Senate
Office of the Secretary

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NINETEENTH CONGRESS OF THE REPUBLIC OF THE PHILIPPINES
First Regular Session

SENATE
S.B. No. 116

Introduced by Senator Maria Lourdes Nancy S. Binay

AN ACT TO PROTECT FILIPINOS FROM THE HARMFUL EFFECTS OF TRANS-FATTY ACIDS, AND FOR OTHER PURPOSES

EXPLANATORY NOTE

Section 15, Article II of the 1987 Philippine Constitution provides that the State shall protect and promote the right to health of the people and instill health consciousness among them.

According to the World Health Organization (WHO), noncommunicable diseases (NCDs) kill 41 million people each year, equivalent to 71% of all deaths globally. NCDs are diseases of long duration and generally slow progression. The four major types of NCDs are cardiovascular diseases (CVDs), cancer, chronic respiratory diseases and diabetes.

In the Philippines, NCDs account for 68% of all deaths. One in every three Filipinos is likely to die before the age of 70 from one of the four major NCDs. CVDs, particularly coronary heart disease (CHD), account for nearly half of the world's NCD related deaths and claim around 70,000 lives in the Philippines every year.

High intake of trans-fatty acids (TFA) increases the risk of death from any cause by 34% and CHD mortality and morbidity by as much as 23% and 28%, respectively. Every year more than half a million deaths are attributed to TFA globally. Dubbed as the "tobacco of nutrition," TFA has no health benefits and is completely replaceable with no difference in taste or cost of food. Thus, the WHO published the REPLACE Technical Action Package as a road map towards a trans fat free world by 2023.

Partially hydrogenated oils (PHOs), the major source of TFA, have been banned in many countries including Denmark, Argentina, Thailand and Singapore in order to reduce TFA consumption. Countries that regulated TFA

have seen a significant decline in CHD deaths. Denmark's regulation limiting TFA content to 2g per 100g of fat in food products resulted in a 75% reduction in CHD-related deaths. In Argentina, an estimated 301 to 1,517 cardiac deaths every year were averted by eliminating industrially-produced TFA, saving the government as much as USD 87 million in healthcare costs annually.

The importance of addressing the problem of CHDs and CVDs as a whole has never been more pronounced than during this COVID-19 pandemic where patients with comorbidities, such as CHD, have a higher risk of serious illness or death. As of June 8, 2020, 49% of COVID-19 deaths in the Philippines had comorbidities. Now more than ever, the need for preventative health care and healthy lifestyle promotion must be realized in line with the vision of universal health care.

In addition, the WHO believes that TFA elimination is considered as one of the simplest and most straightforward public health interventions to reduce the risk of CVDs and improve nutritional quality of diets. As more countries regulate TFA, countries without regulations become vulnerable to dumping of TFA-rich imported food. Thus, it becomes even more urgent to join the global movement to become TFA-free by 2023.

This bill seeks to protect all Filipinos from the harmful effects of trans-fatty acids and promote a healthy lifestyle for all.

In view of the foregoing, the passage of this bill is earnestly sought.

MARIA LOURDES NANCY S. BINAY

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Be it enacted by the Senate and House of Representatives of the Philippines in Congress assembled:

Article I. General Provisions

SECTION 1. *Short Title.* - This Act shall be known as the "Trans Fat Free Philippines Act."

SEC. 2. *Declaration of Policy.* - It is the policy of the State to protect and promote the right to health of the people and instill health consciousness among them. The State recognizes the right of people to safe and nutritious food, free from substances like trans-fatty acids (TFA) that increase their risk of contracting deadly diseases.

The State shall prioritize health promotion and preventive care as it progresses towards universal health care. In this regard, the State shall protect Filipinos from the threat of death and diseases linked to TFA consumption by progressively removing industrially-produced TFA from the food supply.

SEC. 3. *Definitions of Terms.* - For the purposes of this Act, the following terms shall be defined as follows:

(a) *"Certificate of Product Registration" (CPR)* an authorization issued by the Food and Drug Authority (FDA) for specific health products including food, after evaluation and approval of submitted registration requirements.

(b) *"Distributor"* means any person to whom a consumer product is delivered or sold for purposes of distribution in commerce, but excluding the manufacturer or retailer of such product.

