



18. May 2016.

No 426.

Electronic cigarettes etc. Act.^{1) 2)}

WE MARGRETHE THE SECOND, by God's Grace, Queen of Denmark hereby decree:

The Danish Parliament has decided and We with Our agreement assert the following Act of Parliament:

Chapter 1

Area of application and definition of terms

§ 1. This Act applies to electronic cigarettes and refill containers containing nicotine, which are not approved via marketing authorization as per the Medicines Act, or pursuant to EU regulations on the establishment of Community procedures for the authorization of medicinal products for human use, or that are marketed as medicinal equipment bearing the CE Marking in accordance with the Order on medicinal equipment, cf. however clause 2.

Clause 2. Chapter 2, § 15, clause 1, and chapter 7 also cover, apart from electronic cigarettes and refill containers containing nicotine, mentioned in clause 1, electronic cigarettes and refill containers without nicotine.

§ 2. In this Act the following terms are defined as follows :

- 1) Electronic cigarette containing nicotine: A product that can be used for the consumption of nicotine-containing vapor via a mouthpiece, or parts of such a product, including a cartridge, a refillable tank and a device without a cartridge or refillable tank. Electronic cigarettes can be for single use or refillable by means of a refill container and a refillable tank, or can be reloaded with a single use cartridge.
- 2) Refill container containing nicotine: A container that contains a nicotine-containing liquid, which can be used for the refilling of an electronic cigarette containing nicotine.
Electronic cigarette without nicotine: A product that can be used for the consumption of non-nicotine-containing vapor via a mouthpiece, or parts of such a product, including a cartridge, a refillable tank and a

device without a cartridge or refillable tank. Electronic cigarettes can be for single use or refillable by means of a refill container and a refillable tank, or can be reloaded with a single use cartridge.

- 4) Refill container without nicotine: A container that contains a non-nicotine-containing liquid, which can be used for the refilling of an electronic cigarette without nicotine.
- 5) Manufacturer: Any physical or legal person that manufactures an electronic cigarette or a refill container containing nicotine, or arranges their construction or production and marketing under their name or trade mark.
- 6) Importer: The owner of, or a physical or legal person, with disposal rights for electronic cigarettes or refill containers containing nicotine that have been introduced into the EU area.
- 7) Distributor: Any physical or legal person apart from a manufacturer or importer, that markets electronic cigarettes or refill containers containing nicotine with the exception of sales to consumers.
- 8) Retailer: Any physical or legal person that markets electronic cigarettes or refill containers containing nicotine to consumers.
- 9) Marketing. To make electronic cigarettes or refill containers, with and without nicotine, available to consumers for or without payment, including by distance selling. In the case of cross border distance selling, the product is deemed to have been marketed in the country in which the consumer is located.
- 3) Cross border distance selling: Distance selling to consumers, where the consumer at the time point of ordering the pro

1) The Order implements parts of the European Parliament's and Council's directive 2014/40/EU of 3rd of April 2014 on mutual harmonization of member state laws and administrative orders on the production, presentation and sale of tobacco and related products and the abrogation of directive 2001/37/EU, Official Journal of the European Union 2014, no. L 127, page 1.

2) The Act, as a draft, has been notified in accordance with the European Parliament's and Council directive 2015/1535/EU (the information procedure directive).

duct from a retailer is located in a different EU-/EEA country to the retailer

Chapter 2

Use of electronic cigarettes with or without nicotine

§ 3. The use of electronic cigarettes with or without nicotine is not permitted in:

- 1) children's institutes, schools, boarding schools, residential schools, institutions offering 3 year high school courses, accommodation units etc. for children and youths under 18 years, cf. however clauses 2 and 3.
- 2) day-care centers and similar premises used for community care and public schemes, cf. §§ 20 and 21 in Act on Leisure and Club Facilities for children/youths where children are cared for, cf. however clause 4,
- 3) public transport facilities, including Danish passenger ships and Danish and foreign registered passenger planes, operating under Danish license, regardless of whether or not the ship or plane is located outside of Danish territory, cf. however clauses 5 and 6, and
- 4) taxis.

Clause 2. In locations intended for children and youths under 18 years, which also function as homes, the management at these places may allow youths to use electronic cigarettes outside said institution's indoor areas.

