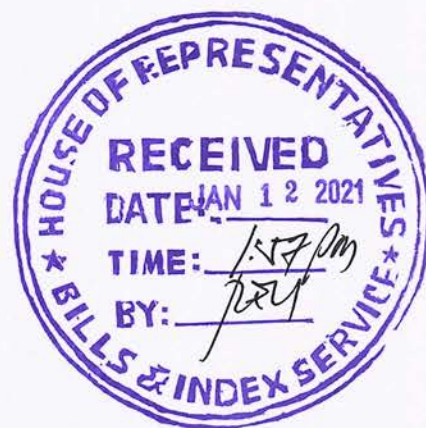


Republic of the Philippines
HOUSE OF REPRESENTATIVES
Quezon City

EIGHTEENTH CONGRESS
Second Regular Session

HOUSE BILL NO. 8342



Introduced by **HON. LUIS RAYMUND "LRAY" F. VILLAFUERTE, JR.**

**AN ACT REGULATING THE IMPORTATION, MANUFACTURE, SALE,
PACKAGING, DISTRIBUTION, USE, AND COMMUNICATION OF VAPOR
PRODUCTS AND HEATED TOBACCO PRODUCTS**

Vaporized Nicotine Products are those that generate a nicotine-containing or non-nicotine containing aerosol without combustion or burning. The use of such products are increasing in the country yet they are yet to be fully regulated.

This proposed measure seeks to regulate, the importation, manufacture, sale, packaging, distribution, use, advertisement, promotion and sponsorship of Vaporized Nicotine Products to reduce the harm caused by smoking, promote a healthy environment and protect the citizens from any potential hazards coming from the use of these novel consumer products.

It seeks to strike a balance between protecting the public from the hazards of tobacco smoke and ensuring access to non-combustible alternatives to cigarettes is not curtailed. This bill grants the Department of Trade and Industry jurisdiction over these products to ensure that defective, dangerous, and substandard products are kept off the market.

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


LUIS RAYMUND "LRAY" F. VILLAFUERTE, JR.

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PRODUCTS AND HEATED TOBACCO PRODUCTS**

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

Section 1. Short Title. - This Act shall be known as the "Vaporized Nicotine Products Regulation Act".

Sec. 2. Declaration of Policy. - It is hereby declared the policy of the State to protect and promote the right to health of the people and instill health consciousness among them.

For this purpose, the government shall regulate, the importation, manufacture, sale, packaging, distribution, use, advertisement, promotion and sponsorship of Vaporized Nicotine Products in order to reduce the harm caused by smoking, promote a healthy environment and protect the citizens from any potential hazards of these novel consumer products.

It is further declared the policy of the State to enact a balanced policy by enforcing harm reduction measures as a public health strategy whereby these novel consumer products are properly regulated in order to promote a healthful environment and to protect the citizens from the hazards of tobacco smoking by ensuring that access to its non-combustible alternatives is not curtailed.

Sec. 3. Definition of Terms. - For purposes of this Act, the following terms shall mean:

a) Advertising refers to the business of conceptualizing, presenting, making available and communicating to the public, through any form of mass media, any fact, data or information about the attributes, features, quality or availability of consumer products, services or credit. For the purpose of this Act, advertising shall be understood as

Vaporized Nicotine Product advertising and shall not include non-promotional communication intended for Informational purposes only;

b) Child-resistant shall refer to the type of containers that can be opened only by operating, puncturing or removing one of its functional and necessary parts using a tool that is not supplied with the container and comply with the existing standards on child-resistant packaging;

c) Designated Vaping Area shall refer to an assigned indoor or outdoor area where the use of Vaporized Nicotine Products shall be allowed.

d) Distributor shall refer to any entity to whom Vaporized Nicotine Products is delivered to or sold for purposes of distribution in commerce, except that such term does not include a manufacturer or retailer or common carrier of such product.

