

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

SIXTEENTH CONGRESS
Second Regular Session

House Bill No. **5580**



Introduced by Magdalo Party-List Representatives
Hon. Francisco Ashley L. Acedillo and Hon. Gary C. Alejano

EXPLANATORY NOTE

Republic Act No. 9211 or the "Tobacco Regulation Act of 2003" was signed into law on June 2003. The law aims to "protect the populace from hazardous products and promote the right to health", and "instill health consciousness among them". Said Act effectively regulates the package, use, sale, distribution, and advertisement of tobacco products. It also provided for the prohibition of smoking in public places.

The passage of RA 9211 serves as a benchmark in implementing a stricter tobacco control initiative in the country. The stricter implementation on tobacco control plus the imposition of higher taxes in tobacco products paved the way for electronic cigarettes (e-cigs) to gain popularity especially among the youth.

Electronic Nicotine Delivery System (ENDS) or more popularly known as e-cigarettes are devices commonly made of plastic or metal that heats a liquid nicotine solution (e-juice) in a disposable cartridge while creating a tiny light on the tip that glows like a real cigarette and produces a vapour that stimulates the act of smoking. E-cigarettes have been promoted as a safer alternative to traditional cigarettes and aids an individual to quit smoking.

Without formal studies on its real health effects on the user, a need for the government to regulate its sale and promotion arises. This measure therefore aims to regulate the sale and use of ENDS by amending various sections of RA 9211 or the "Tobacco Regulation Act of 2003" to effectively regulate the use of e-cigarettes.

In view of the foregoing, immediate approval of this bill is earnestly requested.


HON. FRANCISCO ASHLEY L. ACEDILLO


HON. GARY C. ALEJANO

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AN ACT
AMENDING REPUBLIC ACT NO. 9211 OTHERWISE KNOWN AS “AN ACT
REGULATING THE PACKAGING, USE, SALE, DISTRIBUTION AND
ADVERTISEMENTS OF TOBACCO PRODUCTS AND FOR OTHER PURPOSES”

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

1 **SECTION 1. Title.** This Act shall be known as the “Enhanced Tobacco Regulation Act
2 of 2014”.

3
4 **SEC. 2.** Section 2 of Republic Act No. 9211 otherwise known as the “Tobacco
5 Regulation Act of 2003” is hereby amended to read as follows:

6
7 “Section 2. *Policy* - it is the policy of the State to protect the populace
8 from hazardous products and promote the right to health and instill health
9 consciousness among them. It is also the policy of the State, consistent with the
10 Constitutional ideal to promote the general welfare, to safeguard the Interests of
11 the workers and other stakeholders in the tobacco industry. For these purposes,
12 the government shall institute a balanced policy whereby the use, sale, and
13 advertisements of tobacco **AND OTHER NICOTINE-CONTAINING** products
14 shall be regulated in order to promote a healthful environment and protect the
15 citizens from the hazards of tobacco smoke **AND NICOTINE USE**, and at the
16 same time ensure that the interest of tobacco farmers, growers, workers and
17 stakeholders are not adversely compromised.”

18
19 **SEC. 3.** Section 3 of the same law is hereby amended to read as follows:

20 “Section 3. *Purpose* - It is the main thrust of this Act to:

21 a) Promote a healthful environment;

1 b) Inform the public of the health risks associated with cigarette
2 smoking and tobacco use, **INCLUDING “ROLL-YOUR-OWN” TOBACCO,**
3 **AND NOVEL TOBACCO PRODUCTS;**

4 c) Regulate and subsequently ban all tobacco advertisements and
5 sponsorships;

6 d) Regulate the labeling of tobacco products;

7 e) Protect the youth from being initiated to cigarette smoking and
8 tobacco use by prohibiting the sale of tobacco products to minors;

9 f) Assists and encourage Filipino tobacco farmers to cultivate
10 alternative agricultural crops to prevent economic dislocation; and

11 g) Create an Inter-Agency Committee on Tobacco (IAC-Tobacco) to
12 oversee the implementation of the provision of this Act.