Clause 3. In secure units at 24 hour care centers and partly closed 24 hour care centers, which serve as homes for youths under 18 years, management at the unit may allow the use of electronic cigarettes in areas specially designated for this purpose, in their own rooms and outside of the unit's indoor areas.

Clause 4. The use of electronic cigarettes is not permitted in premises covered by clause 1 no. 2, if the area is primarily as a children's play and habitual area of use.

Clause 5. The ban in clause 1 no. 3, does not apply in those areas of a passenger ships designated for the crew and where the ship's passengers are forbidden access.

Clause 6. On passenger ships, senior crew may allow passengers use of electronic cigarettes outdoors, in cabins and areas designated for such use.

§ 4. Senior staff or employers in work or teaching institutions not covered by § 3, clause 1, and in places with public shall produce a written code of practice on the use of electronic cigarettes. The code of practice must be easily amenable to users, staff and visitors.

Clause 2. The code of practice, cf. clause 1, shall as a minimum contain information as to if, and in what circumstances, electronic cigarettes may be used.

Chapter 3

Marketing of electronic cigarettes and refill containers containing nicotine:

Duty of declaration

§ 5 Electronic cigarettes and refill containers containing nicotine may only be marketed here in Denmark if they have been declared to the Danish Safety Technology Authority.

Clause 2. Said declaration shall be submitted by manufacturers and importers wishing to market an electronic cigarette or a refill container containing nicotine, no later than 6 months before planned marketing.

Clause 3. The Minister for Business sets provisions for the information and statements that shall accompany a declaration as per clause 1, the Safety Authority's processing of the declaration and the product changes that require a new declaration.

§ 6. The Safety Authority publishes and updates on its website a list of electronic cigarettes and refill containers containing nicotine declared as per § 5, clause 1, as well as info and statements received as per the rules set out by § 5, clause 3, cf. however clause 2.

Clause 2. However, the Safety Authority does not publish info on operational or commercial factors outside of public right, as per § 30, no. 2, in the Danish Open Administration Act.

Product quality and properties

§ 7. Manufacturers and importers who have submitted a declaration as per § 5, clause 1, shall ensure that the electronic cigarettes and refill containers containing nicotine they market are of satisfactory quality, composition and safety, cf. clause 2.

Clause 2. The Minister for Health sets provisions for the quality composition and safety of electronic cigarettes and refill containers with nicotine, including requirements for ingredients and measures to guard against injury liquid leakage. The minister can, inter alia, set provisions on the amount, of permitted ingredients and rules to exclude certain substances in electronic cigarettes and refill containers containing nicotine.

Labelling and health warnings

§ 8. The Minister for Health sets provisions for the marking of electronic cigarettes and refill containers containing nicotine, including rules on banning the use of items, elements or features in labelling that can give a false picture of the product's purposes, use or effects.

§ 9. Manufacturers and importers who have submitted a declaration as per § 5, clause 1, shall ensure that electronic cigarettes and refill containers containing nicotine they market carry a health warning, cf. clause 2.

Clause 2. The Minister for Health sets provisions for the wording, form and positioning of the health warning.

Chapter 4

*The collection of data, duty to enact safety measures etc.**Effects harmful to health*

§ 10. Manufacturers and importers who have submitted a declaration as per § 5, clause 1, and distributors of electronic cigarettes and refill containers containing nicotine shall, for all products they market, establish and maintain a system for the collection of data for all assumed harmful effects to health vis-à-vis the products.

Clause 2. The Minister for Business can set more detailed rules for the system described in clause 1, including rules on the information that shall be recorded and technical requirements.

Duty to enact to safety measures

§ 11. If a manufacturer or importer, having submitted a declaration, as per § 5, clause 1, or a distributor of electronic cigarettes or refill containers containing nicotine, has or discovers reasons to believe that an electronic cigarette or refill container containing nicotine, which they market or are considering so doing, does not live up to the requirements stated in § 7, clause 1, § 9, clause 1, or rules pursuant to § 7, clause 2, § 8 or § 9, clause 2, said person shall immediately undertake the necessary measures to bring the product in line with these rules and if necessary withdraw or recall it from the market.

Clause 2. Manufacturers, importers or distributors who enact the measures stated in clause 1 shall immediately inform the Safety Authority of this with specifications of any possible health and safety risks the product is assumed to present, the measures taken and the result of those measures.

Clause 3. The Safety Authority can request that the person filing the report as per clause 2, give more detailed information on risks and measures taken.

