## Draft Act on Tobacco-free Nicotine-containing Products

The following is hereby laid down.

Aim and content of the Act

**Section 1**    This Act aims to limit the health risks and nuisance associated with the use of tobacco-free nicotine-containing products.

**Section 2**    This Act contains provisions on product notification, product requirements, sales and marketing of tobacco-free nicotine-containing products.

Definitions used in this Act

**Section 3**    For the purposes of this Act, the following definitions shall apply:

1. *tobacco-free nicotine-containing product*: a product without tobacco containing nicotine for human consumption;

2. *retail*: sales to consumers;

3. *point of sale*: a physical point of sale or a retail website;

4. *physical point of sale*: specific premises or other delimited space for retail.

Relation to other laws

**Section 4**    This Act shall not apply to:

1. products covered by the Act (2018:2088) on Tobacco and Similar Products;

2. products classified as narcotics under the Narcotic Drugs Punishment Act (1968:64) or as products that are harmful to health under the Act (1999:42) banning certain products that are harmful to health;

3. medicinal products or medical devices covered by the Medicines Act (2015:315) or the Act (2021:600) with supplementary provisions to the EU Regulation on medical devices.

Product notification

**Section 5**    Manufacturers and importers shall notify the Public Health Agency of Sweden of all tobacco-free nicotine-containing products they intend to make available to consumers on the market. A new notification shall be submitted for any substantial modification to the product. The notification shall be submitted no later than six months before the product is intended to be made available to consumers on the market. Notification must also be made when the manufacturer or importer withdraws the product from the market.

Tobacco-free nicotine-containing products may not be made available to consumers on the market unless such notification has been made. The same shall apply if the notification does not comply with the product notification regulations issued pursuant to Section 48(1).

Product requirements

**Section 6**    Manufacturers and importers of tobacco-free nicotine-containing products are responsible for ensuring that the products comply with the requirements laid down in the regulations on content and design issued pursuant to Section 48(2).

Non-compliant tobacco-free nicotine-containing products may not be made available to consumers on the market.

Labelling

**Section 7**    Packages of tobacco-free nicotine-containing products must bear a declaration of contents and text indicating the harmful effects of nicotine (health warning).

Manufacturers and importers of tobacco-free nicotine-containing products are responsible for ensuring that the packaging complies with the first paragraph.

In the event that packaging is non-compliant, the product may not be made available to consumers on the market. The same shall apply if the declaration of contents or health warning does not comply with the regulations on content and design issued pursuant to Section 48(3) and (4).

**Section 8**    The labelling on tobacco-free nicotine-containing products or on the packaging of such products may not:

1. suggest that a particular tobacco-free nicotine-containing product is less harmful than other such products; or

2. resemble a foodstuff or cosmetic product.

Marketing

**Section 9**    When marketing tobacco-free nicotine-containing products to consumers, particular moderation shall be observed. Advertising or other marketing measures may not be insistent, demanding or encourage the use of tobacco-free nicotine-containing products.

Reference to the taste of the product may only be made if justified by the consumer’s need for product information.

Marketing may not be specifically aimed at or depict children or young people under the age of 25.

**Section 10**    A health warning must be clearly displayed when marketing tobacco-free nicotine-containing products to consumers through commercial advertisements in:

1. periodicals or other comparable publications to which the Freedom of the Press Regulations apply;

2. other printed matter to which the Freedom of the Press Regulations apply; or

3. information society services.

If there are several health warnings, at least one of them must be displayed. In the case of repeated advertising, the different health warnings must be used interchangeably and, where possible, to the same extent.

Point 2 of the first paragraph shall not apply to marketing within physical points of sale.

**Section 11**    It is prohibited to market tobacco-free nicotine-containing products to consumers through commercial advertising on broadcast TV, on-demand TV or radio broadcasts.

Providers of video-sharing platforms may not provide the advertising referred to in the first paragraph above during or after user-generated videos or TV programmes on that platform.

**Section 12**    Manufacturers, wholesalers and importers may not sponsor events or activities to which the public has access if the sponsorship promotes tobacco-free nicotine-containing products.