e) Heated Tobacco Product Consumables or Heat-Not-Burn-Product Consumables, also referred to as "Heated Tobacco Products (HTPs)", shall refer to tobacco products that are intended to be consumed through heating tobacco, either electronically or through other means sufficient to release an aerosol that can be inhaled, without combustion of the tobacco. Heated Tobacco Product Consumables or Heat-Not-Burn Product Consumables may also include liquid solutions and gels that are part of the product and are heated to generate an aerosol. HTPs may or may not operate by means of a Heated Tobacco Product Device.

f) Heated Tobacco Product Device or HTP Device shall refer to the component or combination of components of a Heated Tobacco Product System intended to be used in combination with HTP Consumables that generate an aerosol without combustion.

g) Heated Tobacco Product System or HTP System shall refer to a HTP Consumable and HTP Device that are intended to be used together as a system. h) Ingredient means any substance that is used to make the Vapor Product Refills or Heated Tobacco Product Consumables that is present in the finished product;

i) Manufacturer shall refer to an establishment engaged in any and all operations involved in the production of Vapor Products or Heated Tobacco Products including preparatory processing, compounding, formulating, filling, refilling, packaging, repackaging, altering, ornamenting, finishing and labeling for the purpose of its storage, sale or distribution;

j) Nicotine shall refer to nicotinic alkaloids, including any salt or complex of nicotine whether derived from tobacco or synthetically produced;

k) Nicotine Mixture shall refer to the nicotine-containing liquid, solid or other non-tobacco substance in the product;

l) Nicotine Shots refer to nicotine in liquid or any other form/substances that is added to or mixed with vapor product refills or cartridges that has the effect of increasing the dosage or nicotine concentration in a refill or cartridge;

m) Package shall refer to packs, boxes, cartons, or containers of any kind in which Vapor Products or HTPs are contained when offered for sale to consumers;

n) Principal display surface shall refer to the panel of the package that faces the consumer when displayed for sale;

o) Point of Sale shall refer to any location, physical or online, where an individual can purchase or obtain Vaporized Nicotine Products, which may include a product testing area;

p) Product Comprehension Session shall refer to the act of testing by using a Vaporized Nicotine Product for the purpose of informing and familiarizing a prospective buyer, who is of legal age for the purpose of this Act, with the operation and characteristics of the product;

q) Promotion shall refer to an event or activity organized by or on behalf of a Vaporized Nicotine Products manufacturer, importer, distributor, or retailer with the aim of promoting a brand of a Vaporized Nicotine Product, which event or activity would not occur if not for the support given to it by or on behalf of the Vaporized Nicotine Product manufacturer, importer, distributor, or retailer. This includes the paid use of Vaporized Nicotine Product bearing the brand names, trademarks, logos, and the like by performers in movies, television and other forms of entertainment. For the purpose of this Act, promotion shall be understood as Vaporized Nicotine Product promotion;

r) Refill container shall refer to a container for holding e-liquid or nicotine mixture;

s) Retailer shall refer to any establishment which sells or offers to sell any Vaporized Nicotine Product directly to the general public subject to Section 6 of this Act;

t) Sponsorship shall refer to any public or private contribution, whether in cash or in kind, from a third party in relation to an event, team, or activity made with the aim of promoting a brand of Vaporized Nicotine Products, which event, team or activity would still exist or occur without such contribution. For the purpose of this Act, sponsorship shall be understood as Vaporized Nicotine Products sponsorship;

u) Tamper-resistant shall refer to the type of packages constructed such that it has one or more indicators or barriers to entry which, if breached or missing, can reasonably be expected to provide visible evidence that the product or its packaging has been opened, or otherwise comply with standards on tamper-resistant packaging;

v) Vapor Product Refills, also referred to as "Vapor Products", shall refer to the liquid, solid, gel or combination, which may or may not contain nicotine, that is transformed into an aerosol without combustion by a Vapor Product Device;

w) Vapor Product Device shall refer to a device or a combination of devices used to heat a Vapor Product, to produce an aerosol, mist, or vapor that users inhale;

x) Vapor Product System shall refer to the specific combination consisting of the Vapor Product Refill and Vapor Product Device which, based on the information made available to the consumer by the provider, are intended to be used together. These

may include combinations of a liquid solution or gel, that are heated and transformed into an aerosol without combustion through the employment of a mechanical or electronic heating element, battery, or circuit, and includes, but is not limited to a cartridge, a tank, or a device without a cartridge or tank; and

y) Vaporized Nicotine Product shall refer to the category of products used in both HTP System and Vapor Product System, as defined herein, which are novel consumer goods that generate a nicotine-containing or non-nicotine containing aerosol without combustion.