Submission of details to the Safety Authority

§ 12. Manufacturers and importers who have submitted a declaration as per § 5, clause 1, engaged in selling electronic cigarettes and refill containers containing nicotine, shall, no later than the 1st of April each year submit information for the previous year as to sales volume, consumer group preferences, sales channels and any relevant summaries of market research to the Danish Safety Technology Authority.

Clause 2. The Danish Health Authority can access the information submitted as per clause 1, from the Danish Safety Technology Authority with a view to assessing market trends in electronic cigarettes and refill containers containing nicotine and to assess, inter alia, whether the use of, these products leads to nicotine addiction and tobacco consumption amongst young people and nonsmokers.

Clause 3. The Minister for Business sets more detailed rules regarding the information that must be submitted to the Safety Authority, as per clause 1.

Chapter 5

*Cross border distance selling:**Duty of registration*

§ 13. Those who seek to market electronic cigarettes and refill containers containing nicotine to consumers in this country, or in another EU/EEA country, via cross border distance selling, shall register with the Danish Safety Technology Authority before marketing commences. Marketing may only commence once the Authority has confirmed that registration has taken place.

Clause 2. The Minister for Business sets more detailed rules regarding the information that shall accompany a registration, as per clause 1, and the Authority's handling of same.

Clause 3. In the case of any changes to data registered as per clause 2, the registered body has a duty to inform the Safety Authority hereof. The Minister for Business sets more detailed rules on the duty to inform, as per pt. 1.

§ 14. The Danish Safety Technology Authority publishes and updates, on an ongoing basis, a list of registered retailers, as per § 13, clause 1.

Chapter 6

Ban on marketing to persons below 18 years of age

§ 15. The sale of electronic cigarettes and refill containers with and without nicotine to persons under 18 years of age is not permitted.

Clause 2. Retailers of electronic cigarettes and refill containers containing nicotine registered as per § 13, clause 1, shall operate an age checking system, cf. clause 3.

Clause 3. The Minister for Health sets rules for the age checking system, including requirements for this system and the retailer's duty to provide the Danish Safety Technology Authority with details of the system's content and application.

Chapter 7

Advertising etc.

§ 16. Public advertising of electronic cigarettes and refill containers with or without nicotine is not permitted.

Clause 2. The term advertise is understood as every action that has the aim of promoting the sale of electronic cigarettes and refill containers with or without nicotine, or which has this as a direct or indirect effect.

Clause 3. The term public is understood as all citizens of the country, with the exception of persons involved commercially in the production, import or sale of electronic cigarettes and refill containers with or without nicotine.

§ 17. Financial, or other sponsorship, of radio programs, activities or events, individual people and the like with the aim, or direct or indirect effect, of promoting the sale of electronic cigarettes and refill containers with or without nicotine must not take place.

§ 18. The Minister for Health sets more detailed rules on advertising etc. for electronic cigarettes and refill containers with and without nicotine.

Chapter 8
Controls and prohibition of marketing

The Safety Authority's checking system

§ 19. The Safety Authority operates a checking system vis-à-vis the adherence to the rules in chapters 3-6 and rules established for same. This does not however apply for § 15, clause 1.

Clause 2. The Safety Authority can demand all necessary details from manufacturers, importers, distributors and retailers of electronic cigarettes or refill containers containing nicotine for the purpose of control checks, as per clause 1.

§ 20. The Safety Authority can, for checking purposes, cf. § 19, clause 1, undertake register integration of data from its own registers and information in the public domain from other statutory bodies.

Clause 2. The Safety Authority can obtain nonpublic information from statutory bodies for register integration purposes insofar as this is significant for checking purposes, as per § 19, clause 1.

§ 21. In order to obtain information for use in the implementation of control checks, as per § 19, clause 1, Safety Authority representatives have at all times, subject to appropriate authorization, but without needing a search warrant, access to public and private premises linked to manufacturers, importers, distributors and retailers of electronic cigarettes and refill containers containing nicotine. Where necessary, the Police provide support to the Safety Authority for this purpose.

§ 22. The Safety Authority can, without payment but providing a receipt, take possession of electronic cigarettes and refill containers containing nicotine from manufacturers, importers, distributors and retailers of electronic cigarettes and refill containers for checking purposes, as per § 19, clause 1.

