

E-CIGARETTES: COMMON REGULATORY AND DRAFTING ISSUES



Governments have taken different approaches to regulate or ban the retail sale of e-cigarettes (also known as Electronic Nicotine Delivery Systems (ENDS)).

This resource concentrates on common regulatory and drafting issues that arise when e-cigarettes are regulated under existing tobacco control laws and, to a lesser extent, when the products are regulated under a separate regulatory regime. In both instances, it is critical to ensure that lawsⁱ regulating e-cigarettes are fully in line with the WHO Framework Convention on Tobacco Control (WHO FCTC). This means that governments need to take into account provisions in the implementing guidelines of the WHO FCTC and decisions taken by the Conference of the Parties to the WHO FCTC¹ related to e-cigarettes.^{2,3}

Recommendations on how WHO FCTC measures should be applied to e-cigarettes are contained in **E-Cigarettes: Global Regulation and Recommended Measures.**

In addition to determining a regulatory approach, countries must also specify in their laws which products are subject to regulation. Electronic non-nicotine delivery systems (ENNDS) share characteristics with e-cigarettes (for example, both use a device to heat a liquid which produces an aerosol for inhaling). Although ENNDS are marketed as nicotine-free, ENNDS should be subject to the same strong regulatory measures as e-cigarettes.⁴

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i. In this document, the terms “laws,” “legislation,” and “legal measures” are used interchangeably and include legislation, regulations, decrees, resolutions, and any other enactments that have legal force and effect.

Common Regulatory and Drafting Issues include:

1. TITLE AND SCOPE

Whether e-cigarettes are included in the title and objectives of the law.

2. REGULATION OF ENNDS

Whether the law specifically regulates ENNDS.

3. DEFINITIONS

- a. Whether the definition of “tobacco products” in the law is broad enough to apply to e-cigarette devices and liquids.
- b. Whether devices and liquids should be defined separately.
- c. Whether the public use of e-cigarettes/ENNDS falls within the definition of “smoke” or “smoking” in existing laws.

4. SPECIFIC ISSUES TO CONSIDER WHEN THE SALE OF E-CIGARETTES AND/OR ENNDS IS BANNED:

If the sale of e-cigarettes/ENNDS is banned, whether existing or newly developed laws explicitly prohibit the public use of e-cigarettes/ENNDS and advertising, promotion, and sponsorship of the products.

The Campaign for Tobacco-Free Kids’ International Legal Consortium (ILC) has developed a [Template for Effective Tobacco Control Legislation](#), which includes one set of drafting solutions to ensure all e-cigarette components

are effectively covered by relevant WHO FCTC measuresⁱⁱ and addresses these common regulatory issues. Other possible drafting solutions are shown by way of country examples in this resource.

ii. The Legislation Template does not include provisions relating to taxation or illicit trade.

1. TITLE AND SCOPE

ISSUE

Whether e-cigarettes are included in the title and objectives of the law.

SOLUTION

Typically, when developing new legal measures regulating e-cigarettes, drafters will incorporate e-cigarettes specifically into the title and objectives of the measure. However, **when amending laws to regulate e-cigarettes under an existing tobacco control regime, the long title of the law and the objectives should include e-cigarettes to effectively implement the provisions and assist in any judicial interpretation of the measures in the event of a legal challenge.**

The WHO FCTC requires Parties to “adopt and implement effective legislative, executive, administrative and/or other measures...for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.”⁵ Countries that regulate e-cigarettes in their tobacco control legislation should ensure that the law’s title includes e-cigarettes. The objectives of the legislation should include to 1) prevent e-cigarette use by non-smokers, particularly youth; 2) minimize potential health risks to e-cigarette users and non-users; 3) prevent e-cigarettes from undermining progress in reducing tobacco consumption and nicotine addiction; 4) protect public health policy from the commercial interests of the tobacco and e-cigarette industries; and 5) assist smokers to quit and avoid use of multiple tobacco and nicotine products.

COUNTRY EXAMPLE

Canada

When Canada amended its tobacco control legislation to regulate e-cigarettes, both the title and purpose were updated to incorporate e-cigarettes. As such, the short title of the Tobacco Act was amended to the *Tobacco and Vaping Products Act (TVPA)*.⁶ Further, Section 4 of the TVPA details the act’s purpose generally and as it applies to tobacco and vaping products.