Distributors may be importers, exporters, traders and wholesalers.

(c) *"Food"* any substance or product, whether processed, partially processed or unprocessed that is intended for human consumption. It includes drinks, chewing gum, water and other substances that were used as an ingredient or a component in the manufacture, preparation or treatment of food, such as oils and fats, whether sold alone or incorporated in processed food and/or prepackaged food.

(d) *"Food Service Establishment"* means any establishment that prepares, serves, markets, sells, or offers for sale, food or drink to be consumed within the establishment or taken-out.

(e) *"Healthy Alternative Oils, Fats, and Oilseeds"* oils, fats, and oilseeds rich in polyunsaturated fatty-acids or monounsaturated fatty-acids and with low levels of saturated fatty-acids.

(f) *"Importer"* the consignee or the Philippine agent or representative of a foreign owner or consignee of raw materials, ingredients and/or finished products at the time of entry of such article into the Philippines.

(g) *"Industrially-Produced TFA"* trans-fatty acids created as a by-product when fats and oils are modified by the use of industrial processing techniques.

(h) *"License to Operate"* (LTO) a license granted by the FDA to establishments involved in the manufacturing, packaging, re-packaging, importation, exportation, distribution, and retailing of processed foods, drugs, medical devices, in vitro diagnostic reagents, cosmetics, and household hazardous substance products.

(i) *"Manufacturer"* means any person who manufactures, assembles or processes food products, including any person who attaches one's own brand name to a consumer product manufactured, assembled, or processed for them. In the case of imported products, the manufacturer's representatives or, in their absence, the importer shall be deemed the manufacturer.

(j) *"Micro, small and medium enterprise"* (MSME) any business activity or enterprise engaged in industry, agribusiness and/or services, whether single proprietorship, cooperative, partnership or corporation whose total assets, inclusive of those arising from loans but exclusive of the land on which the particular business entity's office, plant and equipment are situated, and must have

value falling under the following categories: (i) Micro: not more than P3,000,000; (ii) Small: P3,000,001 - 15,000,000; and (iii) Medium: P15,000,001 – P100,000,000. The above definitions shall be subject to review and adjustments by the Micro, Small and Medium Enterprises Development (MSMED) Council under Section 6 of RA 9501 or the Magna Carta for Micro, Small and Medium Enterprises, or upon recommendation of sectoral organizations concerned, taking into account inflation and other economic indicators.

(k) *"Partially Hydrogenated Oil"* (PHO) fat or oil that has been hydrogenated, but not to complete or near complete saturation, and with an iodine value greater than 4, as determined by a method that is suitable for this analysis.

(l) *"Prepackaged Food"* processed food prepared in advance and placed in a container, labelled and ready for sale or distribution, or for catering purposes.

(m) *"Processed Food"* any food that has been subjected to any action that substantially alters the initial raw materials or product or ingredients.

(n) *"Retailer"* any establishment that sells or offers to sell any food product directly to the general public.

(o) *"Trans-fatty acids"* (TFA) all fatty acids with a double bond in the trans configuration, regardless of whether they are produced industrially or come from ruminant sources.

SEC. 4. *Scope and Application.* - This Act shall apply to all food business operators as defined under Republic Act No. 10611 or the Food Safety Act.

Article II. Roles and Responsibilities

SEC. 5. *Lead Agency.* - The Department of Health (DOH) shall be responsible for ensuring that the provisions of this Act are implemented. As lead agency, the DOH shall perform the following functions:

(a) Convene and lead the inter-agency TFA Task Force composed of the following agencies for the implementation of this Act:
   i. National Nutrition Council (NNC);
   ii. FDA;
   iii. Department of the Interior and Local Government (DILG);
   iv. Department of Trade and Industry (DTI);

v. Department of Science and Technology (DOST);

vi. Department of Agriculture (DA);

vii. Department of Finance; and

viii. Other agencies identified by the DOH;

(b) Issue policies, rules, regulations and standards for the implementation of this Act; and

(c) Oversee and monitor the implementation of this Act.