Sec. 4. Packaging and Health Warnings. - All manufacturers, Importers, and distributors duly authorized to sell Vapor Product Refills and HTP Consumables shall comply with the following packaging requirements:

a) Only the unit packaging or any outside consumer packaging of Vapor Product Refills or HTP Consumables and refill containers shall bear the following health warnings on the lower fifty percent (50%) of the principal display surface; "This product is harmful and contains nicotine which is a highly addictive substance. It is not recommended for use by non-smokers.";

b) Nothing shall be printed or applied on a location where it is likely to obscure or cover. In part or in whole, the health warning; and

c) No part of the warning may be obliterated, obscured, folded, severed or become unreadable when the package is opened or closed or when a wrapper on the package is removed.

Sec. 5. Tamper-resistant and Child-resistant Design. - The receptacles of Vapor Product Refills shall be child-resistant, tamper-resistant, and shall be protected against 32 breakage and leakage.

Sec. 6. Minimum Age Sales and Purchase. - The minimum allowable age for the purchase, sale and use of Vaporized Nicotine Products shall be eighteen (18) years old. It shall not be a defense for the person selling or distributing that he/she did not know or was not aware of the real age of the purchaser. Neither shall it be a defense that he/she did not know nor had any reason to believe that the product was for the consumption of a person below eighteen (18) years of age.

Sec. 7. Proof-of-Age Verification. - Retailers shall ensure that no individual below eighteen (18) years of age is allowed to purchase Vaporized Nicotine Products. It shall be the responsibility of retailers to verify the age of buyers. For this purpose, the presentation of any valid identification card exhibiting the buyer's photograph and age or date of birth may be required.

Sec. 8. Online Trade. - The sale or distribution of Vaporized Nicotine Products through internet websites or via e-commerce and/or other similar media, shall be allowed: Provided, That the seller or distributor shall adopt measures to ensure that such access shall be restricted to persons below eighteen (18) years of age and that the internet website shall bear the signages required under this Act. In compliance with

the aforementioned age restriction, and when seeking access to such media platform, the person's legal age shall be self-declared in the opening first page of the website.

Sec. 9. Sales within School Perimeters. - The sale or distribution of Vaporized Nicotine Products within one hundred (100) meters from any point of the perimeter of a school, playground or other facility frequented particularly by minors shall be prohibited.

Sec. 10. Point-of-Sale Signage. - Point-of-sale establishments offering, selling, or distributing Vaporized Nicotine Products shall post the following statement in a clear and conspicuous manner: "THE SALE OR DISTRIBUTION OF VAPOR PRODUCTS OR 28 HEATED TOBACCO PRODUCTS TO OR BY PERSONS BELOW EIGHTEEN (18) YEARS OF AGE IS ILLEGAL.

Sec. 11. Product Communication Restrictions. - Advertisements and other forms of consumer communication shall be allowed in points of sale or retail establishments, through direct marketing, and on the internet: Provided, That the following guidelines shall apply:

- a) These shall not be targeted to or particularly appeal to persons under eighteen (18) years of age;
- b) Quit-smoking messages shall not be undermined while non-tobacco and non-nicotine users shall not be encouraged to use Vaporized Nicotine Products;
- c) These shall not contain any information that is false or not scientifically substantiated, particularly with regard to product characteristics, health effects, risks or emissions;
- d) Product comprehension sessions shall be allowed in designated locations, by those licensed to sell Vaporized Nicotine Products; and
- e) These restrictions apply to commercial communications only and shall not prevent a company from providing information regarding its company, its products and other non-promotional information on Vaporized Nicotine Products. No Vaporized Nicotine Product advertisements may be placed on objects or places outside points of sale such as but not limited to vehicles of any kind, billboards, posters, streamers.