Additionally, “vaping product” is defined to include “a substance or mixture of substances, whether or not it contains nicotine, that is intended for use with those devices to produce emissions” (Section 2). Therefore, the act also regulates ENDS, and the title and purpose of the TVPA reflect this.

2. REGULATION OF ENNDS

ISSUE

Whether the law specifically regulates ENNDS.

SOLUTION

Countries should ensure that their laws also regulate ENNDS.

As stated by the WHO, while ENNDS “should not contain nicotine, in practice many e-liquids marked as containing ‘zero-nicotine’ have been found to contain nicotine when tested.”⁷ Also, users can add nicotine to e-liquids that are formulated as nicotine free.⁷ As a result, it is difficult to distinguish between e-cigarettes and ENNDS, which can create challenges for regulators

and enforcement authorities. There is additional evidence supporting regulating ENNDS, including possible long-term health impacts caused by inhaling e-liquids with harmful and potentially harmful constituents and creating a behavior pattern mimicking conventional cigarette smoking.⁷ Therefore, countries should regulate ENNDS in the same manner as e-cigarettes. This can be done by drafting an e-cigarette definition that does not refer to nicotine content or consumption (e.g, New Zealand) or by inserting a separate definition of ENNDS and applying the relevant measures to this product category (e.g, Costa Rica).

COUNTRY EXAMPLES

New Zealand

The Smokefree Environments and Regulated Products Act 1990 (as amended)⁸ defines “vaping substance” as:

“Vaping substance”

(a) means a substance or mixture of substances that is intended to be vaporised or aerosolised with a vaping device; but

(b) does not include a medicinal cannabis product within the meaning of regulation 4 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 or a CBD product within the meaning of section 2A of the Misuse of Drugs Act 1975; and

(c) does not include a heated tobacco product. (Section 2)

Non-nicotine substances are encompassed by the definition of “vaping substances” because it does not require nicotine content. Thus, the definition of “vaping substances” includes e-cigarettes and ENNDS liquids, and both e-cigarettes and ENNDS are regulated by the law.

Costa Rica

Law No. 10066⁹ defines ENNDS separately from nicotine-containing e-cigarettes:

“Electronic non-nicotine delivery system (ENNDS)”: electronic devices or equipment for heating the liquid formulation, without nicotine, which generates an aerosol or vapor that can be inhaled. (Article 2(b))

The law then ensures that relevant provisions apply to both e-cigarettes and ENNDS, including prohibiting use in specified places (Article 3), sales to minors (Article 3), and taxation (Article 4).

3. DEFINITIONS

ISSUE

Whether the definition of “tobacco products” in the law is broad enough to apply to e-cigarette devices and liquids.

The WHO FCTC definition of “tobacco products” refers to products containing tobacco which are manufactured

to be used for “smoking, sucking, chewing or snuffing.”¹⁰ As e-cigarettes do not contain tobacco, the products are typically excluded from laws using the WHO FCTC definition of “tobacco products.” Therefore, e-cigarettes will likely fall outside of tobacco control regulatory regimes in the absence of government action to ensure their coverage.

SOLUTION

Whether amending legislation or developing new measures, an effective way to ensure that tobacco control measures apply to e-cigarettes is to incorporate e-cigarettes into the definition of “tobacco products.”

However, if this approach is taken, careful consideration should be given to those provisions (such as content regulations and nicotine concentration levels) that may apply differently to e-cigarettes than to conventional tobacco products. Also, countries should be mindful of whether defining e-cigarettes as a tobacco product

allows for future product regulation, such as a product’s use of different heating sources, alternative substances containing nicotine and methods of consumption, and/or the development of hybrid products.ⁱⁱⁱ Thus, the definition should be broad enough to cover all existing products containing nicotine, all devices used to consume them, and all new nicotine products/devices.

Alternatively, as discussed below, e-cigarette components may be defined separately from “tobacco products.” The same considerations about future product regulation also exist if this route is taken.

