

Countries that Regulate Heated Tobacco Products December, 2020

The following summary is based on feedback from Ministry of Health and tobacco control policy experts in jurisdictions where we are tracking country-level e-cigarette policies. Information is current as of December, 2020 and is subject to change.

Policy summary by country

Australia

Heated tobacco products are banned.

Argentina

Heated tobacco products are not regulated.

Azerbaijan

Heated tobacco products are not regulated.

Bahrain

Heated tobacco products are not regulated.

Belgium

The EU Tobacco Products Directive (specifically Article 19 on novel tobacco products), is applied to heated tobacco products. Labeling and health warning regulations for heated tobacco products are the same as for cigarettes. Heated tobacco products are notified to the Belgian authorities 6 months before introduction in the market. So far, only one product (Heets) has been notified but is not yet on the market

In addition, Belgium taxes heated tobacco products under the classification "other smoking tobacco products".

Brunei Darussalam

Heated tobacco products are regulated as tobacco products, under Section 3 of the <u>Tobacco Order</u> which regulates any tobacco products that are intended, labeled or described as suitable for inhaling, chewing or any oral use other than smoking.

Cambodia

Heated tobacco products are not regulated under government circular No. 001/14 Sor.Nor.No.NACD.

Canada

Heated tobacco products are regulated as tobacco products under the <u>Tobacco and Vaping Products</u> <u>Act</u> (TVPA). As such, heated tobacco products are subject to the same restrictions as other tobacco products under the TVPA as well as subsequent tobacco product regulations issued under the TVPA, including, among others:

- A minimum sales age of 18;
- Labeling and packaging requirements, including plain packaging; health warnings; and a prohibition on the use of "light," "mild," or similar terms as well as any promotion via packaging that is false, misleading, or deceptive, or that is likely to create an erroneous impression about the characteristics, health effects or health hazards of the tobacco product or its emissions;
- Restrictions on advertising, promotion, and sponsorship;
- Restrictions on retail sales, including via vending machines, self-service displays, and online sales;
- Product standard requirements such as restrictions on additives with flavoring properties and coloring agents;
- Manufacturer and importer reporting requirements on a regular basis; and
- A near-complete prohibition on the use of heated tobacco products in federal government workplaces.

Heated tobacco products are also subject to a tobacco excise tax.

Colombia

Heated tobacco products are regulated as tobacco products under <u>Law No. 1335</u>. This includes a minimum sales age of 18; restrictions on advertising, promotion, and sponsorship, including a complete prohibition on advertising in all forms of media and promotion as contemplated by the WHO FCTC; packaging and labeling requirements, including health warnings and a prohibition on the use of misleading terms such as "light" and "low tar"; and a comprehensive prohibition on the use of heated tobacco products in public places and workplaces.

Heated tobacco products are taxed as conventional, combusted cigarettes.

Costa Rica

Heated tobacco products are regulated as tobacco products under the <u>General Law on Tobacco Control</u> <u>and its Harmful Effects on Health</u> (Ley General de Control del Tabaco y sus efectos nocivos en la salud or LGCT). Under the LGCT, importers and manufacturers must annually notify the Ministry of Health (MOH) with a statement of the ingredients and emissions of nicotine, tar, and carbon monoxide, as well as the methods of analysis used, for any tobacco products or derivatives that they commercialize in the country. Other regulations under the LGCT apply to heated tobacco products, including, among others:

- A minimum sales age of 18;
- Labeling and packaging requirements, including health warnings and a prohibition of the use of "low tar," "light," "ultra-light," "mild," "extra," "ultra," or similar less harmful, false, or misleading descriptors;
- A near-complete prohibition on advertising, promotion, and sponsorship;
- Restrictions on retail sales, including prohibiting vending machine, self-service display, and online sales as well as retail sales at certain locations (e.g. health establishments, educational institutions, etc.);
- A near-complete prohibition on the use of heated tobacco products in public places and workplaces; and
- Taxation

Cyprus

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), as transposed by the Health Protection (Tobacco Control) <u>Law</u> of 2017, is applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling.

Czech Republic

Heated tobacco products are taxed at a rate of CZK 2.46/g, per Act No. 353/2003.

Denmark

Although it should be covered under the <u>EU Tobacco Product Directive</u>, regulation of heated tobacco products is unclear.