13 **h) EMPOWER THE FOOD AND DRUG ADMINISTRATION**
14 **TO REGULATE THE MANUFACTURE, IMPORTATION,**
15 **DISTRIBUTION, PROMOTION AND USE OF ELECTRONIC NICOTINE**
16 **DELIVERY SYSTEMS (ENDS).**

17
18 **IN ORDER TO CARRY OUT ITS REGULATORY TASKS, THE**
19 **STATE MUST REQUIRE COMPREHENSIVE INFORMATION ON THE**
20 **INGREDIENTS AND EMISSIONS FROM TOBACCO AND NICOTINE-**
21 **CONTAINING PRODUCTS TO ASSESS THE ATTRACTIVENESS,**
22 **ADDICTIVENESS AND TOXICITY OF TOBACCO PRODUCTS AND**
23 **THE HEALTH RISKS ASSOCIATED WITH THE CONSUMPTION OF**
24 **SUCH PRODUCTS. TO THIS END, THE REPORTING OBLIGATIONS**
25 **FOR INGREDIENTS AND EMISSIONS SHALL BE ESTABLISHED.**
26 **ADDITIONAL ENHANCED REPORTING OBLIGATIONS SHOULD BE**
27 **PROVIDED FOR IN RESPECT OF ADDITIVES INCLUDED IN A**
28 **PRIORITY LIST ISSUED BY THE IAC-TOBACCO IN ORDER TO**
29 **ASSESS THEIR TOXICITY, ADDICTIVENESS AND CARCINOGENIC,**
30 **MUTAGENIC OR REPROTOXIC PROPERTIES (‘CMR PROPERTIES’),**
31 **INCLUDING IN COMBUSTED FORM. THE BURDEN OF SUCH**
32 **ENHANCED REPORTING OBLIGATIONS FOR MICRO, SMALL, AND**
33 **MEDIUM ENTERPRISES (MSMES) SHOULD BE LIMITED TO THE**
34 **EXTENT POSSIBLE. SUCH REPORTING OBLIGATIONS SHALL BE**
35 **CONSISTENT WITH THE OBLIGATION PLACED ON THE STATE**
36 **UNDER EXISTING LAWS AND WITHIN THE FRAMEWORK OF THE**
37 **WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL**

1 **(‘FCTC’) OF 2003 - TO ENSURE A HIGH LEVEL OF PROTECTION**
2 **FOR HUMAN HEALTH.**

3
4 **SEC. 4.** Section 4 of the said law is hereby amended to read as follows:

5
6 “Section 4. Definition of Terms - As used in this Act:

7 a. "Advertisement" - refers to any visual and/or audible message
8 disseminated to the public about or on a particular product that promote and give
9 publicity by words, designs, images or any other means through broadcasts,
10 electronic, print or whatever form of mass media, including outdoor
11 advertisements, such as but no limited to signs and billboards. For the purpose of
12 this Act, advertisement shall be understood as tobacco advertisement.

13 b. "Advertising" - refers to the business of conceptualizing, presenting,
14 making available and communicating to the public, through any form of mass
15 media, any fact, data or information about the attributes, features, quality or
16 availability of consumers products, services or credit.

17 For the purpose of this Act, advertising shall be understood as tobacco
18 advertising. This shall specifically refer to any messages and images promoting
19 smoking; the purchase or use of cigarette or tobacco trademarks brand names,
20 design and manufacturer's names;

21 c. "Advertiser" - refers to a person or entity on whose account of for
22 whom an advertisement is prepared and disseminated by the advertising agency,
23 which is service established and operated for the purpose of counseling or
24 creating and producing and/or implementing advertising program in various forms
25 of media;

26 d. "Cigarette" - refers to any roll or tubular construction, which contains
27 tobacco or its derivatives and is intended to be burned or heated under ordinary
28 conditions of use;

29 e. "Distributor" - refers to any person to whom a tobacco product is
30 delivered or sold for purposes of distribution in commerce, except that such terms
31 does not include a manufacturer or retailer or common carrier of such product;

32 **F. “E-CIGARETTE” – REFERS TO A COMMON TYPE OF**
33 **ELECTRONIC NICOTINE DELIVERY SYSTEM THAT DELIVERS AN**
34 **AEROSOL BY HEATING A SOLUTION THAT USERS INHALE WHICH,**
35 **IN ADDITION TO NICOTINE WHEN NICOTINE IS PRESENT, ALSO**
36 **CONTAIN PROPYLENE GLYCOL (WITH OR WITHOUT GLYCEROL)**
37 **AND FLAVORING AGENTS, ARE SHAPED TO LOOK LIKE THEIR**
38 **CONVENTIONAL TOBACCO COUNTERPARTS (E.G. CIGARETTES,**

1 CIGARS, CIGARILLOS, PIPES, OR HOOKAHS), BUT ALSO TAKE THE
2 FORM OF EVERYDAY ITEMS SUCH AS PENS, USB MEMORY
3 STICKS, AND LARGER CYLINDRICAL OR RECTANGULAR
4 DEVICES, ETC.