COUNTRY EXAMPLE

Bolivia

Law No. 1280¹¹ defines e-cigarettes as tobacco products. The definitions of “tobacco products” and “electronic nicotine delivery system” are:

“Tobacco products” mean products prepared in whole or in part from tobacco leaves as raw material and intended to be smoked, inhaled, chewed, aspirated, sucked, snorted or otherwise consumed, such as manufactured cigarettes, handmade, pipes, cigars, water pipe (narghile-shisha), bidi, roll-your-own, pipe tobacco, electronic nicotine delivery system, heated tobacco products, dry or wet snuff, and others. (Article 7(m))

“Electronic nicotine delivery system” means a product, or any of its components, including cartridges and the cartridge-free device, that can be used for the consumption of nicotine containing vapor through a mouthpiece. (Article 7(p))

As shown, the law defines e-cigarettes as “electronic nicotine delivery systems” and incorporates that term into the definition of “tobacco products.” By doing so, provisions of the law that regulate tobacco products also apply to e-cigarettes. This includes restrictions on advertising, promotion and sponsorship (Article 13) and point of sale product display (Article 12(d)), and health warning requirements (Article 11). However, the law does not regulate items that apply specifically to e-cigarettes, such as maximum nicotine levels and device requirements, nor does it regulate ENNDS.

iii. For example, Japan Tobacco International (JTI) markets Ploom TECH which “heats nicotine-free liquid to create a vapor that, as inhaled,

passes through the tobacco capsule to pick up tobacco flavor and nicotine.” See <https://www.jti.com/about-us/what-we-do/our-reduced-risk-products> (Accessed March 29, 2023).

3. DEFINITIONS

ISSUE

Whether devices and liquids should be defined separately.

SOLUTION

While some laws may include both “devices” and “liquids” (or variations, such as “refill containers” or “cartridges”) in the definition of “e-cigarettes,” it is advantageous to define “devices” and “nicotine products” individually and broadly to allow for tailored regulation and future product regulation (as discussed above).

This approach has several advantages:

1. It allows the definition of “nicotine products” to encompass oral nicotine products (such as nicotine pouches and lozenges) and other emerging products not licensed as cessation products.

Similarly, the definition of “devices” should not be limited to only products used to consume nicotine aerosols but other emissions too, including non-nicotine liquids.

2. By using separate definitions, regulations can be applied differently to each element. For instance, device regulations could address permitted tank sizes and safety features (e.g, child-resistant containers and battery safety), and nicotine product regulations could prescribe maximum nicotine concentration levels.

If devices and liquids are defined separately, a term can be designated to include both items together.

COUNTRY EXAMPLE

New Zealand

The Smokefree Environments and Regulated Products Act 1990 (as amended)⁵ has separate definitions for “vaping device” and “vaping substance.” The definitions are:

“Vaping device” means a device that—

- (a) vaporises or aerosolises a substance or a mixture of substances by heating it for the purpose of inhalation through a mouthpiece; and
- (b) is sold as a complete unit or to be assembled from individual components. (Section 2)

“Vaping substance”

- (a) means a substance or mixture of substances that is intended to be vaporised or aerosolised with a vaping device; but

- (b) does not include a medicinal cannabis product within the meaning of regulation 4 of the Misuse of Drugs (Medicinal Cannabis) Regulations 2019 or a CBD product within the meaning of section 2A of the Misuse of Drugs Act 1975; and

- (c) does not include a heated tobacco product. (Section 2)

Under the Act, both vaping devices and vaping substances are considered a “vaping product” (Section 2).

As discussed above, a vaping substance includes non-nicotine substances and, therefore, the law also regulates ENNDS. Further, as an example of how devices and liquids are regulated individually, the law provides specific requirements for vaping device safety (Section 80, Schedule 5, Part 2) and maximum nicotine concentration levels for vaping substances containing nicotine (Section 69).

3. DEFINITIONS

ISSUE

Whether the public use of e-cigarettes/ENNDS falls within the definition of “smoke” or “smoking” in existing laws.

Many laws use the definition of “smoking” contained in the WHO FCTC Article 8 Guidelines, which refers to being in possession or control of a “lit tobacco product.”¹² This definition does not encompass the use of e-cigarettes/ENNDS and, therefore, regulations addressing smoking in public places do not apply to e-cigarettes/ENNDS.

SOLUTION

Countries must take specific action to protect individuals from e-cigarette emissions, which typically contain nicotine and other toxic substances that are harmful to those who are exposed to the second-hand aerosols (SHA).¹³ Further, exposure to SHAs from ENNDS may also lead to adverse health effects.⁴

Countries should either:

1. Revise the definition of “smoking” in their tobacco control law to unequivocally apply smoking restrictions to e-cigarettes/ENNDS; or
2. Define e-cigarettes/ENNDS separately and ensure that the provisions prohibiting tobacco use in public places also apply to e-cigarettes/ENNDS.