Dominican Republic

Regulation of heated tobacco products is unclear.

Ecuador

Heated tobacco products are regulated the same as e-cigarettes and other tobacco products in accordance with Article 1 of the Tobacco Control (LORCT) Regulations. Heated tobacco is subject to a 150% Ad valorum tax.

England

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), is applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling. Heated tobacco products are notified to Public Health England (PHE) as the competent authority for tobacco products. So far, only two products (iQOS and IFuse) have been properly notified. The EU TPD was transposed to United Kingdom law via the Tobacco and Related Products Regulations. Heated tobacco products are not required to be sold in plain packaging.

Estonia

Heated tobacco products are regulated per the EU Tobacco Products Directive (specifically Article 19 on novel tobacco products). There are provisions on reporting/notifications and health warning labelling. Heated tobacco products are taxes at the same rate as smoking tobacco per the <u>Alcohol Tobacco, Fuel, and Electricity Excise Duty Act.</u>

Fiji

Heated tobacco products are regulated in the same way that e-cigarettes are. See <u>link</u> for summary on Fiji's e-cigarette regulation.

Finland

Heated tobacco products are not regulated.

France

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), is applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling. Heated tobacco products are not required to be sold in plain packaging.

In addition, France taxes heated tobacco products under the classification "Autres tabacs à fumer" ("other smoking products").

Guatemala

Regulation of heated tobacco products is unclear.

Georgia

Use of heated tobacco products in public places and transportation is prohibited as is advertising and promotion of these products in accordance with the <u>Law of Georgia on Tobacco Control</u>.

Germany

Heated tobacco products are regulated and taxed like pipe tobacco. The sale and use of heated tobacco by minors (18 years or younger) is prohibited. Starting January 1, 2021, it is prohibited to advertise

heated tobacco products in cinemas, with the exception of films with age limit 18+. It is prohibited to distribute free samples outside "specialized shops" and hold promotional events.

Iceland

Heated tobacco products are not regulated.

Indonesia

Regulation of heated tobacco products is unclear.

Iran

Importation, production and sale of heated tobacco products is banned.

Ireland

Heated tobacco products must comply with existing tobacco control legislation, including the requirement that products sold shall be in plain and standardized packaging.

Israel

Heated tobacco products are regulated as tobacco products and are prohibited to be sold to persons under the age of 18. As a tobacco product, heated tobacco is required to be sold in plain and standardized packaging, per <u>Law 5743-1983</u>. The use of heated tobacco is prohibited in specific indoor public places, including government offices, hospitals, childcare facilities, and schools. The Finance Committee voted to enact and implement a new tax order for heated tobacco products, thereby taxing heated tobacco sticks (HEETS) the same as cigarettes.

Italy

Heated tobacco products may be regulated by <u>Law 188/2014</u> as smokeless tobacco products "tabacchi da inalazione senza combustion" ("tobacco product for inhalation without combustion"). Further, the <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), as transposed by Italian <u>law n.6/2016</u>, may be applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling depending on how they are classified (i.e. as novel tobacco products or smokeless tobacco).

Jamaica

Heated tobacco products are regulated as tobacco products in accordance with the <u>Public Health</u> (<u>Tobacco Control</u>) (<u>Amendment</u>) regulations 2014

Japan

Heated tobacco products are regulated by the <u>Health Promotion Act</u>, as amended. Because smoking is defined to include smoke/vapor from burned or heated tobacco, heated tobacco products should be

included in the smoking ban that the amendments stipulate. Smoking is completely banned in Type A facilities: schools, hospitals, children's facilities, government facilities, passenger cars and planes. However, in practice, use of heated tobacco products is allowed in Type B facilities (i.e. other public places including restaurants and passenger ships and trains). Heated tobacco products are currently taxed as pipe tobacco under the Tobacco Tax Act and sale to minors is restricted in accordance with Article 5 on the Act. Further, heated tobacco products are regulated by the Tobacco Business Act.

Lao

It is unclear whether heated tobacco products are not regulated under Notice No. 1297/PMO.

Luxembourg

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), is applied to heated tobacco products. Heated tobacco products are not authorized for sale.

Malaysia

Heated tobacco products are regulated under the <u>Control of Tobacco Product Regulation (Amendment)</u> <u>2015</u>, where smoking is defined as inhaling and expelling the smoke or vapor of any tobacco product and includes the holding of or control over any ignited, heated or vaporized tobacco product.