5 [f.]G. "Mass Media" - refers to any medium of communication designed
6 to reach a mass of people. For this purposes, mass media includes print media
7 such as, but not limited to, newspapers, magazines, and publications; broadcast
8 media such as, but not limited to, radio, television, cable television, and cinema;
9 electronic media such as but not limited to the internet;

10 [g.]H. "Minor" - refers to any person below eighteen (18) years old;

11 [h.]I. "Manufacturer" - refers to any person entity, including a re-packer,
12 who makes, fabricates, assembles, processes, or labels a finished product;

13 J. "NICOTINE"—THE TERM "NICOTINE" MEANS THE
14 CHEMICAL SUBSTANCE NAMED 3-(1-METHYL-2-PYRROLIDINYL)
15 PYRIDINE OR C[10]H[14]N[2], INCLUDING ANY SALT OR COMPLEX
16 OF NICOTINE.

17 [i.]K. "Package" - refers to pack, boxes, cartons or containers of any kind
18 in which any tobacco product is offered for sale to consumers;

19 [j.]L "Persons" - refers to an individual, partnership, corporation or any
20 other business or legal entity;

21 [k.]M. "Point-of-sale" - refers to any location at which an individual can
22 purchase or otherwise obtain tobacco OR NICOTINE-CONTAINING products;

23 [l.]N. "Promotions" - refers to an event or activity organized by or on
24 behalf of a tobacco manufacturer, distributor or retailer with the aim of promoting
25 a brand of tobacco product, which event or activity would not occur but for the
26 support given to it by or on behalf of the tobacco manufacturer's name, trademark,
27 logo, etc. on non-tobacco products. This includes the paid use of tobacco products
28 bearing the brand names, tradenames, logos, etc. In movies, television and other
29 forms of entertainment. For the purpose of this Act, promotion shall be
30 understood as tobacco promotion;

31 [m.]O. "Public Conveyance" - refers to mode of transportation servicing
32 the general population such as, but not limited to, elevators, airplanes, buses,
33 taxicabs, ships, jeepneys, light rail transits, tricycles, and similar vehicles;

34 [n.]P. "Public Places" - refer to enclose or confined areas of all hospitals,
35 medical clinics, schools, public transportation terminals and offices, and building
36 such as private and public offices, recreational places, shopping malls, movie
37 houses, hotels, restaurants, and the like'

1 **Q. "ROLL-YOUR-OWN TOBACCO" — THE TERM "ROLL-**
2 **YOUR-OWN TOBACCO" MEANS ANY TOBACCO PRODUCT WHICH,**
3 **BECAUSE OF ITS APPEARANCE, TYPE, PACKAGING, OR**
4 **LABELING, IS SUITABLE FOR USE AND LIKELY TO BE OFFERED**
5 **TO, OR PURCHASED BY, CONSUMERS AS TOBACCO FOR MAKING**
6 **CIGARETTES;**

7 [o.]R. "Retailer" - refers to any person who or entity that sells tobacco
8 products to individuals for personal consumption;

9 [p.]S. "Smoking" - refers to the act of carrying a lighted cigarette or other
10 tobacco products, whether or not it is being inhale or smoked;

11 [q.]T. "Sponsorship" - refers to any public or private contribution to a
12 third party in relation to an event, team or activity made with the aim of
13 promoting a brand of tobacco product, which event, team or activity would still
14 exist or occur without such contribution. For the purpose of this Act, sponsorship
15 shall be understood as tobacco sponsorship;

16 [r.]U. "Tobacco" - refers to agricultural components derived from the
17 tobacco plant, which are processed for use in the manufacturing of cigarettes and
18 other tobacco products;

19 [s.]V. "Tobacco Products" - refers to any product that consists of loose
20 tobacco that contains nicotine and is intended for use in a cigarette, including any
21 product containing tobacco and intended smoking or oral or nasal use. Unless
22 stated otherwise, the requirements of this Act pertaining to cigarettes shall apply
23 to other tobacco **AND NICOTINE-CONTAINING** products;

24 [t.]W. "Tobacco Grower" - refers to any person who plants tobacco before
25 the enactment of this Act and classified as such by the National Tobacco
26 Administration (NTA); and

27 [u.]X. "Warning" - refers to the notice printed on the tobacco product or
28 its container and/or displayed in print or alert in broadcast or electronic media
29 including outdoor advertising and which shall bear information on the hazard of
30 tobacco use;

31
32 **SEC. 5.** Section 7 of the same law is hereby amended to read as follows:

33 "Section 7. Vending Machines, Self-Service Facilities - unless the vending
34 machine has a mechanism for age verification, the sale or distribution of tobacco
35 **OR NICOTINE-CONTAINING** products to minors by means of a vending
36 machine or any self-service facility or similar contraption or device is prohibited,
37 except at point-of-sale establishments **WHERE THERE IS "FACE-TO-FACE"**
38 **CONTACT."**

