DRAFT FOR COMMENTS

FDA CIRCULAR
No. 2022-_____

SUBJECT: **Guidelines on the Voluntary Certification of Food Contact Articles Used for Prepackaged Processed Food Products**

I. RATIONALE

Pursuant to Section 2 Article II Book I of the Implementing Rules and Regulation (IRR) of the Republic Act 9711 otherwise known as "The Food and Drug Administration Act of 2009", mandates the Food and Drug Administration (FDA) 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 which requires regulation as determined by the FDA.

Furthermore, in Section 9 of Republic Act 10611 or the Food Safety Act of 2013 also known as "An Act to Strengthen the Food Safety Regulatory System in the Country to Protect Consumer Health and Facilitate Market Access of Local Foods and Food Products, and for Other Purposes, the setting of food safety standards "(a) xxx shall be established based on science, risk analysis, scientific advice from expert body/ bodies, standards of other countries, xxx" as its guiding principle.

The safety of Food Contact Articles must be evaluated as chemicals can migrate from the materials into food, wherefore, to ensure that the quality and safety of the food available to the consuming public are free from contaminants that may alter the characteristics of the food unacceptably or have adverse effects on the taste and/or odor of foods, and no migration of unsafe levels of chemical substances from the materials to the food that might result to toxicological risk because of contamination (Linssen, 1992) thus posing a potential public health problem, the determination of the suitability of the Food Contact Articles for use in the packing, packaging, transporting, or holding of food was perceived to be imperative by the FDA. The materials must be manufactured in compliance with Good Manufacturing Practices such that any potential transfer to foods does not raise safety concerns.

II. OBJECTIVES

General Objective

To provide guidelines on the procedure for the voluntary certification of Food Contact Articles.

Objectives

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

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

1. Direct Food Contact Articles which include all primary packaging materials of pre-packaged processed food products having the following materials:
   a. Metal
   b. Glass
   c. Ceramic
   d. Enameled
   e. Synthetic Resin
   f. Phenolic Resin
   g. Melamine Resin
   h. Urea Resin
   i. Synthetic Resin made from Formaldehyde
   j. Polyvinyl Chloride
   k. Polyethylene
   l. Polypropylene
   m. Polystyrene
   n. Polyvinylidene Chloride
   o. Polyethylene Terephthalate
   p. Polymethyl Methacrylate
   q. Nylon
   r. Polymethyl Pentene
   s. Polycarbonate
   t. Polyvinyl Alcohol
   u. Rubber
   v. Paper and paperboard

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

3. Polyethylene and polypropylene resins used as raw materials for processing of articles intended for packaging of food; and;

4. Filter paper for filtration for use in (e.g., milk, coffee, tea, sugar).

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 sleeve labels are most commonly used for any type of food container including bottles and metal cans.

B. **Certification** - refers to the authorization issued by the FDA for food contact articles upon recommendation of the Common Services Laboratory (CSL) after thorough evaluation/ review of application documents.

C. **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.

D. **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.

E. **Food Contact Articles** - is 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.

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

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

H. **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.

I. **Printing Inks** - in this context also called packaging inks, including varnishes, means any product manufactured from colourants, binders, solvents and additives. There are solvent-based, waterborne, oleo-resinous or energy-curing (UV or electron beam) systems. They are applied by printing or varnishing processes, such as flexography, offset, gravure printing and roller varnishing. The term packaging ink is used in order to differentiate the products used on packages from prints for other purposes.

J. **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.

V. GENERAL GUIDELINES

A. Evaluation of the suitability of the food contact articles is 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.

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

E. For the standards, methods of analysis, limits, and guides, the following shall be adopted:

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. 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 must be submitted through online or manual application onsite (under section VI Specific Guidelines).

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

I. Monitoring of the FCA may be conducted as directed by the Center for Food Regulation and Research in coordination with the CSL and the Field Regulatory Operations Office (FROO).

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

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

VI. SPECIFIC GUIDELINES

A. Application for Certification of Food Contact Articles (FCA)

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 application once the testing of FCA by the accredited laboratory is completed.

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 Toxicology Section.

2. Manual filing of application for Certification
   a. The applicant shall submit the scanned 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 Toxicology Section.
   c. The Lab Tech of the CSL/RRU at the FDAC FDA Records shall release the Evaluation Report to the client.

B. Evaluation and Issuance of Certification

1. The Toxicology Section will conduct 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 thorough evaluation and subsequent approval, a certification will be issued if the FCA is determined to be suitable for its intended use. Otherwise, a letter of disapproval will be issued.
5. Certification or letter of disapproval will be issued within 12 working days upon acceptance by the RRU.
6. Certification shall be valid for a period of one (1) year from the date of issuance.
7. 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 following its publication in one (1) newspaper of general circulation and filing of three (3) certified true copies to the Office of the National Administrative Register (ONAR) University of the Philippines.

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health

DTN: 201601281036

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 / Recognized Laboratory as listed in 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

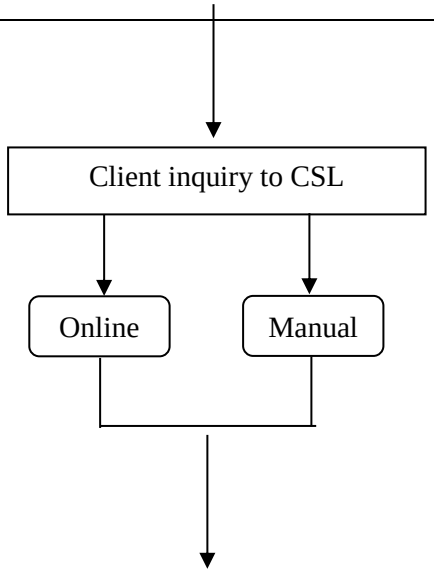
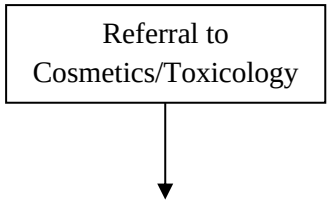
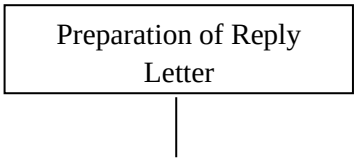
1. Online Pre-Application Query

    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 at 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-Toxicology Section.
    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

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)		
		
CSL/RRU		Letter of inquiry to CSL with the following minimum details on the food contact articles: 1. Formulation/composition 2. Intended use 3. The specific food that will be contained 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		Only those queries with complete details as specified will be referred to CSL-Toxicology Section
CSL-TOXICOLOGY SECTION		Reviewal and recommendation of specific analysis to be conducted by FDA accredited/ recognized laboratory
CSL-TOXICOLOGY SECTION		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	
CSL/RRU at FDAC	Payment of Fee thru Landbank 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). 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?	If incomplete: application is rejected stating the reason of rejection. If complete: assigns a Reference Number and forwards the application to the Toxicology Section

	YES Forwards the application to the Toxicology Section NO Issuance of Letter of Disapproval	
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

Voluntary Certification of Food Contact Articles

ANNEX D
References

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Republic Act 11032 An Act Promoting Ease of Doing Business and Efficient Delivery of Government Services, amending for the purpose Republic Act No. 9485, Otherwise known as the Anti-Red Tape Act of 2007, and for Other Purposes. chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/viewer.html?pdfurl=https%3A%2F%2Farta.gov.ph%2Fwp-content%2Fuploads%2F2020%2F07%2FRA.11032_Certified_True_Copy.pdf&clen=1706199&chunk=true