SEC. 6. *Assistance and Capacity Building for Local Implementation and Enforcement.* - The FDA, in coordination with DILG and other relevant agencies, shall strengthen the capacity of local government units (LGUs) in implementing and enforcing the provisions of this Act with regard to prepackaged and processed food produced and marketed in traditional markets and food service establishments.

The FDA shall assist LGUs in regulating food service establishments, upon request of the LGU. Such assistance shall include the use of laboratories for testing and sharing of information relevant to products registered with the FDA.

SEC. 7. *Research and Development.* - The DOST shall:

(a) Conduct continuing research to identify and develop Healthy Alternative Oils and food products such as:

i. Healthy Alternative Oilseeds through crop diversification programs and agricultural research, in coordination with the DA;

ii. Healthy oils and fats through the application of oil modification techniques and other methods; and

iii. Healthy food products through product reformulation, research and development; and

(b) In coordination with the FDA, develop or adopt technology to reduce the cost of TFA testing.

SEC. 8. *Oilseeds Crop Diversification.* - The DA shall implement an oilseeds crop diversification program and conduct continuing research and development to support the production of Healthy Alternative Oilseeds in coordination with DOST.

SEC. 9. *Trainings and Seminars on Reformulation.* - The DOH, in coordination with FDA, DTI, DOST-Philippine Council for Health Research and Development, DOST-Food and Nutrition Research Institute (DOST-FNRI), DILG, and the Technical Education and Skills Development Authority, shall conduct trainings and seminars for food business operators and food service establishments on the reformulation of food products to comply with the provisions of this Act, and the use of health alternatives of oils.

Article III. Prohibited Acts

SEC. 10. *Prohibition on the manufacture, importation, distribution and sale of PHOs and oils and fats with high TFA content.* - The manufacture, importation, distribution and sale of the following are prohibited:

(a) PHOs to be consumed alone or used in preparation of food products;

(b) Oils and fats made or blended with PHOs; and

(c) Oils and fats with TFA content of more than 2g per 100g.

No registration, license or permit shall be issued to any food manufacturer, importer or distributor that manufactures, imports, distributes, or sells food in violation of this provision.

SEC. 11. *Prohibition on the manufacture, importation, distribution and sale of processed and prepackaged food with PHOs and high TFA content.* - The manufacture, importation, distribution and sale of the following are prohibited:

(a) Processed and prepackaged food prepared with PHOs, including food prepared by food service establishments;

(b) Processed and prepackaged food prepared with oils and fats made or blended with PHOs, including food prepared by food service establishments; and

(c) Processed and prepackaged food with TFA content of more than 2g per 100g of total fat.

No registration, license or permit shall be issued to any food manufacturer, importer or distributor for any processed or prepackaged food manufactured, imported, distributed or sold in violation of this provision.

SEC. 12. *Prohibition on trans fat free claims* - Claims on the packaging, labelling, marketing, or advertising, that a food product is TFA free is prohibited.

A TFA free claim is any claim that states or suggests that the food product does

not contain TFA, such as "Trans Fat Free," with "0g Trans Fat," or any other similar claim.

SEC. 13. *Material misrepresentation.* - Any material misrepresentation with regard to the requirements mandated by the FDA in the application for a CPR shall be a ground for the imposition of appropriate penalties prescribed under this Act. For purposes of this Act, there is material misrepresentation when the applicant makes a false representation of a material fact in the application for a CPR, tending directly to induce the FDA to grant the application when otherwise it will be denied.

Article IV. Enforcement

SEC. 14. *Enforcement agencies.* - The FDA and LGUs shall be responsible for the enforcement of this Act with regard to the following food products:

(a) Processed and prepackaged food - The FDA shall enforce the provisions of this Act in relation to prepackaged and processed food including oils and fats, whether domestic or imported.

(b) Food produced and marketed in traditional markets and food service establishments - The LGUs shall enforce the provisions of this Act with regard to prepackaged and processed food produced and marketed in traditional markets and food service establishments within their jurisdiction.

SEC. 15. *Inspection powers and record-keeping.* - The FDA, through its authorized agents, shall have the power to inspect the premises and records of food manufacturers to determine compliance with this Act. The FDA shall issue guidelines on record-keeping and inspection procedures.

