Republic of the Philippines HOUSE OF REPRESENTATIVES Quezon City, Metro Manila

EIGHTEENTH CONGRESS

First Regular Session

House Bill No. 2862



Introduced by Representatives Ron P. Salo and Juan Fidel F. Nograles

EXPLANATORY NOTE

Electronic cigarettes are a rapidly emerging and diversified product class that typically deliver nicotine via an inhaled aerosol. They have become an increasingly popular choice among smokers, either on the assumption that such products pose less risk to conventional smoking-related diseases. It is marketed as a way to stop or cut down on smoking and provides a similar sensation to inhaling tobacco smoke.

The impact of e-cigarettes on public health, however, remains unclear. Science and public policy have bounced back and forth for over a decade, as different studies produce different, and sometimes contradictory, results. It is surrounded by debate, focusing on the lack of evidence regarding the effects associated with their long-term use, as well as their potential to act as a gateway to smoking among the youth.

As it stands today, there are already many e-cigarette users among our countrymen. Thus, there is a cause for concern because it is still unregulated. E-cigarettes are not regulated in the same manner as tobacco products because they do not contain tobacco- therefore falling outside the ambit of the Tobacco Regulation Act. E-cigarettes are accessible to anyone who wishes to use them, including minors.

In line with the policy of the State to protect and promote the right to health of the people and instill health consciousness among them, this bill seeks to regulate the sale, distribution and manufacture of e-cigarettes and similar devices. This will protect not only the welfare of the users, but most especially the general public.

The proposed measure requires producers to register their e-cigarette products with the Department of Trade and Industry prior to market placement to ensure that such products have sufficiently passed quality and safety requirements and avoid untoward incidents to consumers during use. Health warning is likewise mandated on nicotine containers of these products.

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

RON P. SALO KABAYAN Partylist J. Jidh Morah JUAN FIDEL F. NOGRALES 2nd District, Rizal

Republic of the Philippines HOUSE OF REPRESENTATIVES

Quezon City, Metro Manila

EIGHTEENTH CONGRESS

First Regular Session

House Bill No. 2862

Introduced by Representatives Ron P. Salo and Juan Fidel F. Nograles

AN ACT REGULATING ELECTRONIC CIGARETTES

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

SECTION 1. Short Title. – This Act shall be known as the "E-Cigarette Regulation Act of 2018".

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.

SEC. 3. Definitions. - As used in this Act, the following terms shall mean:

- a) "E-cigarette" refers to a product that can be used for the consumption of a nicotine-containing vapor;
- b) "Ingredient" means any substance that is added to the mixture and present in the finished product;
- c) "Nicotine" means nicotinic alkaloids, including any salt or complex of nicotine whether derived from tobacco or synthetically produced;
- d) "Nicotine mixture" means the nicotine-containing liquid, solid or other non-tobacco substance in the product;
- e) "Refill container" means a container for holding nicotine mixture to refill certain e-cigarettes;

- f) "Emissions" means substances that are released when a product is consumed as intended, such as substances found in cigarette smoke, or the aerosol generated by an e-cigarette;
- g) "Package" shall refer to packs, boxes, cartons, or containers of any kind in which the electronic component of an e-cigarette is offered for sale to consumers;
- h) "Nicotine container" shall refer to bottles, boxes, cartons, or containers of any kind in which a nicotine-containing product is offered for sale to consumers for use with an e-cigarette product system;
- i) "Producer" shall refer to any location at which an individual can purchase or otherwise obtain e-cigarette products;
- j) "Principal display surface" shall refer to the panel of the nicotine container that faces the consumer when displayed for sale;
- k) "Advertising" shall refer to the business of conceptualizing, present, 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 e-cigarette advertising; and
- I) "Vaping" shall refer to the act of using an e-cigarette.
- SEC. 4. Health Warnings. Only nicotine containers shall bear textual health warnings with the following warning: "This product may damage your health and is addictive."

The health warning shall occupy 30% of the lower part of the principal display surface of the nicotine container. No other health warning shall be required for e cigarette products.

- SEC. 5. Minimum Age Sales and Purchase. The following acts shall be prohibited:
 - a) The sale, distribution, or transfer of e-cigarettes by any person to minors (anyone below 18 years old);
 - b) Purchasing, or otherwise receiving e-cigarettes from a minor;
 - c) The sale, purchase, and use of e-cigarettes by minors.

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 minor. 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 the minor to whom it was sold.