Provisions prohibiting sponsorship on TV, radio and on video-sharing platforms and product placement on TV and on video-sharing platforms are laid down in the Radio and Television Act (2010:696).

**Section 13**    For the purposes of applying Sections 5, 23 and 26 of the Marketing Act (2008:486), a marketing measure which is contrary to any one of Sections 8-11 and Section 12, first paragraph, shall be considered unfair to consumers. A marketing measure contrary to Section 11 may give rise to a market disruption fine in accordance with the provisions of Sections 29-36 of the Marketing Act.

Reporting obligation

**Section 14**    Manufacturers and importers of tobacco-free nicotine-containing products shall submit to the Public Health Agency each year:

1. full details of sales volumes; and

2. details of preferences among different consumer groups, including children or young people under the age of 25.

Tobacco-free nicotine-containing products may not be made available to consumers on the market if the reporting obligation resulting from the first paragraph or from regulations issued pursuant to Section 48(5) has not been fulfilled.

Product monitoring

**Section 15**    Manufacturers, importers and distributors of tobacco-free nicotine-containing products shall establish and maintain a system to collect information on any suspected adverse effects of these products on human health.

Upon request, that information shall be provided to the Public Health Agency.

**Section 16**    If a manufacturer, importer or distributor of tobacco-free nicotine-containing products considers, or has reason to believe, that such a product is not safe or of good quality or that it otherwise does not comply with this Act or with related regulations, it shall immediately:

1. take the corrective action necessary to bring the product concerned into conformity with this Act;

2. withdraw the product; or

3. recall the product.

When action in accordance with the first paragraph is taken, the Public Health Agency must immediately be informed of the product’s shortcomings, the corrective action taken and the results of such corrective action.

Notification of sale

**Section 17**    A trader may not engage in retail in tobacco-free nicotine-containing products without prior notification of the sale.

A trader who has its registered office or permanent establishment for business purposes in Sweden shall notify the municipality where the physical point of sale is located. In the absence of a physical point of sale, the notification must be made to the municipality in which the company has its registered office or, in the absence of a registered office in the country, to the municipality in which the company has a permanent establishment.

If the trader does not have a registered office or permanent establishment for business purposes in Sweden, the notification must be made to the Public Health Authority.

Self-monitoring

**Section 18**    Retailers of tobacco-free nicotine-containing products shall exercise self-monitoring with respect to sales and other handling of tobacco-free nicotine-containing products and ensure that there is an appropriate self-monitoring programme for the business.

The notification of sales in accordance with Section 17 must be accompanied by the self-monitoring programme and the other information needed for supervision by the municipality and the Public Health Authority. Any change to such information must be notified to the municipality or the Public Health Agency without delay.

Age requirements

**Section 19**    Tobacco-free nicotine-containing products may not be sold or otherwise supplied in the course of trade to persons under the age of 18. Persons supplying such products shall ensure that the recipient has reached this age.

If there is specific reason to assume that products are intended to be given to someone who is not at least 18 years of age, they must not be supplied.

At points of sale, there must be a clear and visible notice informing of the ban on selling or supplying tobacco-free nicotine-containing products to persons under the age of 18.

**Section 20**    Tobacco-free nicotine-containing products sold to consumers must be made available in such a way that it is possible to check the age of the recipient. This shall also apply where the sale takes place through a vending machine, by means of distance selling or in a similar way.

**Section 21**    Tobacco-free nicotine-containing products may only be brought into the country by those who have reached the age of 18.

Regulatory control

**Section 22**    The Public Health Authority is responsible for supervisory guidance regarding supervision by the municipality under Section 24, first paragraph, points 1-4 and supervision by the municipality and the Police Authority under Section 25.

The Consumer Agency is responsible for supervisory guidance regarding supervision by the municipality under Section 24, second paragraph.

**Section 23**    The county administrative board exercises supervision within the county under Sections 24 and 25. Supervision includes:

1. monitoring the municipalities’ activities and assisting the municipalities by providing information and advice; and

2. promoting cooperation between different supervisory authorities and between supervisory authorities and others.

