Act no 608 of 07/06/2016 (Current)

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Subsequent changes to Order:

None

Tobacco Products etc. Act

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 tobacco products and herbal products for smoking, which are produced or sold in Denmark.
- § 2.1 The following terms in the Act are understood as follows:
- 1) Tobacco: Leaves and other natural, processed or unprocessed, parts of tobacco plants, including expanded and reconstituted tobacco.
- 2) Tobacco products: Products that can be used, and partly consist of tobacco, regardless of whether or not the tobacco is genetically modified.
- 3) Cigarette: A thin cylinder of rolled tobacco that can be consumed via a burning process; defined in more detail in article 3, clause 1, of Council directive 2011/64/EU.
- 4) Rolling tobacco: Tobacco that can be used by consumers or retail sales locations to make cigarettes.
- 5) Smoke-free tobacco product: A tobacco product that is not consumed via a burning process, including plug tobacco, tobacco that is consumed nasally, and tobacco taken orally.
- 6) Smoking tobacco: Tobacco products that are not smoke free.
- 7) Tobacco taken orally: All tobacco products designed for oral ingestion, with the exception of goods designed for inhaling or being chewed, and which entirely or partly consist of tobacco in the form of powder or fine particles, or any combination of these forms, especially goods in sachets or porous pouches.
- 8) Plug tobacco: A smoke-free tobacco product, which is exclusively intended for chewing.
- 9) Additives: A substance other than tobacco that is added to a tobacco product, a single packet or any relevant outer packaging.
- 10) Emissions: Substances that are released when tobacco or a herbal based product for smoking is used as per its intention, such as substances to be found in smoke, or substances released during the use of smoke free tobacco products.
- 11) Characteristic aromas/flavors: A distinctive aroma or taste of something other than tobacco, which stems from additives, or a combination of additives, including fruit, spices, herbs, alcohol, sweets, menthol or vanilla, and which can be smelled or tasted before or during the consumption of the tobacco product.
- 12) New categories of tobacco products: Tobacco products other than cigarettes, rolling tobacco, hookah tobacco, cigars, cigarillos, plug tobacco, tobacco that is ingested nasally, and tobacco taken orally, and marketed after 19th of May 2014.
- 13) Herbal products for smoking: A product based on plants, herbs or fruits, which does not contain tobacco, and which can be consumed via a burning process.

- 14) Single packet: The smallest individual packaging for a tobacco product, or a herbal based product for smoking, marketed.
- 15) Outer packaging: Any wrapping, apart from see-through material, that a tobacco product or a herbal based product for smoking is sold in and which surrounds one or more single packets.
- 16) Health warnings: A warning relating to a product's harmful effects to health, or other undesirable effects from consuming the relevant product, including text warnings, combined health warnings, general warnings and informational messages.
- 17) Manufacturer: Any physical or legal entity that manufactures a tobacco product or a herbal based product for smoking or arranges the design and production and sale of such goods or products under their name or trade mark.
- 18) Importer: The owner of, or a physical or legal person, with disposal rights over tobacco products or herbal products for smoking, which have been made available inside the European Union's common area.
- 19) Distributor: Any physical or legal person apart from a manufacturer or importer, offering for sale tobacco products or herbal products for smoking, with the exception of sales to consumers.
- 20) Retailer: Any physical or legal person offering for sale tobacco products or herbal products for smoking to consumers.
- 21) Marketing: To make tobacco products or herbal products for smoking available to consumers for or without payment. 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.
- 22) Cross border distance selling: Distance selling to consumers, where the consumer, at the time point of ordering the product from a retailer, is located in an EU/EEA country other than where the retailer is located.

Submission of information on tobacco products to the Danish Safety Technology Authority and the European Commission

