntary Certification** – an official document attesting the suitability and safety of the Food Contact Articles issued by the FDA upon recommendation of the Common Services Laboratory (CSL) after thorough evaluation/ review of application documents submitted by the client's own choice and consent.

## V. GENERAL GUIDELINES

A. The evaluation of the suitability of the food contact articles shall be conducted by the CSL to serve the needs of establishments that voluntarily secure a "food grade certification" to substantiate the suitability of their product as required by their clients for the intended application of use.

B. The evaluation of the FCA shall be performed by the CSL of the FDA for the applicant seeking assistance in attesting the suitability of their product for the intended application of use.

C. The determination of the suitability of FCA for use in the packing, packaging, transporting, or holding of food shall be based on the requirements established by the CSL to ensure the suitability of the food contact materials for their intended use and its safety. See Annex A.

D. The establishment involved in the manufacture, importation, exportation, sale, offering for sale, distribution, and transfer of FCA may secure voluntary certification prior to utilization, selling, and commercial distribution.

E. Any or a combination of the following references shall be adopted and be used in the evaluation:

1. Latest edition of the "Specifications and Standards for Foods, Food Additives, etc. Under the Food Sanitation Act (Abstracts)" of the Japan External Trade Organization (JETRO)

2. Latest edition of "Specifications, Standards and Testing Methods for Foodstuffs, Implements, Containers, and Packaging, Toys, Detergents" of JETRO.

3. Code of Federal Regulation Title 21 Part 170 to 199 of the US Food and Drug Administration.

4. Other references for Food Contact Articles recognized by ASEAN member states.

5. Regulatory requirements of the importing country for products intended for export, if necessary.

F. The documentary requirements are listed in Annex A. Incomplete submission of these documents shall be a ground for disapproval of the application.

G. Complete documentary requirements shall be submitted through online or onsite application onsite (under section VI Specific Guidelines).

H. Test parameters to be conducted by an FDA-accredited/recognized laboratory shall depend on the type and conditions of use where the food contact article shall be utilized. Samples for analysis shall be in the finished or final form of the product.

I. Pre-application queries from applicants shall be entertained thru Online or face-to-face. The process is indicated in Annex B.

J. Application Fee shall be based on Administrative Order No. 50 s 2001 or current FDA Fees and Charges.

## VI. SPECIFIC GUIDELINES

### A. Pre-Application Query

The client may inquire thru the following options:

1. Online Pre-Application Query

    a. The establishment/applicant shall send an email inquiry to the csl@fda.gov.ph with "Email Subject: **Pre-Application Query on FCA Evaluation**"
    b. The CSL/Receiving and Releasing Unit (RRU) personnel shall receive and acknowledge receipt of the email inquiry, and generates the Document Tracking Number (DTN).
    c. The CSL/RRU personnel shall forward the email inquiry to the assigned unit
    d. Once response is already available, the CSL/RRU personnel shall forward the Reply Letter (Original Hard Copy) to the FDA – Records, and shall send the scanned copy to the applicant.
    e. The FDA Records Section shall release reply letter (Original Hard Copy) to client.

2. Onsite Pre-Application Query

    a. Establishment/Applicant shall submit letter of inquiry at the Food and Drug Action Center (FDAC).
    b. The CSL/RRU personnel at the FDAC shall receive and forward the letter of inquiry to the Common Services Laboratory Receiving and Releasing Unit (CSL-RRU).
    c. The CSL/RRU personnel shall forward the letter of inquiry to the assigned unit.

d. Once response is already available, CSL/RRU personnel shall forward the Reply Letter to the FDAC.
e. CSL/RRU personnel assigned at FDAC shall release the Reply Letter to the client.

**B. Application for Certification of Food Contact Articles (FCA)**

The client may apply for the certification through the following options:

1. Online filing of application for Certification of FCA

   a. The applicant shall submit the scanned copy of the requirements (ANNEX A) to csl@fda.gov.ph with "Email Subject: **Voluntary Application for Food Suitability Evaluation of FCA**" FDA shall only accept applications once the testing of FCA by the accredited laboratory is completed. (To access the List of FDA-accredited laboratories see Annex D)
   b. The Receiving and Releasing Unit (RRU) shall review the application for completeness of requirements.
      *If incomplete: application is returned stating the reason for rejection.
      *If complete: assigns a Reference Number and forwards the application to the assigned unit.