Maldives

Heated tobacco products are regulated as tobacco products (which is defined as any product that contains tobacco or its extracts in any form) in accordance with the <u>Tobacco Control Act</u> (Law 15/2010). The Tobacco Control Act requires tobacco products not previously sold in the Maldives or introduced to the Maldivian market to obtain approval from the Ministry of Health.

Sale to minors under 18 years is prohibited as is sale via vending machines, post, internet or automated service where age cannot be verified prior to purchase.

The law currently requires all tobacco products imported, manufactured or sold to carry text warnings covering a minimum of 30% of the surface area of the front and back of the pack/package. The five approved messages should be rotated periodically (rotational frequency not specified). Health warnings are also required to be placed at venues selling tobacco products as well as in designated smoking areas in eateries.

All forms of advertising, promotion and sponsorship are prohibited.

Use of heated tobacco products is prohibited where smoking is banned.

In accordance with <u>Act No. 31/79</u> (Export Import Act of Maldives), 200% of the cost, insurance and freight (CIF) value of tobacco products (other than cigarettes) and articles used in the consumption of tobacco products, are levied at the time of importation; further, a 6% goods and services tax (GST) is

levied at the time of sale. However, gadgets used in the consumption of heated tobacco products are taxed as electronic devices rather than as articles used for consumption of tobacco products.

Malta

Because heated tobacco products are being classified by manufacturers as smokeless tobacco products, they are subject to <u>Legal Notice 67</u> which bans the import, manufacture, sale, etc. of any smokeless tobacco product.

Mexico

Heated tobacco products are prohibited under Article 16(VI) of the <u>General Law on Tobacco Control</u> (Ley General para el Control del Tabaco or LGCT), which has been confirmed by <u>presidential decree</u> and statements by the Federal Commission for the Protection against Health Risks (Comisión Federal para la Protección contra Riesgos Sanitarios or COFEPRIS) in <u>February 2020</u> and COFEPRIS and the Ministry of Health in <u>September 2020</u>. However, the statements by COFEPRIS and the Ministry of Health also make clear that some prohibited products are legally commercialized under "amparo" court orders, which apply only to the party that won their case. It does not appear that any "amparo" court orders have been issued for heated tobacco products, and thus, they remain prohibited under the LGCT.

Moldova

Heated tobacco products are regulated as novel tobacco products and are regulated by the <u>Law on Tobacco Products</u>. Heated tobacco products are exempted from the tobacco legal provisions on presentation and promotion.

Nepal

Heated tobacco products are regulated as tobacco products and their use is defined as "consumption of a tobacco product" by <u>Tobacco Product (Control and Regulation) Act, 2010</u>.

The law prohibits advertising, promotion and sponsorship. Use in public places is prohibited. The law requires warning messages depicting harmful effects of tobacco products to be placed on the packaging.

Netherlands

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), is applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling. The sale of heated tobacco products is prohibited to persons 18 years or younger. Heated tobacco sticks must adhere to the same rules and regarding ingredients and emissions as traditional cigarettes. Heated tobacco products are included in the nation-wide indoor smoking ban that came into force on July 1, 2020. The advertising and sponsorship of heated tobacco products is prohibited, as well as their display. Heated tobacco sticks are subject to excise taxes. At present, heated tobacco is not covered under the new plain packaging regulations that went into October 1, 2020.

New Zealand

Heated tobacco products are regulated as tobacco and vaping products under the <u>Smokefree Environments and Regulated Products Act 1990</u> (SERPA), as amended by the <u>Smokefree Environments and Regulated Products (Vaping) Amendment Act 2020</u> (SERPVA Act) and the <u>Smokefree Environments (Prohibiting Smoking in Motor Vehicles Carrying Children) Amendment Act 2020</u> (Motor Vehicles Act).

The SERPVA Act was adopted in response to a 2018 District Court <u>decision</u> (*Ministry of Health v. Philip Morris (New Zealand) Limited*) that permitted the sale of heated tobacco products under the SERPA as it was previously named (Smokefree Environments Act 1990). The SERPVA Act came into force on November 11, 2020 with various provisions, including the Motor Vehicles Act, being <u>phased in</u> through February 11, 2022. Among the early provisions already in force that apply to heated tobacco products are a minimum sales age of 18; workplace use restrictions; and restrictions on advertising, sponsorship, and promotion. Additional product regulation and restrictions on the packaging and sale of heated tobacco products will be forthcoming, including limiting the sale of flavored products and prenotification requirements. However, health warnings for tobacco product packages are already required under the <u>Smoke-free Environments Regulations 2017</u>, and there is no exemption for heated tobacco products.