Sec. 12. Restrictions on Vaporized Nicotine Product Promotional Activities. - The following restrictions shall apply to any promotional activity related to Vaporized Nicotine Product:

- a) Promotional events and activities, such as, but not limited to, product sampling or product offers, must be directed only to persons at least eighteen (18) years of age. No person below eighteen (18) years of age shall participate in such promotions. The participants in such promotions must be required to provide proof of age;
- (i) Communications to consumers about promotional events for Vaporized Nicotine Products shall comply with the provisions of this Act governing Vaporized Nicotine Products advertising. In addition to the required health warning, the age requirement

for participation in any all promotional activity must be clearly marked on the program materials distributed to consumers;

(ii) All stalls, booths, and other displays concerning Vaporized Nicotine Product promotions must be limited to point-of-sale locations or adult only facilities; and

(iii) Telecommunications concerning promotional offers, programs or events must include a recorded health warning message in English or Filipino consistent with the warnings specified in this Act.

b) No product promotional placement or advertisement shall be made by any manufacturer, distributor, or retailer of any Vaporized Nicotine Product package, including use of the product, in any manner. In a video game or in any television program or motion picture authorized by regulatory agencies concerned for viewing by those under eighteen (18) years of age;

c) No promotional merchandise such as, but not limited to, t-shirts, caps, sweatshirts, visors, backpacks, sunglasses, writing Implements and umbrellas, may be distributed, sold or offered, directly or indirectly, with the name, logo or other indicia of a Vaporized Nicotine Product brand displayed so as to be visible to others when worn or used;

d) No name, logo, or other indicia of a Vaporized Nicotine Product brand, may appear on promotional merchandise or element of a brand-related marketing activity that is marketed to or likely to be used by minors such as, but not limited to, sports equipment, toys, dolls, video games, and food. The manufacturer or company must take all available measures to prevent third parties from using the company's brand names, logos, or other proprietary symbol on products that are directed toward minors; and

e) No Vaporized Nicotine Product advertisements may be placed on shopping bags.

Sec. 13. Restrictions on Sponsorship. - The following restrictions shall apply on Vaporized Nicotine Product promotional sponsorships:

a) Sponsorships shall be limited to industry associations or trade events, where only persons at least eighteen (18) years of age shall be allowed to participate. No person below eighteen (18) years of age may participate in such a sponsored event. The participants in the sponsored event must be 2 required to provide proof of age;

b) Communications to consumers about Vaporized Nicotine Product sponsored events shall comply with the provisions of this Act governing Vaporized Nicotine Product advertising. In addition to the mandatory health warning, the age requirement for participation in any sponsored events must be clearly marked on the program materials distributed to consumers;

c) All display materials concerning Vaporized Nicotine Product sponsored events must be limited to point-of-sale locations or adult-only facilities; and

d) Telecommunications concerning sponsored events must Include a recorded health warning message In English or Filipino consistent with the warnings specified in this

Sec. 14. Use in Public Place. -The use of Vaporized Nicotine Products shall be allowed in public places except that indoor use is prohibited in schools, hospitals, government offices, and facilities intended particularly for minors. In other indoor places open to the general public, the use of Vaporized Nicotine Products shall not be allowed except in designated vaping areas or in point-of-sale establishments for purposes of conducting product comprehension sessions.

Sec. 15. Standards for Designated Vaping Areas. - Designated Vaping Areas (DVAs) shall comply with the following standards:

- a) Persons below eighteen (18) years of age shall not be allowed within the DVA;
- b) Every DVA shall have the following signages highly visible and prominently displayed: i. "Vaping Area" signage; and ii. Prohibition on entry of persons below eighteen (18) years of age;
- c) Smoking shall not be allowed in DVAs; and
- d) The number of persons allowed inside shall be controlled by the establishment owner taking into consideration the size of the DVA and its location.