Whichever approach is taken, at a minimum, the ban on e-cigarette/ENNDS use should apply in indoor public places, indoor workplaces, and on public transport.

COUNTRY EXAMPLES

Moldova

Law No. 278-XVI on Tobacco Control¹⁴ defines “smoking” in a manner that explicitly includes possession, control, and use of e-cigarettes:

“Smoking” means being in possession or in control of a lit tobacco product...or a related product, regardless of whether the smoke is being actively inhaled or exhaled. For the purposes of this Law, possession or control of an activated device for heating...a related product...regardless of whether the aerosol is being actively inhaled or exhaled, is considered smoking. (Article 2)

“Related products” are defined as “products made of plants for smoking and products which contain nicotine, including electronic cigarettes” (Article 2). Therefore, e-cigarette use is included in the definition of “smoking.” Further, Moldova has a comprehensive smoking ban which includes not only all indoor public places, workplaces, and public transport but also certain outdoor places and private vehicles when minors are present (Article 26). Yet, the smoking ban does not apply to ENNDS because they are not included in the definition of “related products.”

3. DEFINITIONS

COUNTRY EXAMPLES (CONTINUED)

Costa Rica

Law No. 10066⁷ prohibits the use of e-cigarettes and ENNDS in all indoor public places, indoor workplaces, and on public transport (Article 3).

Ukraine

Law No. 2899-IX,¹⁵ as amended by Law No. 1978-IX,¹⁶ prohibits the consumption and use of e-cigarettes and ENNDS in all places where smoking, consumption, and use of tobacco products is banned. This includes public transport and virtually all indoor public places and workplaces, with the exception of designated smoking areas in airports (Law No. 2899-IX, Article 13; Law No. 1978-IX, Section I.3(9)). As the law defines “electronic cigarette” as “a product that can be used to inhale aerosols (vapors) formed by heating by the components of such a product of liquids that contain or do not contain nicotine”, ENNDS are included in the smoking ban (Law No. 2899-IX, Article 1; Law No. 1978-IX, Section I.3(1)).

4. SPECIFIC ISSUES TO CONSIDER WHEN THE SALE OF E-CIGARETTES AND/OR ENNDS IS BANNED

ISSUE

If the manufacture, import, and/or sale of e-cigarettes/ENNDS is banned, whether existing or newly developed laws explicitly

prohibit the public use of e-cigarettes/ENNDS and advertising, promotion, and sponsorship of the products.

SOLUTION

Countries that prohibit the manufacture, import, and/or sale of e-cigarettes/ENNDS, or allow their sale only under a medicinal or pharmaceutical regime, should also take measures to ensure that there is a comprehensive ban on:

1. E-cigarette/ENNDS use in indoor public places, indoor workplaces, and on public transport;
2. Domestic and cross-border e-cigarette/ENNDS advertising, promotion, and sponsorship.

Even in countries where the manufacture, import, and/or sale of e-cigarettes is banned, products may be available under exceptions allowing import for personal use, on the illicit market, and/or as approved medicinal or pharmaceutical devices. Thus, it is important that provisions banning their use in public and domestic and cross-border advertising, promotion, and sponsorship are included in the law to protect against potential health risks from e-cigarette emissions, prevent uptake by non-smokers, and/or provide clarity to enforcement authorities.

COUNTRY EXAMPLE

Mauritius

The Public Health (Restrictions on Tobacco Products) Regulations 2022 (as amended)¹⁷ ban the manufacture, import, and sale of e-cigarettes and ENNDS (Articles 4(4)(c)-(d)).

In addition, the law comprehensively prohibits the use of e-cigarettes/ENNDS in indoor public places, indoor workplaces, and on public transport (Articles 2, 3(1), First Schedule), and bans e-cigarette/ENNDS advertising, promotion, and sponsorship (Articles 2, 6).

FURTHER DETAILS ON COUNTRIES' EXISTING LAWS REGULATING E-CIGARETTES ARE AVAILABLE AT WWW.TOBACCOCONTROLLAWS.ORG.

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