1
2 **SEC. 6.** Section 9 of the said law is hereby amended to read as follows:

3 “Section 9. *Minimum Age Sales* - Under this Act, It shall be unlawful:

4 a. For any retailer of tobacco products to sell or distribute tobacco **AND**
5 **OTHER NICOTINE-CONTAINING** products to any minor;

6 b. For any person to purchase cigarettes, [or] tobacco **AND OTHER**
7 **NICOTINE-CONTAINING** products from a minor;

8 c. For a minor to sell or buy cigarettes or any tobacco **AND OTHER**
9 **NICOTINE-CONTAINING** products; and

10 d. For a minor to smoke cigarettes, [or any other] tobacco **AND OTHER**
11 **NICOTINE-CONTAINING** products.

12 It shall not be a defense for the person selling or distributing that he/she
13 did not know or was aware of the real age of the minor. Neither shall it be a
14 defense that he/she did not know nor had any reason to believe that the cigarette
15 or [any other] tobacco **AND OTHER NICOTINE-CONTAINING** product was
16 for the consumption of the minor to whom it was sold.”

17
18 **SEC. 7.** Section 10 of the said law is hereby amended to read as follows:

19
20 “Section 10. *Sale of Tobacco AND OTHER NICOTINE-CONTAINING*
21 *Products Within School Perimeters* - The sale or distribution of tobacco **AND**
22 **OTHER NICOTINE-CONTAINING** products is prohibited within one hundred
23 (100) meters from any point of the perimeter of a school, public playground or
24 other facility frequented particularly by minors.”

25
26 **SEC. 8.** Section 11 of the said law is hereby amended to read as follows:

27
28 “Section 11. Signage - Point-of-Sale establishments offering, distributing
29 or selling tobacco products to consumers, shall post the following statement in a
30 clear and conspicuous manner: "SALE/DISTRIBUTION TO OUR PURCHASE
31 BY MINORS OF TOBACCO **AND OTHER NICOTINE-CONTAINING**
32 **PRODUCTS IS UNLAWFUL**" or " IT IS LAWFUL FOR TOBACCO
33 **PRODUCTS AND OTHER NICOTINE-CONTAINING TO BE**
34 **SOLD/DISTRIBUTED TO OR PURCHASED BY PERSONS UNDER 18**
35 **YEARS OF AGE**.”

1 **SEC. 9.** Section 12 of the same measure is hereby amended to read as follows:

2
3 “Section 12. Proof Of Age Verification - In case of doubt as to the age of
4 the buyer, retailers shall verify, by means of any valid from of photographic
5 identification containing the date of birth of the bearer, that no individual
6 purchasing a tobacco **OR OTHER NICOTINE-CONTAINING PRODUCT** is
7 below eighteen (18) years of age.”

8
9 **SEC. 10.** Section 13 of the same measure is hereby amended to read as follows:

10
11 “Section 13. Warning On Cigarette **AND E-CIGARETTE** Packages -
12 Under this Act:

13 a. All packages in which tobacco **AND OTHER NICOTINE-**
14 **CONTAINING** products are provided to consumers withdrawn from the
15 manufacturing facility of all manufacturers or imported into the Philippines
16 intended for sale to the market, starting 1 January 2004 JANUARY 1, 2015, shall
17 be printed, in either English or Filipino, on a rotating basis or separately and
18 simultaneously, the following health warnings:

19 “GOVERNMENT WARNING: Cigarette Smoking is Dangerous to your
20 Health;”

21 “GOVERNMENT WARNING; Cigarettes are Addictive”;

22 [“GOVERNMENT WARNING; Tobacco Can harm your Children”];

23 [“GOVERNMENT WARNING; Smoking Kills;”]