Sec. 16. Product Notification. - Three (3) months prior to placing Vaporized Nicotine Products in the market, all manufacturers and importers must notify the Department of Trade and Industry (DTI) and submit information demonstrating compliance with product standards and assessment requirements in accordance with this Act. For products that are already in-market, they shall be given eighteen (18) months to register their products with the DTI and submit information demonstrating compliance with product standards and assessment requirements consistent with Section 16 of this Act.

Sec. 17. Product Standard Requirements for Vapor Product Refills/Devices and Systems. - The DTI shall set technical standards for safety, consistency and quality of Vapor Product Refills, Devices and Systems in line with international practice for Vapor 10 Products.

- a) The substances listed below may not be added to Vapor Product Refills:
 - i. Additives that have carcinogenic, mutagenic or reprotoxic properties in unburnt form;
 - ii. Vitamins or other additives that create the impression that the product has a health benefit or presents reduced health risks;
 - iii. Caffeine, taurine, or other additives and stimulant compounds that are associated with energy and vitality;
 - iv. Additives having coloring properties for emissions;
 - v. Ethylene glycol;
 - vi. Diethylene glycol;

vii. Diacetyl; and

viii. 2,3-pentanedione;

b) Producers of electrical Vapor Product Devices intended to be used in combination with Vapor Product Refills shall ensure that such devices comply with the applicable electrical safety standards as may be determined by the BPS of the DTI;

c) Batteries must comply with applicable industry requirements as may be determined by the BPS of the DTI;

d) All ingredients in the Vapor Product Refill should be listed on the label where they are used in quantities of 0.1% or more of the final formulation of the e-liquid. Where a flavor ingredient contains several component chemicals, it can be described on the label by the name of the flavor. For confidentiality reasons, companies may choose to describe individual ingredients used in quantities below 0.1% of the final formulation by category;

e) A full list of ingredients in the flavoring must be included in notifications through the DTT;

f) Nicotine, propylene glycol and glycerol used in the manufacture of the liquids shall meet the requirements of either the European or American Pharmacopoeia and other ingredients in the manufacture of the e-liquids, such as flavors, shall be of food grade;

g) Consumer packaging of Vapor Product Refills shall include an information leaflet about the safe use of the product. This shall also include appropriate advice on product storage, particularly on how to ensure that the battery does not malfunction;

h) Vapor Product Refills may not be marketed, packed or presented with characterizing flavors other than tobacco and menthol. Fruit flavors, nuts, coffee, tea, vanilla, and caramel flavored e-liquids shall be prohibited.

Sec. 18. Product Standard Requirements for Heated Tobacco Product Consumables, Devices and Systems. - The DTI shall have exclusive jurisdiction to set standards on HTP Consumables, Devices, and System as guided by the following requirements:

a) The substances listed below may not be added to HTP Consumables:

i. Additives that have carcinogenic, mutagenic or reprotoxic properties in unburnt form;

ii. Vitamins or other additives that create the impression that the product has a health benefit or presents reduced health risks:

iii. Caffeine, taurine, or other additives and stimulant compounds that are associated with energy and vitality;

iv. Additives having coloring properties for emissions;

v. Ethylene glycol;

vi. Diethyleneglycol;

vii. Diacetyl; and 31

viii. 2,3-pentanedione;

b) Manufacturers of electrical HTP Devices, intended for use in combination with HTPs, shall ensure that such devices do not combust or burn the tobacco mixture;

c) Manufacturers of electrical HTP Devices, intended for use in combination with HTPs, shall ensure that such devices comply with the applicable safety standards as may be determined by the BPS of the DTI; and

d) Batteries must comply with applicable industry requirements as may be determined by the BPS of the DTT.

Sec. 19. Restriction on the Retail and Sale of Nicotine Shots. - The retail or use of nicotine shots and/or concentrates shall be strictly prohibited.

Sec. 20. Jurisdiction. - Vaporized Nicotine Products are novel consumer products that do not combust tobacco and are to be governed exclusively by this Act and such other regulations as may be issued by the DTI pursuant to this Act in their sole and exclusive authority and jurisdiction.