Information on ingredients and emissions

- § 3. Manufacturers and importers of tobacco products marketed in this country, shall for each separate tobacco product, divided by brand name and type, submit the following details to the Danish Safety Technology Authority:
- 1) Details of all ingredients in declining sequence by weight of each ingredient used in the production of the relevant tobacco product, including:
 - a) a list of details for each ingredient by name and amount thereof,
 - b) an explanation as to why the relevant ingredient is used in the tobacco product,
 - c) details of the status of the ingredient, including whether it is registered as per European Parliament and Council Order (EU) no. 1907/2006, and its classification vis-à-vis European Parliament and Council regulation (EU) no. 1272/2008,
 - d) relevant toxicological information on the ingredient and
 - e) for cigarettes and rolling tobacco, a technical document with a general description of the additive and its properties.
- 2) Details of the tobacco product's emission contents.
- Details of the measurement methodology used for emissions, with the exception of those stated in § 9, clauses 1 and 2.
- Clause 2. The Minister for Business can set more detailed rules for the submission of information described in clause 1, including rules for the details to be submitted; when a submission is made and in what format, as well as, information in the event of a change in the relevant tobacco products.
- § **4.** Manufacturers and importers offering cigarettes and rolling tobacco in this country with an additive that is on the priority list mentioned in article 6, clause. 1, in directive 2014/40/EU, shall carry out a comprehensive study of the relevant additive, cf. however clause 2.

- Clause 2. The Danish Health Authority sets more detailed rules on the studies that shall be carried out, as per clause 1, and rules to the effect that a manufacturer or importer covered by the obligation as per clause 1, in certain instances can undertake such studies together with other manufacturers or importers and in certain instances, may be completely exempted from this obligation.
- § 5. Manufacturers and importers covered by § 4, clause 1, shall produce and submit a report on the studies carried out as per § 4, clause 1, to the Danish Safety Technology Authority and the European Commission, no later than 18 months after the relevant additive has been added to the priority list mentioned in § 4, clause 1.
- Clause 2. The European Commission and Danish Safety Technology Authority can, each separately, request supplementary information from the manufacturer and importer regarding the report described in clause 1, and can demand that an evaluation of the report by an independent scientific body.
- Clause 3. The Minister for Business sets more detailed rules on the submission of reports, as per clause 1, and also on format requirements.
 - Clause 4. The Danish Health Authority sets more detailed rules on the evaluation as per clause 2.
- § 6. The Safety Authority publishes and updates, on an ongoing basis, on its website the information, declarations and reports it receives as per § 3, clause 1 no. 1, schedule a, and no. 2, § 5 clause 1, and rules set as per § 3, clause 2, cf. § 3, clause 1 no. 1, schedule a, and no. 2, § 5 clause 3. This does not apply, however, to operational or commercial concerns to the extent that it is of significant commercial importance to the relevant person or company that such information is not published.

Market research information

- § 7. Manufacturers and importers of tobacco products marketed in this country, shall submit market analysis details on their tobacco products, as well as studies carried out in connection with the launch of their tobacco products, to the Danish Safety Technology Authority.
- Clause 2. Manufacturers and importers of tobacco products marketed in this country, shall no later than the 1st of May every year, submit details of sales volumes for the previous year to the Danish Safety Technology Authority.
- Clause 3. The Danish Health Authority can, with a view to appraising trends in the market, collect the data submitted as per clause 1, from the Danish Safety Technology Authority.
- Clause 4. The Minister for Business sets more detailed rules regarding the information that must be submitted to the Safety Authority, as per clauses 1 and 2.

Chapter 3

Threshold limits for emission levels from tobacco products and measurement methodology for emission content

- § 8. The Minister for Health sets rules on threshold limits for the maximum content of tar, nicotine and carbon monoxide in emissions from cigarettes marketed or produced in this country.
- *Clause* 2. The Minister for Health can set rules on threshold limits for emissions other than those stated in clause 1, and for emissions from tobacco products other than cigarettes.
- § 9. The Minister for Health sets rules on the measurement methodology used in evaluating the emission content of tar, nicotine and carbon monoxide in cigarettes marketed or produced in this country.
- *Clause 2.* The Minister for Health can set rules on the measurement methodology for emissions other than those stated in clause 1, and from tobacco products other than cigarettes.
- § 10. The measurements described in § 9, must be checked by a laboratory that is authorized by the Safety Authority, as per § 11.

