Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2021-028-A

26 OCT 2022

SUBJECT: **Updated Guidelines on Prepackaged Processed Food Products Containing Industrially Produced Trans-Fatty Acids (IPTFA) amending FDA Circular 2021-028 entitled "Guidelines for Prepackaged Processed Food Products Containing Trans-Fatty Acids (TFA)"**

I. RATIONALE

The FDA Circular (FC) No. 2021-028 was issued on 31 December 2021 to provide guidelines for the implementation of the Department of Health Administrative Order (AO) No. 2021-0039 entitled "National Policy on the Elimination of Industrially-Produced Trans-Fatty Acids for the Prevention and Control of Non-Communicable Diseases," with the purpose of eliminating the industrially-produced Trans-Fatty Acids (TFA) in the Philippines food supply chain by 18 June 2023. Due to its effect on the body's Low Density Lipoprotein, high intake of TFA increases the risk of developing coronary heart disease and other non-communicable diseases. Pursuant to FDA mandate of protecting the general public by ensuring the safety and quality of processed food products, thus, the issuance of this updated Circular is deemed imperative.

II. OBJECTIVE

The guidelines aim to provide updated information and clarity on certain provisions of FC No. 2021-028.

III. SCOPE

This Circular covers manufacturers, traders, importers-distributors of raw materials, ingredients, and prepackaged processed food products containing industrially-produced TFA intended for the Philippine market. This Circular does not cover retailers and exporters.

IV. GUIDELINES

The following Sections of FDA Circular 2021-028 are hereby amended, as follows:

Provisions to be Amended	Amended to
V. GENERAL GUIDELINES B. The manufacture, trading, importation, distribution, and sale of the following shall be prohibited: 1. PHO to be consumed alone or used in the preparation of processed food products; 2. Oils and fats made blended with PHO; 3. Oils and fats with more than 2 g TFA per 100 g or 100 ml of total fat; 4. Prepackaged processed food with PHO and high TFA content (as defined in this Circular).	**V. GENERAL GUIDELINES** The following items in the General Guidelines shall be revised, to read as: B. The manufacture, trading, importation, distribution, and sale of the following shall be prohibited: 1. Partially Hydrogenated Oil (PHO) to be consumed alone or used in the preparation of processed food products; 2. Oils and fats blended with PHO; and 3. **Prepackaged processed food with PHO and industrially-produced TFA** content of more than 2g per 100g or ml.
VI. SPECIFIC GUIDELINES A. The initial application for product registration of any prepackaged processed food product containing TFA and products containing hydrogenated oil, whether local or imported, shall include submission of the following documents: 1. technical specifications of raw materials indicating specific oil(s) and/or fat(s) used and the processing it underwent; and 2. recent (within 12 months) certificate of analysis of the finished product from an accredited laboratory of the FDA and Philippine Accreditation	**VI. SPECIFIC GUIDELINES** The following items in the Specific Guidelines shall be revised, to read as: A. The initial application for product registration of any prepackaged processed food product containing TFA and products containing hydrogenated oil, whether local or imported, shall include submission of the following documents: 1. technical specifications of raw materials indicating specific oil(s) and/or fat(s) used and the processing it underwent; 2. recent (within 12 months **from date of application**) certificate of analysis of the finished product from an accredited laboratory of the FDA and Philippine Accreditation Board/Office

Board/Office (PAB/PAO), reflecting the TFA content per 100g, reference methods of analysis, and the limit of detection for the method used in the analysis of TFA.	(PAB/PAO) **or from the country of origin (for imported products)**, reflecting the TFA content per 100g **or ml**, validated reference methods of analysis, and the limit of detection for the method used in the analysis of TFA; and **3. for prepackaged processed food containing naturally-occurring TFA of more than 2g TFA per 100g or ml of the total fat, recent (within 12 months from date of application) certificate of analysis showing that the TFA is naturally-occurring and/or obtained from ruminant animal, from an accredited laboratory of the FDA and Philippine Accreditation Board/Office (PAB/PAO) or from the country of origin, with validated reference method of analysis and the limit of detection for the method used in the analysis.**
VI. SPECIFIC GUIDELINES F. After the transition period, prepackaged processed food products formulation shall not contain PHO, oils and fats blended with PHOs, and TFA beyond the specified limits, and shall be compliant to these guidelines as specified under V. B. 1-4.	**VI. SPECIFIC GUIDELINES** The following items in the Specific Guidelines shall be added and revised, to read as: F. **As appropriate, 'oil' together with either the term 'vegetable' or 'animal', qualified by the term 'hyrogenated' or 'partially-hydrogenated', shall be declared in the data entry for ingredient listing and on the label in accordance with AO No. 2014-0030.** **G.** After the transition period, prepackaged processed food products formulation shall not contain PHO, oils and fats blended with PHOs, **industrially produced -** TFA beyond the specified limits, and

	shall be compliant to these guidelines as specified under **Section** V. B.1 **to 3**.
VIII. TRANSITORY PROVISIONS After 18 June 2023, all product formulations and labels of prepackaged processed food containing TFA shall be fully compliant with these guidelines.	**VIII. TRANSITORY PROVISIONS** The following items in the Transitory Provisions shall be added, to read as: **During the transition period, food products covered in Section V.B.1 to 3 with valid certificate of product registration (CPR) shall be applied for initial CPR complying with the provisions of this Circular. Applications for renewal or amendment of CPRs of such products shall be denied.**

As thus amended, all the other provisions of FC No. 2021-028 not affected by this amendment shall remain in full force and in effect.

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.

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Director General