- SEC. 6. Retailer Signage. Producer establishments offering, distributing, or selling e-cigarettes to consumers shall post the following statement in a clear and conspicuous manner: "SALE/DISTRIBUTION TO OR PURCHASE BY MINORS OF E-CIGARETTES IS UNLAWFUL" or "IT IS UNLAWFUL FOR E-CIGARETTES TO BE SOLD/DISTRIBUTED TO OR PURCHASED BY PERSONS UNDER 18 YEARS OF AGE".
- SEC. 7. Proof of Age Verification. Retailers shall ascertain that no individual purchasing an e-cigarette is below eighteen (18) years of age.
- SEC. 8. Product Communication Restrictions. Advertisements shall be allowed in retailer establishment, through direct marketing, and on the Internet. These shall not be aimed at or particularly appeal to persons under eighteen (18) years of age. These should not undermine quit smoking messages and encourage non-tobacco or nicotine users to use the product. These should not contain any information that is untrue or not scientifically substantiated, in particular with regards to product characteristics, health effects, risks or emissions.
- **SEC. 9. Restrictions on Advertisement in Print Media.** Advertising and other promotional communications of e-cigarettes shall be permitted so long as the publication is not intended for minors and generally has an adult readership or subscriber base.
- SEC. 10. Public Place Use. Use of e-cigarettes indoors is prohibited in schools, hospitals, government offices, and facilities intended particularly for minors. In all other enclosed places open to the general public, e-cigarette use shall be allowed, provided that the owner of such places shall post the following statement in a clear manner at every entrance point of such places: "USE OF E CIGARETTES IS ALLOWED INSIDE." For places that do not allow e-cigarette use indoors, the owner of such places shall post the following statement at every entrance: "NO VAPING INSIDE."
- **SEC. 11. Product Standard Requirements.** The following shall be required for all e-cigarettes sold in the Philippines:
 - a) E-cigarette tanks shall have a capacity of no more than 5ml;
 - The maximum volume of nicotine-containing e-liquid for sale in one refill container shall be limited to 30ml;
 - c) E-liquids shall have a nicotine strength of no more than 20mg/ml;
 - d) Nicotine containers shall be child-resistant and tamper evident;

- e) Producers of electrical devices intended to be used in combination with an
 e-cigarette shall ensure that such devices comply with applicable electrical
 safety standards as may be determined by the Bureau of Product Standards
 of the Department of Trade and Industry
- f) Batteries must comply with applicable industry requirements as may be determined by the Bureau of Product Standards of the Department of Trade and Industry
- g) All ingredients in the product 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;
- A full list of ingredients in the flavoring must be included in notifications through the DTI;
- Packs shall include an information leaflet about safe use of the product. This shall also include appropriate advice on product storage, particularly on how ensure the battery does not malfunction; and
- j) All e-cigarettes and e-liquids shall be notified to the Department of Trade and Industry before they can be sold in the market.
- SEC. 12. Market Placing. Producers and distributors must comply with the following:
 - a) Producers must submit information about their products to the DTI;
 - b) Retailers do not need to submit information for any products they sell unless they also qualify as a producer. Retailers shall have six (6) months from the date of effectivity of this Act to sell through stock of products that do not comply with the labeling and product composition requirements of this Act;
 - c) This Act shall not cover nicotine-containing products that are authorized as medicines and those that have health claims; d. Producers shall have six months to register their products with the DTI and submit information demonstrating compliance with product standards and assessment requirements.
- **SEC. 13. Penalties for Noncompliance.** The following penalties shall individually apply to producers, importers, distributors, and sellers of e-cigarettes as well as their agents for any violation of this Act:

- a) On the first offense, a fine of not more than FIFTY THOUSAND PESOS (Php 50,000.00);
- b) On the second offense, a fine of not more than ONE HUNDRED THOUSAND (PhP 100,000.00); and
- c) On the third offense, a fine of not more than FIVE HUNDRED THOUSAND PESOS (PhP 500,000.00) 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 on cancelled.

Non-compliant e-cigarettes found in the market for sale or distribution shall be subject to confiscation.

If the guilty officer is a foreign national, he 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. 14. Implementing Rules and Regulations. Within three (3) months from the date of effectivity of this Act, the DTI shall issue the implementing rules and regulations for this Act. The non-issuance of the IRR will not suspend the effectivity of this Act of the introduction of new e-cigarettes in the market.
- SEC. 15. Separability Clause. Should any provision herein be declared unconstitutional, the same shall not affect the validity of the other provisions of this Act.
- **SEC. 16. Repealing Clause.** All laws, decrees, orders, rules, and regulations or other issuances or parts inconsistent with the provisions of this Act are hereby repealed, amended, or modified accordingly.
- SEC. 17. Effectivity Clause. This Act shall take effect in fifteen (15) days after publication in the Official Gazette or in one (1) newspaper of general circulation in the Philippines.