**Section 24**    The municipality shall exercise supervision of physical points of sale to ensure that this Act and related regulations are followed in respect of:

1. the product notification under Section 5;

2. product requirements under Section 6;

3. the declaration of contents, health warning and labelling under Sections 7 and 8; and

4. the reporting obligation under Section 14.

The municipality shall also exercise supervision of or in connection with physical points of sale to ensure that this Act and related regulations are followed in respect of marketing under Sections 9 and 10.

**Section 25**    The municipality and the Police Authority shall exercise supervision to ensure this Act and the related regulations are followed in respect of:

1. notification of sales and self-monitoring under Sections 17 and 18 when the trader has a registered office or a permanent establishment for business purposes in Sweden; and

2. age requirements under Sections 19 and 20.

**Section 26**    The Public Health Agency shall exercise supervision to ensure this Act and related regulations are followed in respect of:

1. product notification, product requirements, reporting obligation and product monitoring under Sections 5, 6 and 14-16, in cases other than those referred to in Section 24, first paragraph;

2. the declaration of contents, health warning and labelling under Sections 7 and 8, in cases other than those referred to in Section 24, first paragraph; and

3. notification of sales and self-monitoring under Sections 17 and 18 where the trader does not have a registered office or permanent establishment for business purposes in Sweden.

**Section 27**    The Consumer Agency shall exercise supervision to ensure this Act and related regulations are followed in respect of marketing under Sections 9-11 and 12, first paragraph, in cases other than those referred to in Section 24, second paragraph.

The Consumer Agency’s supervision is subject to the provisions of the Marketing Act (2008:486).

Powers

**Section 28**    A supervisory authority referred to in Sections 24-26 may, in its supervisory activities, impose the injunctions or prohibitions necessary for compliance with this Act and its related regulations.

**Section 29**    In the event of serious or repeated infringements of this Act, the municipality may prohibit the retailer of tobacco-free nicotine-containing products from continuing the sale or, if such prohibition is considered to be an excessive measure, issue a warning. The municipality’s decision shall apply with immediate effect, unless otherwise stated in the decision.

A prohibition may be issued for a period not exceeding six months.

**Section 30**    If the Public Health Authority finds or has reasonable grounds to believe that a type of or specific tobacco-free nicotine-containing product may pose a serious risk to human health despite the fact that the product complies with this Act, it may prohibit the products from being made available to consumers on the market.

Where such products have been made available to consumers on the market, the Public Health Authority may order the manufacturer, importer or distributor of the products to withdraw or recall them.

**Section 31**    Decisions under Sections 28 and 30 may be subject to a fine. The fine may not be converted into a prison sentence.

Right to information and access

**Section 32**    A supervisory authority may, upon request, obtain the information, documents, samples and the like necessary for supervision by the authority under this Act.

**Section 33**    In order to fulfil its duties under this Act, a supervisory authority has the right to gain access to areas, premises and other spaces affected by this Act or related regulations and may carry out investigations and take samples there. No compensation will be paid for samples taken.

**Section 34**    The Police Authority shall, upon request by another supervisory authority, provide the assistance required in the application of Section 33.

A request pursuant to the first paragraph may be made only if:

1. on the basis of special circumstances, there are concerns that the measure cannot be carried out without resorting to a police officer’s special powers under Section 10 of the Police Act (1984:387); or

2. there are some other exceptional reasons.

Mutual provision of information

**Section 35**    The municipality and the Police Authority shall inform one another of circumstances relevant to supervision.

A municipality which has taken a decision in a matter under this Act shall send a copy of the decision to the Public Health Agency, the Police Authority and the county administrative board that is affected by the decision.

**Section 36**    The municipalities shall inform the Public Health Agency if they become aware of anything that may be of importance to supervision by the Public Health Agency.

Control purchases

**Section 37**    A municipality may carry out control purchases in order to provide a basis for dialogue between the municipality and the supplier of tobacco-free nicotine-containing products on the obligation to ensure that the recipient has reached the age of 18. For such purchases, the municipality may only use persons who have reached the age of 18.