24 **“GOVERNMENT WARNING; NICOTINE IS HARMFUL TO**
25 **YOUR HEALTH”;**

26 **“GOVERNMENT WARNING; SMOKING CAUSES 9 OUT OF 10**
27 **LUNG CANCERS”**

28 **“GOVERNMENT WARNING; SMOKING CAUSES MOUTH AND**
29 **THROAT CANCER”**

30 **“GOVERNMENT WARNING; SMOKING DAMAGES YOUR**
31 **LUNGS”**

32 **“GOVERNMENT WARNING; SMOKING CAUSES HEART**
33 **ATTACKS”**

34 **“GOVERNMENT WARNING; SMOKING CAUSES STROKES**
35 **AND DISABILITY”**

36 **“GOVERNMENT WARNING; SMOKING CLOGS YOUR**
37 **ARTERIES”**

1 **“GOVERNMENT WARNING; SMOKING INCREASES THE RISK**
2 **OF BLINDNESS”**

3 **“GOVERNMENT WARNING; SMOKING DAMAGES YOUR**
4 **TEETH AND GUMS”**

5 **“GOVERNMENT WARNING; SMOKING CAN KILL YOUR**
6 **UNBORN CHILD”**

7 **“GOVERNMENT WARNING; YOUR SMOKE HARMS YOUR**
8 **CHILDREN, FAMILY AND FRIENDS”**

9 **“GOVERNMENT WARNING; SMOKERS' CHILDREN ARE**
10 **MORE LIKELY TO START SMOKING”**

11 **“GOVERNMENT WARNING; QUIT SMOKING – STAY ALIVE**
12 **FOR THOSE CLOSE TO YOU”**

13 **“GOVERNMENT WARNING; SMOKING REDUCES**
14 **FERTILITY”**

15 **“GOVERNMENT WARNING; SMOKING INCREASES THE RISK**
16 **OF IMPOTENCE”**

17
18 b. Upon effectivity of this Act until 30June 2006, the health warning shall
19 be located on one side panel of every tobacco product package and occupy not
20 less than fifty percent (50%) of such side panel including any border of frame.

21
22 c. Beginning 1 July 2006, the health warning shall be on the bottom
23 portion of one (1) front panel of every tobacco product package and occupy not
24 less than thirty percent (30%) of such panel including any border or frame. The
25 text of the warning shall appear in clearly legible type in black text on a white
26 background with a black border and in contrasts by typography; layout or color to
27 the other printer materials on the package. The health warning shall occupy a total
28 area of less than fifty percent (50%) of the total warning frame.

29
30 d. The warning shall be rotated periodically, or separately and
31 simultaneously printed, so that within any [twenty-four (24)] **SIXTY-FOUR (64)**
32 month period, the [four (4)] **SIXTEEN (16)** variations of the warnings shall
33 appear with proportionate frequency.

34
35 e. The warning shall not be hidden or obscured by other printed
36 information or images, or printed in a location where tax or fiscal stamps are
37 likely to be applied to the package or placed in a location where it will be
38 damaged when the package is opened. If the warning to be printed on the package

1 is likely to be obscured or obliterated by a wrapper on the package, the warning
2 must be printed on both the wrapper and the package.

3
4 f. In addition to the health warning all packages of tobacco **AND OTHER**
5 **NICOTINE-CONTAINING** products that are provided to consumers shall
6 contain, on one side panel the following statement in a clear, legible and
7 conspicuous manner; "NO SALE TO MINORS" or "NOT FOR SALE TO
8 MINORS." The statement shall occupied an area of not less than ten percent
9 (10%) of such side panel and shall appear in contrast by color, typography or
10 layout with all the other printed material on the side panel.

11
12 g. No other printed warnings, except the health warning and the message
13 required in this Section, paragraph F shall be placed on cigarette packages.”

14
15 **SEC. 11.** Section 14 of the same law is hereby amended to read as follows:

16
17 “Section 14. Warning On Advertising - Under this Act:

18 a. All tobacco **AND NICOTINE PRODUCT** advertising in mass media
19 shall contain either in English or Filipino, the following health warning;
20 "GOVERNMENT WARNING: Cigarette Smoking **AND NICOTINE USE** is
21 Dangerous to Your Health."

22 b. X X X

23 c. X X X

24 d. X X X”

25
26 **SEC.12.** Section 15 of the same law is hereby amended to read as follows:

27
28 “Section 15. Restrictions On Advertising - The following restrictions shall
29 apply to all tobacco advertising:

30 a. X X X

31 b. X X X

32 c. X X X

33 d. Advertisement shall not show, portray or depict scenes where the actual
34 use of, or the act of using, puffing or lighting cigarettes or other tobacco **AND**
35 **OTHER NICOTINE-CONTAINING** products is presented to the public.”

1 **SEC. 13.** Section 22 of the same law is hereby amended to read as follows:

2
3 “Section 22. Ban On Advertisements - Beginning 1 January [2007] 2015,
4 all tobacco **NICOTINE-CONTAINING PRODUCT** advertising on television,
5 cable television and radio shall be prohibited.

6 Beginning 1 July [2007] 2015, all cinema and outdoor advertising shall be
7 prohibited. No leaflets, posters and similar outdoor advertising materials be
8 posted, except inside the premises of point-of-sale retail establishments.

9 Beginning 1 July [2008] 2015, all forms of tobacco advertising in mass
10 media shall be prohibited except tobacco advertisements placed inside the
11 premises of point-of sale establishments.