Approved.

Republic of the Philippines HOUSE OF REPRESENTATIVES Quezon City, Metro Manila

EIGHTEENTH CONGRESS

First Regular Session

House Bill No. 2862

Introduced by Representatives Ron P. Salo and Juan Fidel F. Nograles

EXPLANATORY NOTE

Electronic cigarettes are a rapidly emerging and diversified product class that typically deliver nicotine via an inhaled aerosol. They have become an increasingly popular choice among smokers, either on the assumption that such products pose less risk to conventional smoking-related diseases. It is marketed as a way to stop or cut down on smoking and provides a similar sensation to inhaling tobacco smoke.

The impact of e-cigarettes on public health, however, remains unclear. Science and public policy have bounced back and forth for over a decade, as different studies produce different, and sometimes contradictory, results. It is surrounded by debate, focusing on the lack of evidence regarding the effects associated with their long-term use, as well as their potential to act as a gateway to smoking among the youth.

As it stands today, there are already many e-cigarette users among our countrymen. Thus, there is a cause for concern because it is still unregulated. E-cigarettes are not regulated in the same manner as tobacco products because they do not contain tobacco- therefore falling outside the ambit of the Tobacco Regulation Act. E-cigarettes are accessible to anyone who wishes to use them, including minors.

In line with the policy of the State to protect and promote the right to health of the people and instill health consciousness among them, this bill seeks to regulate the sale, distribution and manufacture of e-cigarettes and similar devices. This will protect not only the welfare of the users, but most especially the general public.

The proposed measure requires producers to register their e-cigarette products with the Department of Trade and Industry prior to market placement to ensure that such products have sufficiently passed quality and safety requirements and avoid untoward incidents to consumers during use. Health warning is likewise mandated on nicotine containers of these products.

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

RON P. SALO KABAYAN Partylist J. Jidh Marah JUAN FIDEL F. NOGRALES 2nd District, Rizal

Republic of the Philippines HOUSE OF REPRESENTATIVES

Quezon City, Metro Manila

EIGHTEENTH CONGRESS

First Regular Session

House Bill No. 2862

Introduced by Representatives Ron P. Salo and Juan Fidel F. Nograles

AN ACT REGULATING ELECTRONIC CIGARETTES

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

SECTION 1. Short Title. - This Act shall be known as the "E-Cigarette Regulation Act of 2018".

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.

SEC. 3. Definitions. - As used in this Act, the following terms shall mean:

- a) "E-cigarette" refers to a product that can be used for the consumption of a nicotine-containing vapor;
- b) "Ingredient" means any substance that is added to the mixture and present in the finished product;
- c) "Nicotine" means nicotinic alkaloids, including any salt or complex of nicotine whether derived from tobacco or synthetically produced;
- d) "Nicotine mixture" means the nicotine-containing liquid, solid or other nontobacco substance in the product;
- e) "Refill container" means a container for holding nicotine mixture to refill certain e-cigarettes:

- f) "Emissions" means substances that are released when a product is consumed as intended, such as substances found in cigarette smoke, or the aerosol generated by an e-cigarette;
- g) "Package" shall refer to packs, boxes, cartons, or containers of any kind in which the electronic component of an e-cigarette is offered for sale to consumers;
- "Nicotine container" shall refer to bottles, boxes, cartons, or containers of any kind in which a nicotine-containing product is offered for sale to consumers for use with an e-cigarette product system;
- "Producer" shall refer to any location at which an individual can purchase or otherwise obtain e-cigarette products;
- j) "Principal display surface" shall refer to the panel of the nicotine container that faces the consumer when displayed for sale;
- k) "Advertising" shall refer to the business of conceptualizing, present, 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 e-cigarette advertising; and
- I) "Vaping" shall refer to the act of using an e-cigarette.
- SEC. 4. Health Warnings. Only nicotine containers shall bear textual health warnings with the following warning: "This product may damage your health and is addictive."

The health warning shall occupy 30% of the lower part of the principal display surface of the nicotine container. No other health warning shall be required for e cigarette products.

- SEC. 5. Minimum Age Sales and Purchase. The following acts shall be prohibited:
 - a) The sale, distribution, or transfer of e-cigarettes by any person to minors (anyone below 18 years old);
 - b) Purchasing, or otherwise receiving e-cigarettes from a minor;
 - c) The sale, purchase, and use of e-cigarettes by minors.

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 minor. 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 the minor to whom it was sold.