Licensing and checking of laboratories for the measurement of emission contents

- § 11. The Danish Safety Technology Authority can, following an application, license laboratories to carry out checks on measurements of the emission content of tar, nicotine and carbon monoxide in cigarettes marketed or produced in this country, cf. § 9.
- Clause 2. In order to obtain a license, as per clause 1, the laboratory must be accredited by DANAK, the Danish Accreditation Fund, or by a corresponding accreditation body that is a co-signatory of a relevant EA (European cooperation for Accreditation) multilateral agreement for mutual accreditation for the implementation of tasks as per clause 1 and be located in Denmark or another EU/EEA country.
- Clause 3. Laboratories seeking a license, or are approved as per clause 1, must not be owned or directly or indirectly controlled by the tobacco industry.
- Clause 4. The Minister for Business can set more detailed rules on the processing of license applications as per clause 1 and the content of accreditation as per clause 2.
- § 12. The Danish Safety Technology Authority carries out checks to ensure that laboratories approved as per § 11, clause 1, are complying with requirements in § 11, clauses 2 and 3.
- Clause 2. With a view to the implementation of checking controls as per clause 1, the Danish Safety Technology Authority can demand documentation from laboratories approved as per § 11, clause 1, to ensure the requirements in § 11, clauses 2 and 3 are being complied with.

Chapter 4

Ban on marketing certain tobacco products etc.

- § 13. Tobacco that is ingested orally must not be marketed in this country.
- § 14. Cigarettes and rolling tobacco with a distinctive aroma/flavor must not be marketed in this country.
- Clause 2. The Danish Health Authority can set more detailed rules for the ban described in clause 1, including rules as to whether a specific cigarette or type of rolling tobacco is covered by the ban in clause 1, and on threshold limits for additive content, or combinations of additives, in cigarettes and rolling tobacco that provide a distinctive aroma/flavor.
- § 15. Cigarettes and rolling tobacco that contain flavoring/aromas in their component parts such as filters, paper, wrapping, packaging, capsules or any technical function that facilitates a change in the relevant tobacco product's scent or taste, or their smoke intensity capacities, must not be marketed in this country.
- § 16. Cigarettes and rolling tobacco that consist of filters, paper or capsules containing tobacco or nicotine, must not be marketed in this country.
 - § 17. Tobacco products containing the following additives must not be marketed in this country:
- Vitamins or other additives that give the impression that a tobacco product offers a health advantage, or constitutes a more limited health risk.
- 2) Caffeine, taurine or other additives and stimulating compounds.
- 3) Additives whose emissions have coloring characteristics.
- 4) Additives that have carcinogenic, mutagenic or reprotoxic properties in an unburned state.
- Clause 2. Smoking tobacco must not be marketed in this country if the tobacco product contains additives mentioned in clause 1, or additives that make inhaling or nicotine uptake easier.
- § 18. Tobacco products that contain additives in volumes which during consumption significantly or measurably increase the tobacco product's toxic or addictive effect, or carcinogenic, mutagenic or reprotoxic properties, must not be marketed in this country.
- Clause 2. The Danish Health Authority can set more detailed rules for the ban described in clause 1, including rules as to whether a specific tobacco product is covered by the ban and for threshold content limits on additives in tobacco products as described in clause. 1.

Health warnings on tobacco products etc.

§ 19. Those marketing a tobacco product in this country shall ensure that every single packet and any exterior packaging carry health warnings in Danish.

Clause 2. The Minister for Health sets rules for:

- 1) the number and type of health warnings the individual category of tobacco products shall carry,
- 2) the form, wording, layout, positioning and size and
- 3) prohibition of the whole or partial obscuring or breaking of a health warning as part of the marketing of a tobacco product.

Chapter 6

Marking and packaging of tobacco products etc.

- § 20. Those marketing a tobacco product in this country, shall ensure, that each single packet and any exterior packaging does not contain elements or features that
- 1) promote a tobacco product or encourage use of it by giving a false impression of the product's characteristics, effects, risks or emissions,
- 2) gives the impression that a particular tobacco product is less harmful than others, or that its purpose is to reduce the effects of specific harmful components in the smoke,
- 3) gives the impression that a particular tobacco product has revitalizing, energizing, healing, rejuvenating, natural, ecological characteristics, or other positive purposes and effects with regard to health and/or lifestyle.
- 4) refers to tastes, scents, flavoring or other additives, or states that the product does not contain same,
- 5) make the product resemble a food item or a cosmetic product or
- 6) give the impression that a particular tobacco product has enhanced biological degradability or environmentally friendly advantages.
- Clause 2. Those marketing a tobacco product in this country shall ensure that a single packet, and any exterior packaging, does not carry information on the tobacco product's content of nicotine, tar and carbon monoxide.
 - Clause 3. The Danish Health Authority can set more detailed rules for labelling cf. clauses 1 and 2.
- § 21. The Danish Health Authority sets more detailed rules for size, form, functionality and component parts vis-àvis single packets of cigarettes and rolling tobacco.
- § 22. Those marketing tobacco products in this country shall ensure each single packet and any exterior packaging does not contain coupons offering discounts, free samples, two for one offers, or other similar offers.