12
13 **SEC. 14.** Section 23 of the same law is hereby amended to read as follows:

14
15 “Section 23. Restrictions on Tobacco **AND NICOTINE-CONTAINING**
16 **PRODUCT** Promotions - The following restrictions shall apply on all tobacco
17 promotions.

- 18 a. X X X
19 b. X X X
20 c. X X X
21 d. X X X
22 e. X X X
23 f. X X X
24 g. X X X
25 h. X X X
26 i. X X X”

27
28 **SEC. 15.** Section 29 of the same law is hereby amended to read as follows:

29
30 “Section 29. Implementing Agency. - An Inter-Agency Committee-
31 Tobacco (IAC-Tobacco), which shall have the exclusive power and function to
32 administer and implement the provisions of this Act, is hereby created. The IAC-
33 Tobacco shall be chaired by the Secretary of the Department of Trade and
34 Industry (DTI) with the Secretary of the Department of Health (DOH) as Vice
35 Chairperson. The IAC-Tobacco shall have the following members:

- 36 a. Secretary of the Department of Agriculture (DA);
37 b. Secretary of the Department of Justice (DOJ);

1 c. Secretary of the Department of Environment and Natural Resources
2 (DENR);

3 d. Secretary of the Department of Science and Technology (DOST);

4 e. Secretary of the Department of Education (DepEd);

5 f. Administrator of the National Tobacco Administration (NTA);

6 g. **DIRECTOR GENERAL OF THE FOOD AND DRUG**
7 **ADMINISTRATION;**

8 h. A representative from the Tobacco Industry to be nominated by the
9 legitimate and recognized associations of the industry; and

10 I. A representative from a nongovernment organization (NGO) involved in
11 public health promotion nominated by DOH in consultation with the concerned
12 NGO's;

13 The Department Secretaries may designate their Undersecretaries as their
14 authorized representatives to the IAC.”

15
16 **SEC. 16.** Section 30 of the same law is hereby amended to read as follows:
17

18 **“Section 30. *Application to Tobacco Products*** - This provision of this Act
19 shall apply to all tobacco products placed into commerce in the Philippines.

20 **ALL TOBACCO PRODUCTS HAVE THE POTENTIAL TO**
21 **CAUSE MORTALITY, MORBIDITY AND DISABILITY, THEREFORE,**
22 **THEIR MANUFACTURE, DISTRIBUTION AND CONSUMPTION**
23 **SHOULD BE REGULATED. HENCE, IT IS IMPORTANT TO MONITOR**
24 **DEVELOPMENTS AS REGARDS NOVEL TOBACCO PRODUCTS.**
25 **MANUFACTURERS AND IMPORTERS MUST THEREFORE SUBMIT A**
26 **NOTIFICATION OF NOVEL TOBACCO PRODUCTS, WITHOUT**
27 **PREJUDICE TO THE POWER OF THE STATE TO BAN OR TO**
28 **AUTHORIZE SUCH NOVEL PRODUCTS.**

29 **THE STATE SHALL PROHIBIT THE PLACING ON THE**
30 **MARKET OF TOBACCO PRODUCTS WITH A CHARACTERIZING**
31 **FLAVOR. HOWEVER, IT SHALL NOT PROHIBIT THE USE OF**
32 **ADDITIVES WHICH ARE ESSENTIAL FOR THE MANUFACTURE OF**
33 **TOBACCO PRODUCTS, FOR EXAMPLE, SUGAR TO REPLACE**
34 **SUGAR THAT IS LOST DURING THE CURING PROCESS, PROVIDED**
35 **THOSE ADDITIVES DO NOT RESULT IN A PRODUCT WITH A**
36 **CHARACTERIZING FLAVOR AND DO NOT INCREASE TO A**
37 **SIGNIFICANT OR MEASUREABLE DEGREE THE ADDICTIVENESS,**
38 **TOXICITY OR THE CARCINOGENIC, MUTAGENIC OR**
39 **REPROTOXIC (CMR) PROPERTIES OF THE TOBACCO OR**
40 **NICOTINE-CONTAINING PRODUCT.**

1 Except as provided below, no provision of this Act shall apply to tobacco
2 products intended or offered by the manufacturer for export and not for (retail)
3 sale in the Philippines.

4 Tobacco products intended or offered for export shall be subject only to
5 the requirement that the shipping container shall be prominently marked on the
6 outside "Export Only": Provided, that tobacco products which are marked for
7 export, but are sold/traded or distributed in the Philippine market, shall be subject
8 to immediate confiscation and destruction.