2. Onsite filing of application for Certification
   a. The applicant shall submit the hard copy of the requirements (ANNEX A) at the Food and Drug Action Center (FDAC). FDA shall only accept application once the testing of FCA by the accredited laboratory is completed.
   b. The RRU of the CSL at FDAC shall review the application for completeness of Requirements.
      * If incomplete: application is returned stating the reason for rejection.
      * If complete: assigns a Reference Number and forwards the application to the assigned unit.
   c. FDAC FDA Records shall release the Evaluation Report to the client.

**C. Evaluation and Issuance of Certification**

1. The CSL shall conduct the evaluation based on the submitted documents and samples.

2. The evaluation shall be based on the type of FCA and its intended use as indicated in the request letter.
3. The test results and other provided information shall be evaluated in accordance with the adopted standards and other regulations as deemed appropriate.
4. After a thorough evaluation and subsequent approval, a certification shall be issued if the FCA is determined to be suitable for its intended use. Otherwise, a letter of disapproval shall be issued.
5. A certification or a letter of disapproval shall be issued within 12 working days upon acceptance by the RRU.
6. Reapplication may be done once the observations on the initial application have been addressed. Reapplication entails the payment of the required application fee.

## VII. SEPARABILITY CLAUSE

If any provision of this Circular be declared invalid or unconstitutional, the remaining portions shall remain legal and in full force.

## VIII. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register.

**DR. SAMUEL A. ZACATE**
Director General

DTN: 20160128103625

**ANNEX A**

**Requirements for Application of Certification of Food Contact Articles**

A. Checklist of Requirements for Online Application:

1. Request Letter stating the intended use of the food contact article(s) (FCA).
2. FCA Information must include the following information;
   - Technical Specification
   - Intended use of the product (i.e., primary or secondary packaging/ direct or indirect contact with food)
   - Overview of the production process

   *For products wherein part of its component is recycled material, the following should be submitted:

   a. Recycling process

   b. Source of starting material or major material that will be recycled
3. Certificate of Analysis/Quality Control Inspection Report, wherein the batch or lot number and production date of the concerned product should be indicated;
4. Health and Safety Information/Safety Data Sheet (SDS) of the concerned product, (Finished product and raw materials)
5. Formulation/ Composition of the concerned FCA;
   - Specific chemical name and corresponding percentage composition
   - Chemical Abstract Service Registry Number (CAS No.)
   - Percentage of all raw materials used (include the colorants and additives, if any).

   *For food contact articles FCA made from metals and its alloy, the specific alloy should be indicated along with its elemental composition.

   *For food contact articles FCA in which part of its component are recycled materials, all the chemicals used in the recycling process must be reflected.
6. Report of Analysis from an FDA Accredited Laboratory as listed on the FDA website (Batch/Lot No. must be indicated in the Test Report)
7. Clear Photo of the FCA (All parts – i.e., inner and outer parts)
   *For consideration: Submission of FCA samples via courier
8. Proof of payment (e.g., Official Receipt, Landbank Oncoll Machine-Validated Payment, verified and posted payment by the FDA Cashier).

B. Checklist of Requirements for Manual Application

1. Request Letter (State the intended use of the product).
2. Food Contact Article (FCA) Information must include the following information;
   - Technical Specification
   - Intended use of the product (i.e., primary or secondary packaging/ direct or indirect contact with food)
   - Overview of the production process

*For products wherein part of its component is recycled material, the following should be submitted:
   a. Recycling process
   b. Source of starting material or major material that will be recycled

3. Certificate of Analysis/Quality Control Inspection Report, wherein the batch or lot number of the concerned product should be indicated;
4. Health and Safety Information/Safety Data Sheet (SDS) of the concerned product (Finished product and raw materials)
5. Formulation/ Composition of the concerned Food Contact Article FCA;
   - Specific chemical name,
   - Chemical Abstract Service Registry Number (CAS No.)
   - Numbers of all raw materials used (include the colorants and additives, if any).

   * For food contact materials (FCM) made from metals and its alloy, the specific alloy should be indicated along with its elemental composition.
   * For products wherein part of its component is recycled materials, all the chemicals used in the recycling process must be reflected.
6. Report of Analysis from an FDA Accredited / Recognized Laboratory as listed in the FDA website (Batch/Lot No. must be indicated in the Test Report)
7. Representative sample
8. Proof of payment (e.g., Official Receipt, Landbank Oncoll Machine-Validated Payment, verified and posted payment by the FDA Cashier).