SEC. 16. *Enforcement procedure for processed and prepackaged food.* - The existing rules of procedure in administrative proceedings of the FDA shall apply in the handling of cases and violations committed under this Act with regard to processed and prepackaged food.

SEC. 17. *Enforcement for traditional markets and food service establishments.* - LGUs, through an appropriate issuance, shall establish a mechanism to enforce the provisions of this Act with regard to prepackaged and processed food produced and marketed in traditional markets and food service establishments within their jurisdiction and shall impose penalties for violations thereof.

SEC. 18. *Civil society participation for monitoring and surveillance.* - The FDA shall implement programs encouraging citizen participation in the conduct of post-market monitoring and surveillance of TFA content in food and reporting violations of this Act. For this purpose, the FDA shall develop and publicize a

web-based user-friendly consumer complaints portal to encourage citizen participation.

Article V. Fines and Penalties

SEC. 19. *Administrative Penalties.* - The following administrative penalties shall be imposed on food business operators found to be in violation of Sections 10, 11, and 12 of this Act:

(a) For the first violation, a fine of not less than Fifty Thousand Pesos (P50,000.00) but not more than One Hundred Thousand Pesos (P100,000.00) and suspension of the CPR and/or LTO for one (1) month;

(b) For the second violation, a fine of not less than One Hundred Thousand Pesos (P100,000.00) but not more than Two Hundred Thousand Pesos (P200,000.00) and suspension of CPR and/or LTO for three (3) months; and

(c) For the third violation, a fine of not less than Two Hundred Thousand Pesos (P200,000.00) but not more than Three Hundred Thousand Pesos (P300,000.00). Suspension of CPR and/or LTO for one (1) year or revocation of the CPR, LTO, and other relevant licenses and permits.

The following administrative penalties shall be imposed on food businesses operators found to be in violation of Section 13 of this Act:

(a) For the first violation, a fine of not less than One Hundred Thousand Pesos (P100,000.00) but not more than Two Hundred Thousand Pesos (P200,000.00) and suspension of the CPR and/or LTO one (1) year; and

(b) For the second violation, a fine of not less than Two Hundred Thousand pesos (P200,000.00) but not more than Three Hundred Thousand Pesos (P300,000.00) and revocation of CPR and/or LTO.

The imposition of fines shall take into consideration the annual gross sales, capital investment and employee size of the food business operator.

SECTION 20. *Imprisonment.* - In addition to administrative penalties, the following penalties of imprisonment may be imposed on food business operators:

(a) For violations under Sections 10, 11, and 12, imprisonment of not less than one (1) month but not more than six (6) months; and

(b) For violations under Section 13, imprisonment of not less than six (6) months but not more than one (1) year.

Criminal and administrative actions for violations of this Act may be instituted separately and independently from one another. Should the offense be committed by a juridical person, the Chair of the Board of Directors, the President, General Manager, or the partners and/or the persons directly responsible therefor shall be penalized.

If the offender is an alien, he shall be deported after service of sentence and payment of fine without further deportation proceedings.

In case the violation is committed by, or in the interest of, a foreign juridical person duly licensed to engage in business in the Philippines, such license to engage in business in the Philippines shall immediately be revoked.

The above penalties shall not preclude the imposition of applicable penalties by LGUs, and any other sanctions under applicable laws, rules, and regulations.

SEC. 21. *Other Penalties.* - In addition to the foregoing fines and penalties, the following sanctions may also be imposed:

(a) Seizure and condemnation, destruction and/or appropriate disposition of noncompliant food products by the FDA; and/or

(b) Closure of establishment by the LGUs having jurisdiction.

Article VI. TFA Testing and Enforcement Capacity

SEC. 22. *Accredited laboratories and testing centers.* - The FDA and DTI-Philippine Accreditation Board (PAB) shall jointly accredit public and private laboratories capable of testing TFA content in food. The FDA and DTI-PAB shall develop, issue, and publish accreditation procedures and qualification requirements for testing facilities within six (6) months from the effectivity of this Act. The FDA shall adopt mechanisms to reduce the cost of TFA testing in all accredited laboratories and testing centers.

SEC. 23. *Regional laboratories and testing centers.* - Regional laboratories and testing centers shall assist LGUs in monitoring and enforcing the provisions of this Act within their respective jurisdictions as provided in Section 14.