Sec. 21. Penalties for Noncompliance. - The following penalties shall individually apply to manufacturers, importers, distributors, and sellers of Vaporized Nicotine Products as well as their agents for any violation of this Act:

a) On the first offense, a fine of not more than One Hundred Fifty Thousand Pesos (P150,000.00);

b) On the second offense, a fine of not more than Two Hundred Fifty Thousand Pesos (P250,000.00);

c) On the third offense, a fine of not more than Five Hundred Thousand Pesos (P500,000.00); or imprisonment of not more than five (5) years, or both, at the discretion of the court: Provided, That the business permits and licenses, in the case of a business entity or establishment shall be revoked or cancelled. Non-compliant Vaporized Nicotine Products found in the market for sale or distribution shall be subject to confiscation. Online sellers and distributors of Vaporized Nicotine Products and online platforms that are non-compliant with Section 8 of this Act shall be ordered by the DTI to immediately suspend trading of such products, and shall be liable for the fines and penalties imposed under this Section. Suspension shall continue until the seller, distributor or online platform has complied with the requirements provided under Section 8 of this Act. If the guilty officer is a foreign national, the officer shall be deported after service of sentence and/or payment of applicable fines without need of further deportation proceedings and shall be permanently barred from re-entering the Philippines.

Sec. 22. Role of Local Government Units (LGUs). - All LGUs shall ensure that this Act is implemented within their respective jurisdictions. No LGU may establish or continue to Implement any of its requirement for a vapor product or heated tobacco product, which is different from, or in addition to, any requirement under the provisions of this Act.

Sec. 23. Congressional Oversight Committee on Vaporized Nicotine Products. - A Congressional Oversight Committee on Vaporized Nicotine Products (COC-VNP) is hereby constituted to monitor and review the Implementation of this Act for a period not exceeding three (3) years. The COC-VNP shall be composed of the Chairpersons of the Senate Committees on Health, Trade and Commerce, Agriculture, and Public Information, and the House of Representatives Committees on Trade and Industry, Health, Public Information, and Agriculture, and a Member of the House of Representatives representing the tobacco producing provinces. The Secretariat of the COC-VNP shall be drawn from the existing personnel of the standing committees comprising the Congressional Oversight Committee and its funding requirements shall be charged against the appropriations of both the House of Representatives and Senate of the Philippines.

Sec. 24. Implementing Rules and Regulation. - Within three (3) months from the date of effectivity of this Act, the DTI shall issue the implementing rules and regulations ("IRR") for this Act. The non-promulgation of the IRR shall not prevent the implementation of this Act upon its effectivity.

Sec. 25. Appropriations. - The amount necessary to implement the provisions of this Act shall be charged against the current year's appropriations of the national government agencies concerned. Thereafter, such funds as may be necessary for the continued implementation of this Act shall be included in the budgets of the national government agencies concerned under the annual General Appropriations Act.

Sec. 26. Transitory Provision. - Existing industries and businesses affected by the implementation of this Act shall be given an eighteen (18) month transitory period from the effectivity of this Act to comply with the requirements herein.

Sec. 27. Separability Clause. -If any provision or any part hereof is held invalid or unconstitutional, the remainder of the law or the provisions not otherwise affected shall remain valid and subsisting.

Sec. 28. Repealing Clause. - All laws, decrees, rules and regulations or parts thereof which may govern the product category, market access, period of compliance, jurisdiction, labeling, packaging and health warning, sales and purchase, online trade, age restrictions, product and brand communications, promotions, sponsorships, use and designated vaping area, and product standards, of Vaporized Nicotine Products, and those other laws, decrees, rules and regulations or parts thereof which are inconsistent with the provisions of this Act, are hereby repealed, amended or modified accordingly.

Sec. 29. Effectivity. - This Act shall take effect fifteen (15) days after its publication in the Official Gazette or in at least two (2) newspapers of general circulation.

Approved,