Heated tobacco products are <u>taxed</u> under the Customs and Excise Act 2018 under the category of "other manufactured tobacco."

Norway

Heated tobacco products are banned in Norway under <u>Regulations no. 1044 of 13 October 1989</u> <u>Concerning the Prohibition against New tobacco and Nicotine Products.</u>

Oman

Heated tobacco products are banned.

Pakistan

Regulation of heated tobacco products is unclear.

Palau

Regulation of heated tobacco products is unclear.

Panama

<u>Resolution no. 0953</u> of May 15, 2018 prohibits the sale of heated tobacco products, including of component parts intrinsic to heated tobacco products. It also prohibits use in places where smoking is prohibited.

Paraguay

Regulation of heated tobacco products is unclear.

Philippines

Heated tobacco sticks are taxes at 25 pesos/twenty pack/unit. The tax levied will increase by 2.50 peso/twenty pack/unit each year until 2023. From 2024 onward, a 5% tax increase will occur. Beginning 26 February, 2020, the importation of unregistered heated tobacco products is prohibited. The sale, distribution, or advertising of heated tobacco products within 100 meters of schools or venues designated for minors is prohibited.

Poland

Tax of 1141.29 Polish Zloty per kilogram and 31.41% of the weighted average retail selling price of smoking tobacco is applied to heated tobacco products.

Portugal

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), as transposed by <u>Law No. 37/2007</u> is applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling. Heated tobacco is subject to the tobacco excise tax. The tax rate applied is the same rate as for combustible tobacco (which includes fine-cut tobacco for rolling cigarettes and other smoking tobacco products). There is a 15% ad valorem tax and 0.080 euros/gram tax.

Romania

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), as transposed by <u>Law 201/2016</u> is applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling. The <u>Fiscal Code</u> regulates them under "non-harmonized excise" products. All the other regulations do not define/include them in any way. The tax structure is included in the applicable Fiscal Code, Title VIII, <u>non-harmonized excise taxes</u>.

Saudi Arabia

Heated tobacco products are not required to be sold in plain and standardized packaging.

Scotland

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), is applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling. Their composition must be notified to reference labs for approval and the products must comply with the Directive to be marketed. In UK and Scottish law these products cannot be advertised or promoted and cannot be displayed for sale – similar to cigarettes. Heated tobacco products are not required to be sold in plain packaging.

Senegal

Heated tobacco products are regulated as tobacco derivatives in accordance with <u>Law No. 2014-14</u> (Concerning the Manufacture, Packaging, Labeling, Sale and Use of Tobacco).

Seychelles

Heated tobacco products are regulated as tobacco products in accordance with the <u>Tobacco Control Act</u> 2009.

Singapore

Heated tobacco products are banned.

Slovenia

Heated tobacco products are regulated by the Law on <u>Restriction on the Use of Tobacco or Tobacco-related Products Act (OUTP)</u> as tobacco-related products. Heated tobacco is not required to be sold in plain and standardized packaging.

South Africa

Heated tobacco products are considered and regulated as tobacco products in accordance with the <u>Tobacco products Control Act 83 of 1993</u> (as amended).

South Korea

Heated tobacco products are regulated as tobacco products under the <u>Tobacco Business Act</u> (TBA) and <u>National Health Promotion Act</u> (NHPA).

Heated tobacco product manufacturers, wholesalers, and retailers must be licensed, and manufacturers must indicate on packaging the levels of tar and nicotine in the product. Graphic health warnings are also required on heated tobacco product packages. The minimum sales age for heated tobacco products is 19, and the retail sale of heated tobacco products is further limited by restrictions on online sales, via vending machines, and at certain locations (e.g. health-related establishments such as pharmacies and hospitals, youth-oriented locations such as arcades, and places restricted at the sub-national level). The use of heated tobacco products in public places is restricted in the same way as for smoking, which largely provides for separate smoking rooms. Sub-national restrictions on use are more restrictive in most areas. There are also limited advertising restrictions (e.g. use of the terms like "light," "mild," "low tar," or "genuine" that may mislead consumers about harm) for heated tobacco products, but legislation is pending to further restrict the promotion of all tobacco products, including heated tobacco products.