SEC. 24. Resources and manpower. - The FDA shall determine and ensure the sufficient number of resources and manpower needed for the implementation of this Act.

In coordination with DOST, the FDA shall ensure that all FDA and DOST regional laboratories have the equipment and resources to conduct testing of TFA content in food.

In coordination with relevant agencies, the FDA shall determine and ensure the adequacy of personnel trained on TFA regulation, testing, monitoring and surveillance.

SEC. 25. *Duty-free importation of TFA testing equipment.* - The importation of laboratory equipment for testing TFA shall be exempt from payment of customs duties and taxes.

Article VII. Incentives for Replacing TFA

SEC. 26. *Early compliance incentives for MSMEs.* - The DTI and LGUs, through its business process and licensing offices, shall develop and implement policies and programs providing incentives for MSMEs to encourage early voluntary compliance with this Act.

SEC. 27. *Expedited processing for CPR applications on reformulated products.* - The FDA shall expedite the assessment of new CPR applications for food products reformulated in compliance with this Act.

Article VIII. Miscellaneous Provisions

SEC. 28. *Consumer information, education and communication program.* - The DOH, in coordination with the Philippine Information Agency, Department of Education, Commission on Higher Education, and Department of Information and Communication Technology shall develop and implement a comprehensive information, education and communications program to raise public awareness on the provisions of this Act, the health harms resulting from TFA, sources of TFA in the diet, and ways to replace PHOs with Healthy Alternative Oils, Fats, and Oilseeds.

SEC. 29. *Implementing Rules and Regulations.* - Within sixty (60) days from the effectivity of this Act, the DOH shall develop and issue implementing rules and regulations (IRR) of this Act in consultation with NNC, FDA, DILG, DTI, DOST, DA, and other relevant government agencies and stakeholders.

SEC. 30. *Transitory Provisions.* - Within two (2) years from the effectivity of this Act:

(a) Food manufacturers and importers shall comply with the additional requirements for CPR application as determined by the FDA; and

(b) Food business operators shall be allowed to sell their existing food products that do not comply with Sections 10 and 11 of this Act.

All manufacturers, importers, distributors, and retailers of oils and fats, and food service establishments shall be required to submit their existing inventory of food products as of the date of effectivity of this Act to the FDA and DTI. Food business operators shall submit their inventory within sixty (60) days from the effectivity of the IRR of this Act to monitor the phase out of noncompliant food products.

SEC. 31. *Monitoring and Evaluation.* - The DOH shall periodically report to the President and the Congressional Committees on Health, Agriculture and Food, and Trade and Industry on the implementation of this Act. The DOH shall, in coordination with DOST-FNRI, further monitor and evaluate the following:

(a) TFA exposure screening and surveillance - The DOST-FNRI shall include the regular screening and monitoring of TFA population consumption in the expanded national nutrition survey; and

(a) TFA nutrient profiling - The DOST-FNRI shall include the testing and monitoring of TFA content in food in the food composition table and food composition databases.

SEC. 32. *Appropriations and Use of Fees, Charges and Penalties.* - The initial amount necessary for the implementation of this Act shall be charged against the current appropriation of all concerned agencies. Such funds necessary for the continued implementation of this Act shall be included in the annual General Appropriations Act.

All fines and fees that may be collected from the enforcement of this Act shall be used exclusively for its implementation.

SEC. 33. *Conflict of Interest.* - Pursuant to the fundamental objective of this Act to advance public health, the implementation and enforcement of this Act and the development of related policies shall promote multisectoral coordination while safeguarding against potential conflict of interest.

SEC. 34. *Separability Clause.* - If any provision or part hereof is held invalid or unconstitutional, the remainder of the law or the provision not otherwise affected shall remain valid and subsisting.

SEC. 35. *Repealing Clause.* - Any law, presidential decree or issuance, executive order, letter of instruction, administrative order, rule or regulation contrary to or inconsistent with the provisions of this Act is hereby repealed, modified, or amended accordingly.

SEC. 36. *Effectivity Clause.* - Notwithstanding the non-issuance of the IRR, this Act shall take effect fifteen (15) days after its complete publication in the Official Gazette or in a newspaper of general circulation.

Approved,