9 **THE FDA SHALL ESTABLISH MAXIMUM LIMITS FOR TAR,**
10 **NICOTINE AND CARBON MONOXIDE YIELDS OF CIGARETTES**
11 **THAT SHOULD ALSO BE APPLICABLE TO CIGARETTES WHICH**
12 **ARE EXPORTED FROM THE PHILIPPINES. FOR MEASURING THE**
13 **TAR, NICOTINE AND CARBON MONOXIDE YIELDS OF**
14 **CIGARETTES (REFERRED TO AS 'EMISSION LEVELS'), REFERENCE**
15 **SHOULD BE MADE TO THE RELEVANT, INTERNATIONALLY-**
16 **RECOGNIZED ISO STANDARDS. THE VERIFICATION PROCESS**
17 **SHOULD BE PROTECTED FROM TOBACCO INDUSTRY INFLUENCE**
18 **BY USING INDEPENDENT LABORATORIES, INCLUDING**
19 **GOVERNMENT LABORATORIES. THE FDA SHOULD BE ABLE TO**
20 **USE LABORATORIES SITUATED IN OTHER COUNTRIES. FOR**
21 **OTHER EMISSIONS FROM TOBACCO PRODUCTS WHERE THERE**
22 **ARE NO INTERNATIONALLY AGREED STANDARDS OR TESTS FOR**
23 **QUANTIFYING MAXIMUM LEVELS, THE STATE SHALL MONITOR**
24 **ONGOING EFFORTS AT INTERNATIONAL LEVEL TO DEVELOP**
25 **SUCH STANDARDS OR TESTS SHOULD BE ENCOURAGED.**

26 **AS REGARDS ESTABLISHING MAXIMUM EMISSION LEVELS,**
27 **IT COULD BE NECESSARY AND APPROPRIATE AT A LATER DATE**
28 **TO REDUCE THE EMISSION LEVELS FOR TAR, NICOTINE AND**
29 **CARBON MONOXIDE OR TO ESTABLISH MAXIMUM LEVELS FOR**
30 **OTHER EMISSIONS FROM TOBACCO PRODUCTS, TAKING INTO**
31 **CONSIDERATION THEIR TOXICITY OR ADDICTIVENESS."**

32
33 **SEC. 16.** A new section is hereby inserted under the same law to be designated as
34 Section 30-A, to read as follows:

35 **"SECTION 30-A. E-CIGARETTES. - THE FOOD AND DRUG**
36 **ADMINISTRATION (FDA) SHALL ENSURE THAT ELECTRONIC**
37 **CIGARETTES AND REFILL CONTAINERS COMPLY WITH THE**
38 **REQUIREMENTS OF THIS ACT. WHERE THE MANUFACTURER OF**

1 THE RELEVANT PRODUCT IS NOT ESTABLISHED IN THE
2 PHILIPPINES, THE IMPORTER OF THAT PRODUCT SHOULD BEAR
3 THE RESPONSIBILITIES RELATING TO THE COMPLIANCE OF
4 THOSE PRODUCTS WITH THIS ACT.

5 MANUFACTURERS AND IMPORTERS OF ELECTRONIC
6 CIGARETTES AND REFILL CONTAINERS SHALL SUBMIT A
7 NOTIFICATION TO THE FDA (FOR REGULATION PURPOSES) AND
8 THE DTI (FOR COMMERCIAL PURPOSES) OF ANY SUCH
9 PRODUCTS WHICH THEY INTEND TO PLACE ON THE MARKET.
10 THE NOTIFICATION SHALL BE SUBMITTED IN ELECTRONIC
11 FORM SIX MONTHS BEFORE THE INTENDED PLACING ON THE
12 MARKET. FOR ELECTRONIC CIGARETTES AND REFILL
13 CONTAINERS ALREADY PLACED ON THE MARKET BEFORE THE
14 EFFECTIVITY OF THIS PROVISION, THE NOTIFICATION SHALL BE
15 SUBMITTED WITHIN SIX MONTHS OF THAT DATE. A NEW
16 NOTIFICATION SHALL BE SUBMITTED FOR EACH SUBSTANTIAL
17 MODIFICATION OF THE PRODUCT. THE NOTIFICATION SHALL,
18 DEPENDING ON WHETHER THE PRODUCT IS AN ELECTRONIC
19 CIGARETTE OR A REFILL CONTAINER, CONTAIN THE
20 FOLLOWING INFORMATION:

21 (A) THE NAME AND CONTACT DETAILS OF THE
22 MANUFACTURER, A RESPONSIBLE LEGAL OR NATURAL PERSON
23 WITHIN THE PHILIPPINES, AND, IF APPLICABLE, THE IMPORTER
24 INTO THE PHILIPPINES;

25 (B) A LIST OF ALL INGREDIENTS CONTAINED IN, AND
26 EMISSIONS RESULTING FROM THE USE OF, THE PRODUCT, BY
27 BRAND NAME AND TYPE, INCLUDING QUANTITIES THEREOF;