Heated tobacco products are also subject to several different taxes.

Spain

Heated tobacco products are regulated as novel tobacco products in accordance with <u>Royal Decree</u> <u>579/2017</u>, of June 9, 2017. Therefore, <u>Law 28/2005</u> (Sanitary Measures Against Smoking, and Regulating the Sale, Supply, Consumption and Advertising of Tobacco Products) which restricts the sale, advertising, promotion and sponsorship, and use in public places, also applies to heated tobacco products.

See Public Health Commission publication.

Sweden

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), as transposed by The Tobacco and Similar Products Act - Law (2018:2088) (chapter 2 § 3) is applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling. The Public Health Agency of Sweden has regulatory authority over these products; however, this authority has not been exerted.

Switzerland

Heated tobacco products are considered <u>tobacco</u> products, i.e. they can be marketed like other tobacco products, without being subject to a preliminary approval; however, the warnings and taxation do not correspond to those of cigarettes.

Tajikistan

Heated tobacco products are regulated as tobacco products in accordance with the <u>Law on Limiting the</u> <u>Use of Tobacco Products</u> which extends the definition of tobacco products to include electronic products that deliver nicotine.

Thailand

Heated tobacco products are classified as e-cigarettes according to the definition of e-cigarette under the Consumer Board Announcement and MOC Announcement. As such, their sale and importation are banned under existing regulations. See e-cigarette policy summary for Thailand.

Timor-Leste

Heated tobacco products are regulated by <u>Decree-Law N. º 14 /2016 of June 8 on the Tobacco Control Regime</u>, which places restriction on use in public places, as well as prohibits their sale and marketing.

Turkey

Heated tobacco products are tobacco products by definition and thus regulated under the <u>tobacco</u> <u>control law (Law on Prevention and Control of Hazards of Tobacco Products)</u>. Heated tobacco use is prohibited in most indoor workplaces and public spaces under the smoke-free law.

Turkmenistan

The <u>2013 Tobacco Control Law</u> defines tobacco products broadly to include heated tobacco products and are thus regulated as such. Heated tobacco products are subject to smoke-free provisions, including the prohibition of use in indoor public spaces and public transit, as well as parks, gardens, playgrounds, and other such communal outdoor spaces. The advertising and promotion of heated tobacco products are also prohibited.

United States

Heated tobacco products are regulated as tobacco products under the <u>Family Smoking Prevention and Tobacco Control Act</u> (TCA). All "new tobacco products" (i.e. those introduced into the U.S. market after February 15, 2007 or modified after that date) must obtain U.S. Food and Drug Administration (FDA) marketing authorization before they may be legally sold. While two sets of heated tobacco products have obtained FDA marketing authorization (Eclipse and IQOS), only one (IQOS) appears to be on the market.

In July 2020, IQOS obtained an "exposure modification" order from FDA, allowing it to be marketed as a "modified risk tobacco product" (MRTP) containing reduced levels of, and presenting reduced exposure to, harmful chemicals. However, the FDA's authorization of IQOS as an MRTP does not mean the products are "safe" or "FDA approved," and the exposure modification orders do not permit the company to make un-authorized modified-risk claims or any express or implied statements that convey or could mislead consumers into believing that the products are "safe" or "FDA approved."

Because IQOS meets the TCA and tax definitions of "cigarette," it is taxed and regulated as such. This means the minimum sales age is 21 and marketing, packaging, and other product requirements applicable to cigarettes apply to IQOS.

Finally, heated tobacco products are also regulated at the sub-national level by tribes, states, and local (e.g. city and county) jurisdictions.

Uruguay

Heated tobacco products are banned.

Viet Nam

There are no clear definitions of novel tobacco products, including heated tobacco products.

Wales

The <u>EU Tobacco Products Directive</u> (specifically Article 19 on novel tobacco products), is applied to heated tobacco products. There are provisions on reporting/notification and health warning labeling. Heated tobacco products are taxed at the same rate as hand rolled tobacco, which is currently at £234.79 per kilogram. A Value Added Tax of 20% of the retail price is also applied. Heated tobacco products are not required to be sold in plain packaging.