Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2021-028

31 DEC 2021

SUBJECT : Guidelines for Prepackaged Processed Food Products Containing Trans-Fatty Acids (TFA)

I. RATIONALE

On 18 June 2021, the Department of Health (DOH) issued 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", which prohibits Industrially-Produced TFA (IP TFA) from prepackaged processed food products due to the alarming global and local magnitude of the problem involving Non-Communicable Diseases (NCD). As stated in the said DOH AO and the 2017 Non-Communicable Disease Report of the World Health Organization (WHO), about 3,000 people in the Philippines suffer yearly from premature mortality related to high consumption of TFA. Further, according to WHO in 2020, cardiovascular diseases have been the leading cause of death globally for the past three decades. The biggest killer is coronary heart disease, responsible for 16% of the world's total deaths. From 2000 to 2019, deaths from ischemic heart disease rose faster than deaths from any other disease, increasing from more than 2 million in 2000 to nearly 9 million in 2019. The said DOH AO No. 2021-0039 stated that studies have consistently suggested that there is no safe level of TFA consumption and that TFA intake has no known health benefit. Due to its effect on the body's Low Density Lipoprotein (LDL), high intake of TFAs increases the risk of developing coronary heart disease and other NCD. A preliminary exposure assessment of FNRI in 2018 reported that high level consumers among children under 6 years old (95th percentile) are at risk of TFA exposure at 150% upper limit. Despite the availability of such exposure assessments, there is still a lack of a more rigorous monitoring and evaluation system to further assess the impact of TFA intake among Filipinos. With neighboring countries implementing bans on Partially-Hydrogenated Oils (PHO) and setting mandatory limits on TFA content in food, the Philippines is vulnerable to dumping of TFA-rich food products in the absence of similar regulations.

In accordance with the mandate of the Food and Drug Administration (FDA) under Republic Act (RA) No. 9711 or the "Food and Drug Administration (FDA) Act of 2009", RA No. 10611 or the "Food Safety Act of 2013", and their respective Implementing Rules and Regulations, as well as the FDA's roles and responsibilities as stated in Section VII (D) of DOH AO No. 2021-0039, the FDA issues this Circular to: (1) provide and implement guidelines for TFA regulation in prepackaged processed food products and (2) determine the appropriate transitory period that shall not be more than two (2) years from the said AO's effectivity.

II. OBJECTIVES

1. To provide guidelines for evaluation during product registration of prepackaged processed food products containing TFA intended to be manufactured, used, imported, distributed and offered for sale in the Philippine market.

2. To prohibit the importation, local manufacture, distribution, use and sale of PHO, and Oils and Fats blended with PHO; Oils and Fats with TFA content more than 2g per 100g/ml of total fat; and prepackaged processed food products with PHO and high TFA content exceeding 2g per 100g/ml of total fat.

3. To set additional requirements for the registration of prepackaged processed food products containing TFA, and specify the transitory period of its implementation.

III. SCOPE

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

IV. DEFINITION OF TERMS

1. **High Trans Fatty Acids content** – for the purpose of this Circular, shall refer to TFA content of more than 2g per 100g or 100ml of total fat prepackaged processed food products and non-alcoholic beverages in accordance with the WHO Module on Legislate or Regulate.

2. **Industrially-Produced TFA (IP TFA)** – refers to artificial trans fat that is developed through the partial hydrogenation of oils, as opposed to the naturally occurring trans fatty acids that are found in the fat of animal origin. Also developed in small amounts through re-heating and frying of oils at high temperatures.

3. **Naturally-occurring TFA** – refer to trans fatty acids that are found in meat and dairy products from ruminant animals, such as cattle, sheep, goats, and camels.

4. **Partially Hydrogenated Oil (PHO)** – refers to the processed products that contain IP TFA, which are typically used to increase shelf-life and ensure flavor stability of oils. It means oils or fats that have been hydrogenated, but not to complete or near saturation, and with an Iodine Value (IV) greater than 4, according to WHO REPLACE Action Package Module 3.

5. **Prepackaged** - is a processed food made up in advance in a container, labeled and ready for sale to the consumer, or for catering purposes.

6. **Processed Food Products** – refer 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.

7. **Raw Materials** – refer to all substances that are employed in the processing of a finished product, packed in bulk containers, and not labelled as finished product. Raw Materials or ingredients would have product specifications that comply with the client requirements and not necessarily a single document.