Control purchases may be carried out without the trader being given any prior notification of the control purchase. The municipality shall notify the trader of the control purchase as soon as possible once the control purchase has been carried out.

**Section 38**    The findings of control purchases may not constitute grounds for the municipality to issue an injunction, prohibition or warning under Sections 28 or 29.

Professional secrecy

**Section 39**    A person who has become involved with some matter under this Act must not, without authorisation, disclose or otherwise take advantage of what he or she has learned in this way regarding trade secrets or business conditions.

In public administration, the provisions of the Public Access to Information and Secrecy Act (2009:400) shall apply.

Fees

**Section 40**    A municipality may charge fees for its supervision of persons engaged in sales requiring notification pursuant to Section 17.

**Section 41**    The Public Health Agency may charge fees to manufacturers and importers of tobacco-free nicotine-containing products for receiving, storing, handling, analysing and publishing the information submitted to the authority under Section 5.

The Public Health Agency may charge fees to manufacturers and importers for receiving, storing, handling and analysing the information submitted to the authority under Section 14 and for publishing that the reporting obligation has been fulfilled.

The Public Health Agency may charge fees for its supervision of persons engaged in sales requiring notification under Section 17.

Appeals

**Section 42**    Appeals against decisions under this Act or related regulations may be lodged with a general administrative court.

Leave to appeal is required, when appealing to the Administrative Court of Appeal.

Penalties and forfeiture

**Section 43**    Anyone who intentionally provides consumers with tobacco-free nicotine-containing products that do not meet the requirements concerning declarations of content or health warnings in breach of Section 7 third paragraph shall be sentenced to a fine or imprisonment of up to six months for *unauthorised handling of tobacco-free nicotine-containing products*.

If the act is minor, it shall not give rise to liability.

**Section 44**    Anyone who intentionally sells tobacco-free nicotine-containing products in breach of a prohibition imposed pursuant to Section 29 shall be sentenced to a fine or imprisonment of up to six months for *unauthorised sale of tobacco-free nicotine-containing products*.

If the act is minor, it shall not give rise to liability.

**Section 45**    Anyone who, intentionally or negligently, engages in retail in tobacco-free nicotine-containing products in breach of Section 17 or sells or supplies tobacco-free nicotine-containing products in breach of Section 19, first or second paragraphs, shall be sentenced to a fine or imprisonment of up to six months.

If the act is minor, it shall not give rise to liability.

**Section 46**    Anyone who has violated an injunction or a prohibition with a fine attached shall not be sentenced under this Act for the act(s) covered by the injunction or prohibition.

**Section 47**    Tobacco-free nicotine-containing products which have been the subject of an offence under this Act or their value and proceeds from such an offence shall be forfeited, unless it is manifestly unreasonable.

Authorisations

**Section 48**    The government or the authority appointed by the government may issue regulations on:

1. the product notification under Section 5;

2. the product contents and the design of tobacco-free nicotine-containing products under Section 6;

3. the content and design of the declaration of contents under Section 7;

4. how a health warning is to be designed and displayed under Sections 7 and 10;

5. the performance of the reporting obligation under Section 14;

6. the information collection system under Section 15;

7. the obligation to inform under Section 16, second paragraph;

8. the design of self-monitoring programmes under Section 18;

9. the implementation of control purchases under Section 37; and

10. the amount of the fees under Section 41.

1. This Act shall enter into force on 1 January 2023 as regards Sections 6-8, 10, 15 and 43, on 1 January 2024 as regards Sections 5 and 14, and otherwise on 1 August 2022.

2. Tobacco-free nicotine-containing products manufactured or released for free circulation before 1 January 2023, which do not comply with the product requirements under Section 6 or labelling requirements under Sections 7 and 8, are to be allowed to continue being made available to consumers on the market after 1 January 2023 unless they present a serious risk to human health, until no later than 1 July 2023.

3. For tobacco-free nicotine-containing products that have been made available to consumers on the market before 1 January 2024, a product notification under Section 5 shall be made by no later than 1 February 2024.