C. Checklist of Requirements for Online Pre-Application Query
   1. Email Inquiry which contains at least the following information about the FCA to be applied for evaluation:
      a. formulation/composition;
      b. intended use and the specific food that will be contained

D. Checklist of Requirements for Onsite-Pre-Application Query
   1. Letter of Inquiry which contains at least the following information about the FCA to be applied for evaluation:
      a. formulation/composition;
      b. intended use and the specific food that will be contained.

**ANNEX B**

**Process for Pre application Query**

A. Pre-Application Query

1. Online Pre-Application Query

    a. The establishment/applicant shall send an email inquiry to the csl@fda.gov.ph with "Email Subject: **Pre-Application Query on FCA Evaluation —"**
    b. The CSL/Receiving and Releasing Unit (RRU) personnel receives and acknowledges receipt of the email inquiry, and generates DTN.
    c. The CSL/RRU personnel forwards the email inquiry to the CSL-Toxicology Section.
    d. Once response is already available, The CSL/RRU personnel forwards the Reply Letter (Original Hard Copy) to the FDA – Records, and sends the scanned copy to the applicant.
    e. FDA Records Releases reply letter (Original Hard Copy) to client.

2. Manual Pre-Application Query

    a. Establishment/Applicant shall submit letter of inquiry to the Food and Drug Action Center (FDAC).
    b. The CSL/Receiving and Releasing Unit (RRU) personnel at the FDAC receives and forwards the letter of inquiry to the Common Services Laboratory Receiving and Releasing Unit (CSL RRU).
    c. The CSL/RRU personnel forwards the letter of inquiry to the CSL.
    d. Once response is already available, CSL/RRU personnel forwards the Reply Letter to the FDAC.
    e. CSL/RRU personnel assigned at FDAC releases the Reply Letter to the client.

**ANNEX C**
**Process Flow**

**Voluntary Certification of Food Contact Articles**

| Responsible | Process | Notes |
|---|---|---|
| **A. Pre-application Query on Tests to be conducted (for applicants who have not had any previous evaluation report/ certification from FDA)** | | |
| | START | |
| CSL/RRU | Client inquiry to CSL<br>Online / Manual | Letter of inquiry to CSL with the following minimum details on the food contact articles:<br>1. Formulation/ Composition<br>2. Intended use and the specific food that will be contained<br>May also inquire through csl@fda.gov.ph with subject "Email Subject: **Pre-Application Query on FCA Evaluation** —" with the same minimum details on the food contact articles |
| CSL/RRU | Referral to Cosmetics/Toxicology | Only those queries with complete details as specified will be referred to CSL-Toxicology Section |
| CSL-TOXICOLOGY SECTION | Conduct review and give recommendation | Reviewal and recommendation of specific analysis to be conducted by FDA accredited/ recognized laboratory |

| | | |
|---|---|---|
| CSL-TOXICOLOGY SECTION | Preparation of Reply Letter | The assigned FDRO shall prepare and send reply letter with the recommended specific analysis and documentary requirements |
| CSL/RRU | Forward to FDAC | Total: 7 working days |
| | END | |

**B. Filing of application for Certification of Food Contact Articles**

| | | |
|---|---|---|
| | START | |
| | Pre-assessment of documentary requirements as to completeness | |
| CSL/RRU at FDAC | Receiving of Official Receipt<br>Payment of Fee thru Landbank<br>Filing of application | Once the testing of the food contact article by the accredited laboratory is completed, the applicant shall submit the requirements at the Food and Drug Action Center (FDAC).<br>The applicant may also apply online by submitting the scanned copy of the requirements to csl@fda.gov.ph with "Email Subject: **Voluntary Application for Food Suitability Evaluation of FCA___**" |

| | | |
|---|---|---|
| CSL/RRU at FDAC | Review of submitted documents | Reviews application for completeness of requirements |
| CSL/RRU | Compliant?<br>YES: Forwards the application to the Toxicology Section<br>NO: Issuance of Letter of Disapproval | If incomplete: application is rejected stating the reason of rejection. If complete: assigns a Reference Number and forwards the application to the Toxicology Section |
| CSL/RRU | Forward the application for Evaluation | |
| CSL-Toxicology Section | Food Suitability Evaluation and preparation of Report | Evaluation shall be conducted by the CSL-Toxicology Section |
| CSL/RRU | Forward the Evaluation Report to the FDA Records | Hard copy shall be forwarded to FDA Records |
| FDA RECORDS | Releasing of Evaluation Report | Releases the Evaluation Report shall to the client |
| | END | Total: 12 working days |

## ANNEX D
## References


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