- SEC. 6. Retailer Signage. Producer establishments offering, distributing, or selling e-cigarettes to consumers shall post the following statement in a clear and conspicuous manner: "SALE/DISTRIBUTION TO OR PURCHASE BY MINORS OF E-CIGARETTES IS UNLAWFUL" or "IT IS UNLAWFUL FOR E-CIGARETTES TO BE SOLD/DISTRIBUTED TO OR PURCHASED BY PERSONS UNDER 18 YEARS OF AGE".
- SEC. 7. Proof of Age Verification. Retailers shall ascertain that no individual purchasing an e-cigarette is below eighteen (18) years of age.
- SEC. 8. Product Communication Restrictions. Advertisements shall be allowed in retailer establishment, through direct marketing, and on the Internet. These shall not be aimed at or particularly appeal to persons under eighteen (18) years of age. These should not undermine quit smoking messages and encourage non-tobacco or nicotine users to use the product. These should not contain any information that is untrue or not scientifically substantiated, in particular with regards to product characteristics, health effects, risks or emissions.
- **SEC. 9. Restrictions on Advertisement in Print Media.** Advertising and other promotional communications of e-cigarettes shall be permitted so long as the publication is not intended for minors and generally has an adult readership or subscriber base.
- SEC. 10. Public Place Use. Use of e-cigarettes indoors is prohibited in schools, hospitals, government offices, and facilities intended particularly for minors. In all other enclosed places open to the general public, e-cigarette use shall be allowed, provided that the owner of such places shall post the following statement in a clear manner at every entrance point of such places: "USE OF E CIGARETTES IS ALLOWED INSIDE." For places that do not allow e-cigarette use indoors, the owner of such places shall post the following statement at every entrance: "NO VAPING INSIDE."
- **SEC. 11. Product Standard Requirements.** The following shall be required for all e-cigarettes sold in the Philippines:
 - a) E-cigarette tanks shall have a capacity of no more than 5ml;
 - The maximum volume of nicotine-containing e-liquid for sale in one refill container shall be limited to 30ml;
 - c) E-liquids shall have a nicotine strength of no more than 20mg/ml;
 - d) Nicotine containers shall be child-resistant and tamper evident;

- e) Producers of electrical devices intended to be used in combination with an
 e-cigarette shall ensure that such devices comply with applicable electrical
 safety standards as may be determined by the Bureau of Product Standards
 of the Department of Trade and Industry
- Batteries must comply with applicable industry requirements as may be determined by the Bureau of Product Standards of the Department of Trade and Industry
- g) All ingredients in the product 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;
- A full list of ingredients in the flavoring must be included in notifications through the DTI;
- Packs shall include an information leaflet about safe use of the product. This shall also include appropriate advice on product storage, particularly on how ensure the battery does not malfunction; and
- j) All e-cigarettes and e-liquids shall be notified to the Department of Trade and Industry before they can be sold in the market.
- SEC. 12. Market Placing. Producers and distributors must comply with the following:
 - a) Producers must submit information about their products to the DTI;
 - b) Retailers do not need to submit information for any products they sell unless they also qualify as a producer. Retailers shall have six (6) months from the date of effectivity of this Act to sell through stock of products that do not comply with the labeling and product composition requirements of this Act;
 - c) This Act shall not cover nicotine-containing products that are authorized as medicines and those that have health claims; d. Producers shall have six months to register their products with the DTI and submit information demonstrating compliance with product standards and assessment requirements.
- **SEC. 13. Penalties for Noncompliance.** The following penalties shall individually apply to producers, importers, distributors, and sellers of e-cigarettes as well as their agents for any violation of this Act:

- a) On the first offense, a fine of not more than FIFTY THOUSAND PESOS (Php 50,000.00);
- b) On the second offense, a fine of not more than ONE HUNDRED THOUSAND (PhP 100,000.00); and
- c) On the third offense, a fine of not more than FIVE HUNDRED THOUSAND PESOS (PhP 500,000.00) 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 on cancelled.

Non-compliant e-cigarettes found in the market for sale or distribution shall be subject to confiscation.

If the guilty officer is a foreign national, he 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. 14. Implementing Rules and Regulations. Within three (3) months from the date of effectivity of this Act, the DTI shall issue the implementing rules and regulations for this Act. The non-issuance of the IRR will not suspend the effectivity of this Act of the introduction of new e-cigarettes in the market.
- SEC. 15. Separability Clause. Should any provision herein be declared unconstitutional, the same shall not affect the validity of the other provisions of this Act.
- SEC. 16. Repealing Clause. All laws, decrees, orders, rules, and regulations or other issuances or parts inconsistent with the provisions of this Act are hereby repealed, amended, or modified accordingly.
- SEC. 17. Effectivity Clause. This Act shall take effect in fifteen (15) days after publication in the Official Gazette or in one (1) newspaper of general circulation in the Philippines.

Approved.