28 (C) TOXICOLOGICAL DATA REGARDING THE PRODUCT'S
29 INGREDIENTS AND EMISSIONS, INCLUDING WHEN HEATED,
30 REFERRING IN PARTICULAR TO THEIR EFFECTS ON THE HEALTH
31 OF CONSUMERS WHEN INHALED AND TAKING INTO ACCOUNT,
32 INTER ALIA, ANY ADDICTIVE EFFECT;

33 (D) INFORMATION ON THE NICOTINE DOSES AND UPTAKE
34 WHEN CONSUMED UNDER NORMAL OR REASONABLY
35 FORESEEABLE CONDITIONS;

36 (E) A DESCRIPTION OF THE COMPONENTS OF THE
37 PRODUCT; INCLUDING, WHERE APPLICABLE, THE OPENING AND

1 REFILL MECHANISM OF THE ELECTRONIC CIGARETTE OR
2 REFILL CONTAINERS;

3 (F) A DESCRIPTION OF THE PRODUCTION PROCESS,
4 INCLUDING WHETHER IT INVOLVES SERIES PRODUCTION, AND A
5 DECLARATION THAT THE PRODUCTION PROCESS ENSURES
6 CONFORMITY WITH THE REQUIREMENTS OF THIS ARTICLE;

7 (G) A DECLARATION THAT THE MANUFACTURER AND
8 IMPORTER BEAR FULL RESPONSIBILITY FOR THE QUALITY AND
9 SAFETY OF THE PRODUCT, WHEN PLACED ON THE MARKET AND
10 USED UNDER NORMAL OR REASONABLY FORESEEABLE
11 CONDITIONS.

12 NICOTINE-CONTAINING LIQUID SHOULD ONLY BE
13 ALLOWED TO BE PLACED ON THE MARKET WHERE THE
14 NICOTINE CONCENTRATION DOES NOT EXCEED 20 MG/ML. THIS
15 CONCENTRATION ALLOWS FOR A DELIVERY OF NICOTINE THAT
16 IS COMPARABLE TO THE PERMITTED DOSE OF NICOTINE
17 DERIVED FROM A STANDARD CIGARETTE DURING THE TIME
18 NEEDED TO SMOKE SUCH A CIGARETTE. IN ORDER TO LIMIT THE
19 RISKS ASSOCIATED WITH NICOTINE, MAXIMUM SIZES FOR
20 REFILL CONTAINERS, TANKS AND CARTRIDGES SHOULD BE SET
21 BY THE FDA.

22 ONLY E-CIGARETTES THAT DELIVER NICOTINE DOSES AT
23 CONSISTENT LEVELS SHOULD BE ALLOWED TO BE PLACED ON
24 THE MARKET UNDER THIS ACT. DELIVERY OF NICOTINE DOSES
25 AT CONSISTENT LEVELS UNDER NORMAL CONDITIONS OF USE IS
26 NECESSARY FOR HEALTH PROTECTION, SAFETY AND QUALITY
27 PURPOSES, INCLUDING TO AVOID THE RISK OF ACCIDENTAL
28 CONSUMPTION OF HIGH DOSES.

29 E-CIGARETTES AND REFILL CONTAINERS COULD CREATE
30 A HEALTH RISK WHEN IN THE HANDS OF CHILDREN.
31 THEREFORE, IT IS NECESSARY TO ENSURE THAT SUCH
32 PRODUCTS ARE CHILD- AND TAMPERPROOF, INCLUDING BY
33 MEANS OF CHILD-PROOF LABELLING, FASTENINGS AND
34 OPENING MECHANISMS.”

35
36 **SEC. 17. *Sunset Review.*** – As the need arises or within five (5) years after its effectivity,
37 the Congressional Oversight Committee shall conduct a sunset review of this Act. The term
38 “Sunset Review” shall mean a systematic evaluation of the accomplishments and impact of this

1 Act as well as the performance and organizational structures of the implementing agencies, for
2 purpose of determining remedial legislation.

3
4 **SEC. 18. *Separability Clause.*** – If any provisions of this Act shall be held
5 unconstitutional or invalid, the other provisions not otherwise affected shall remain in full force
6 and effect.

7
8 **SEC. 19. *Repealing Clause.*** – All laws, executive orders, rules and regulation
9 inconsistent with or contrary to this Act, are hereby deemed accordingly repealed or amended.

10
11 **SEC. 20. *Effectivity Clause.*** - This act shall take effect after fifteen (15) days from its
12 publication in at least two (2) newspaper of national circulation.

Approved,