Clause 2. The Safety Authority can undertake, or arrange for, a technical examination of electronic cigarettes and refill containers containing nicotine pursuant to clause 1.

Inspection and checking by other statutory bodies

§ 23. As per the provisions in chapter 2, inspection is overseen by the Danish Working Environment Agency, cf. § 79 a, Working Environment Act and § 66 a, Offshore Safety Act, Danish Maritime Authority, cf. § 20 a, on safety at sea, and the Ministry of Transport Building and Housing, cf. § 150 f, in the Air Transport Act.

§ 24. The Consumer Ombudsman is responsible for inspection vis-à-vis adherence to the rules in chapter 7 and rules issued pursuant to same. Inspection is carried out as per the rules in the Marketing Act.

Prohibition of sales etc.

§ 25. The Safety Authority can forbid sales of electronic cigarettes and refill containers with nicotine, if:

- 1) the products are sold here without being declared as per § 5, clause 1,
- 2) the products do not fulfil requirements in § 7, clause 1, § 9, clause 1, or rules pursuant to § 7, clause 2, § 8 or § 9, clause 2, or
- 3) a product description has not been submitted, as per § 12, clause 1.

§ 26. The Safety Authority can in the instances set out in § 25, nos. 1 and 2, or where the Authority assesses that the products present a serious risk to public health, force manufacturers, importers, distributors and retailers of electronic cigarettes and refill containers containing nicotine to pull the products off the market or recall them from consumers.

§ 27. If the Safety Authority finds, or has reasonable grounds to believe, that certain electronic cigarettes or refill containers containing nicotine, or particular types of electronic cigarette or refill container with nicotine, expected to fulfil requirements in this Act and rules pursuant to the Act, may present a serious, to public health, the Authority can temporarily ban sales of the products.

Clause 2. The Safety Authority immediately informs the EU Commission and relevant authorities in other EU/EEA countries of the temporary ban issued as per clause 1.

§ 28. The Safety Authority can advise the public of the risks from electronic cigarettes and refill containers containing nicotine when a ban or Order is issued as per §§ 25 or 26 or § 27, clause 1.

Clause 2. The Safety Authority may not in such publicity, as per clause 1 issue operational or commercial info that is exempt from public right, as per § 30, no. 2, in the Act on Open Administration, unless this proves necessary to protect health and safety, or security.

§ 29. The Minister for Health can set rules with a view to implementing EU laws, which ban certain electronic cigarettes or refill containers containing nicotine or a particular type of electronic cigarette or refill containers containing nicotine:

Chapter 9

Digital communication

§ 30. The Minister for Business can set rules to the effect that written communication to and from the Authority regarding factors covered by chapters 3-5, § 15, clause 2, §§ 19-22 and §§ 25-28 and chapter 10 or 11, or for rules, pursuant hereof shall proceed digitally.

Clause 2. The Minister for Business can set more detailed rules, for digital communication, including the use of specific IT systems, digital formats and digital signatures etc.

Clause 3. A digital message is deemed to have been delivered when it is accessible by the addressee.

Chapter 10 *Right of appeal*

§ 31. Safety Authority rulings as per this Act, or rules, pursuant to this Act cannot be raised with another statutory body.

Chapter 11 *Fees*

§ 32. The Danish Safety Technology Authority demands fees, as per § 5, clause 1, and for annual maintenance of product declarations.

Clause 2. The Minister for Business can set rules on exceptions to fee demands, as per clause 1.

Clause 3. The Minister for Business can set more detailed rules on fee amounts and demanding of fees, as per clause 1.

Chapter 12 *Penalties*

§ 33. Unless a more serious penalty, or other Act, is warranted, persons concerned incur fines if they

- 1) contravene § 3, clauses 1 and 4, § 4, § 9 clause 1, § 10, clause 1, § 11, clause 1, § 15, clause 1 and 2, § 16, clause 1, or § 17,
- 2) fail to comply with the duty of declaration in § 5, clause 1 and 2.
- 3) fail to comply with the duty of registration in § 13, clause 1,
- 4) contravene a declared ban as per § 25 or § 27, clause 1, or
- 5) fail to comply with a directive, or duty to inform as per § 11, clauses 2 or 3, § 12, clause 1, § 19, clause 2, or § 26,

Clause 2. In rules pursuant to § 7, clause 2, § 8 or § 9, clause 2, § 10, clause 2, § 12, clause 3, § 13, clause 2, § 15, clause 3, and § 18, fines can be imposed for contravention of provisions in said rules.