8. **Trans-Fatty Acids** – refer to the fatty acids with at least a double bond in the trans configuration, regardless of whether they are produced industrially or come from ruminant sources, including linoleic acid.

9. **TFA-Free Claim** – refers to any claim that states or suggests that the processed food product does not contain TFA. This includes claims as "Trans Fat Free", with "0 g Trans Fat ", or any other similar claim.

V. GENERAL GUIDELINES

A. Prepackaged processed food products for human consumption, commercial sale or use shall not contain PHO whether as a single ingredient or raw material, or as an ingredient to any prepackaged processed food product. Similarly, the manufacture, trading, importation and distribution in the Philippine market of these products are prohibited in accordance with the DOH AO No. 2021-0039 and this Circular.

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 2g TFA per 100g or 100ml of total fat consistent with Section VI. A. 3. of DOH AO No. 2021-0039; and
4. Prepackaged processed food products with PHO and high TFA content as defined in this Circular.

C. Prepackaged processed food products for export shall follow the rules and regulations for PHO and TFA of the country of destination.

D. The label claim *TFA-Free*, *0 g Trans Fat* or *No transfat* or any similar claim shall be prohibited on the label and in the marketing/advertising of any processed food.

E. The TFA content of food products shall be declared on the Nutrition Information/Nutrition Facts panel of the label in accordance with AO No. 2014-0030 or the "Revised Rules and Regulations Governing The Labeling of Prepackaged Food Products Further Amending Certain Provisions of Administrative Order No. 88-B s. 1984 or the 'Rules and Regulations Governing the Labeling of Pre-packaged Food Products Distributed in the Philippines,' and For Other Purposes", its amendment, or the latest FDA labeling guidelines.

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/or Philippine Accreditation Board/Office (PAB/PAO), reflecting the TFA content per 100g or 100ml of total fat, reference methods of analysis, and the limit of detection for the method used in the analysis of TFA.

B. All prepackaged processed food products, which fall under Section V. B. of this circular and are covered by a Certificate of Product Registration (CPR) that is valid for a period of less than two (2) years, shall exhaust current product labels until 18 June 2023. Upon exhaustion of said labels, the manufacturer, trader, importer, or distributor of the product shall file for an initial CPR application. Distribution or sale of old products with remedial stickers on the label as a temporary remedy shall be allowed exhaustion before 18 June 2023, and the Market Authorization Holder thereof shall ensure that the remedial sticker is durable and not easily removable.

C. All prepackaged processed food products, containing TFA, PHO, and oils and fats blended with PHO and covered by a CPR that is valid for a period of more than two (2) years, shall apply for an Initial CPR before 18 June 2023.

D. All applications for processed prepackaged food products containing TFA within the mandatory limit set in this Circular, PHO, and oils and fats blended with PHO, including those with shelf life of more than two (2) years shall ensure that the labels are consistent with its product contents in compliance with DOH AO No. 2021-0039 and other pertinent laws.

E. The evaluation of application for product registration of prepackaged processed food products shall be in accordance with FDA Circular No. 2020-033 its amendment, or the latest guidelines thereon.

F. After the transition period, prepackaged processed food products formulation shall not contain PHO, oils and fats blended with PHO, and TFA beyond the specified limits, and shall be compliant to these guidelines as specified under V. B. 1-4.

VII. PENALTY CLAUSE

Immediately after the transitory period 18 June 2023, any establishment found to be in violation of any provision of this issuance shall be a ground for disapproval of application and suspension or cancellation of CPR or Authorization pursuant to Section 4, Article 1, Book II of the Implementing Rules and Regulations (IRR) of RA No. 9711.

Notwithstanding the preceding paragraph, nothing in this section shall restrict the FDA in imposing the penalty and sanctions as prescribed under RA No. 10611 and its IRR.

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.

IX. SEPARABILITY CLAUSE

If any provision of this Circular be declared as invalid or unenforceable, the validity and enforceability of the remaining portions or provisions shall be in full force and in effect.

X. REPEALING CLAUSE

Other issuances inconsistent with this Circular are hereby repealed and/or modified accordingly.

XI. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in an official gazette or in a newspaper of general circulation and upon filing three (3) certified true copies with the University of the Philippines Law Canter.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

DTN 20210922152323