Clause 3. Companies (legal entities) can face criminal liability charges as per the stipulations in Chapter 5 of the Criminal Law Act.

Chapter 13

Coming into force and transitional orders etc.

§ 34. The Act comes into force on the 7th of June 2016.

Clause 2. Manufacturers and importers may sell electronic cigarettes and refill containers containing nicotine that are produced before the 20th of November 2016, as per the hitherto applicable rules up until the 7th of June 2017.

Clause 3. Manufacturers and importers selling electronic cigarettes and refill containers containing nicotine on the 7th of June 2016 who are compliant with the provisions of this Act and rules pursuant hereof, shall submit a product declaration to the Safety Authority, as per § 5, clause 1, no later than the 20th of November 2016.

Clause 4. However, for agreements made before the 7th of June 2016, the stipulation in § 17 only comes into use from the 7th of June 2018, unless said agreement has cross border effect and concerns electronic cigarette and refill containers containing nicotine.

§ 35. Those who, on the 7th June 2016, are engaged in activities covered by § 13, clause 1, as per the hitherto applicable rules wishing to continue these activities after this date, shall no later than the 20th of August 2016, ensure they are registered, as per § 13, clause 1.

Changes in other relevant legislation

§ 36. In the Medicines Act, cf. consolidated legislation no. 506 of 20th of April 2013, as amended by § 1 in Act no. 518 of 26th of May 2014 and § 2 in Act no. 542 of 24th of April 2015, the following amendments are made:

1. In § 4, *clause 1*, inserted after »medicinal equipment«,«: »tobacco products and similar products containing nicotine«.

§ 37. In the Working Environment Act, cf. consolidated legislation no. 1072 of 7th of September 2010, as most recently amended by § 7 in Act no. 395 of 2nd of May 2016, the following amendments are made:

1. In § 79 a, *clause 1, pt. 1*, »legislation on smoke-free environments« is changed to: »legislation on smoke-free environments and chapter 2 in the Electronic Cigarettes etc. Act.«

2. In § 79 a, *clause 1, pt. 2*, »legislation on smoke-free environments« is changed to: »legislation on smoke-free environments and chapter 2 in the Electronic Cigarettes etc. Act.«

§ 38. In the Marine Safety Act, cf. consolidated legislation no. 72 of 17th of January 2014, as most recently amended by § 1 in Act no. 724 of 25th of June 2014, the following amendments are made:

1. In § 20 a, *clause 1, pt. 1*, »legislation on smoke-free environments« is changed to: »legislation on smoke-free environments and chapter 2 in the Electronic Cigarettes etc. Act.«

2. In § 20 a, *clause 3, pt. 2*, »legislation on smoke-free environments« is changed to: »legislation on smoke-free environments and chapter 2 in the Electronic Cigarettes etc. Act.«

§ 39. In the Air Transport Act, cf. consolidated legislation no. 1036 of August 2013, as amended most recently by Act no. 1896 of 29th of December 2015, the following amendments are made:

1. In § 150 f, *clause 1, pt. 1*, »legislation on smoke-free environments« is changed: »« to: »legislation on smoke-free environments and chapter 2 in the Electronic Cigarettes etc. Act.«

2. In § 150 f, *clause 1, pt. 2*, »legislation on smoke-free environments« is changed to: »legislation on smoke-free environments and chapter 2 in the Electronic Cigarettes etc. Act.«

§ 40. In the Offshore Safety Act, cf. consolidated legislation no. 831 of 1st of June 2015, the following amendments are made:

1. In § 66 a, clause. 1, pt. 1. »legislation on smoke-free environments« is changed: »« to: »legislation on smoke-free environments and chapter 2 in the Electronic Cigarettes etc. Act.«
2. In § 66 a, clause 1, pt. 2 »the Act« is changed to: »legislation on smoke-free environments and chapter 2 in the Electronic Cigarettes etc. Act.«

Evaluation

§ 41. The Minister for Health will carry out an evaluation of the Act's chapter 2, which will be published no later than 20th of May 2018.

§ 42. The Act does not apply In the Faroe Islands or Greenland.

Issued at Amalienborg, this 18th of May 2016

By Our Royal Hand and Seal

MARGRETHE R.

/ Sophie Løhde