Chapter 7

Cross border distance selling:

Duty of registration for tobacco products etc.

Those who seek to market tobacco products 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 Safety Authority has confirmed that registration has taken place.

Clause 2. The Minister for Business sets more detailed rules for

- 1) the information that shall accompany a registration as per clause 1,
- 2) the duty to inform the Danish Safety Technology Authority if changes occur in this information and
- 2) the Authority's handling of same.

- § 24. Retailers of tobacco products who are registered as per § 23, clause 1, shall operate an age checking system.
- Clause 2. The Minister for Health sets more detailed rules for the age checking system mentioned in clause 1, including more detailed requirements for retailer obligations vis-à-vis informing the Danish Safety Technology Authority as to the system's content and use.
- § 25. The Danish Safety Technology Authority publishes and updates, on an ongoing basis, a list of registered retailers, registered as per § 23, clause 1.

Declarations of new categories of tobacco products

- § 26. New categories of tobacco products may only be marketed in this country if they are declared to the Danish Safety Technology Authority.
- Clause 2. Product declarations described in clause 1 shall be submitted by every manufacturer and importer wishing to market a new category of tobacco product, no later than 6 months before the planned marketing takes place.

Clause 3. The Minister for Business sets rules for

- 1) the information and statements that shall accompany a product declaration as per clause 1,
- 2) the duty to inform the Danish Safety Technology Authority if changes occur in this information and
- 3) the Safety Authority's processing of the product declaration.
- § 27. The Danish Health Authority can set rules as to which of the Act's regulations will apply for, new categories of tobacco products, depending on whether it's a smoke free tobacco product or smoking tobacco product.

Chapter 9

Marketing of herbal products for smoking

Description details

- § 28. Manufacturers and importers marketing herbal products for smoking in this country shall submit details of the relevant product's composition to the Danish Safety Technology Authority.
- Clause 2. Product declarations as per clause 1 must be made before a new or altered herbal based product for smoking is brought onto the market.

Clause 3. The Minister for Business sets more detailed rules for

- 1) the information that shall be submitted to the Safety Authority as per clause 1,
- 2) the duty to inform the Safety Authority if changes occur in this information and
- 3) the Safety Authority's processing of submitted information.
- § 29. The Safety Authority publishes and updates, on an ongoing basis, on its website the information it receives as per § 28, clause 1, and rules set as per § 28, clause 3 no. This does not apply, however, to operational or commercial concerns to the extent that it is of significant commercial importance to the relevant person or company that such information is not published.

Health warnings and labelling

- § 30. Those marketing a herbal based product for smoking in this country, shall ensure each single packet and any exterior packaging carries a health warning in Danish.
 - Clause 2. The Minister for Health sets rules for the wording, positioning and size of the health warning.
- § 31. Those marketing a herbal based product for smoking in this country shall ensure single packets and any exterior packaging do not carry statements that the product is free of additives, flavoring, nicotine, tar or carbon monoxide, or contains items or features that

- 1) promote a herbal based product for smoking or encourage use of it by giving a false impression of the product's characteristics, effects, risks or emissions,
- 2) gives the impression that a particular herbal based product for smoking is less harmful than others, or that its purpose is to reduce the effects of specific harmful components in the smoke,
- 3) gives the impression that a particular a herbal based product for smoking has revitalizing, energizing, healing, rejuvenating, natural, ecological characteristics, or other positive purposes and effects with regard to health and/or lifestyle.
- 4) make the product resemble a food item or a cosmetic product
- *Clause* 2. The Danish Health Authority can set more detailed rules for the requirements stated in clause 1, for the labelling of herbal products for smoking.

The Safety Authority's checking system

- § 32. The Danish Safety Technology Authority runs checks to ensure this Act, and rules pursuant to it, are being complied with.
- Clause 2. The Danish Safety Technology Authority can request from manufacturers, importers, distributors and retailers of tobacco products and herbal products for smoking all information that may be necessary for checking purposes, as per clause 1.
- § 33. The Safety Authority can, for checking purposes, cf. § 32, 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 non-public information from statutory bodies for register integration purposes insofar as this is significant for checking purposes, as per § 32, clause 1.
- § 34. In order to obtain information for use in the implementation of control checks, as per § 32, 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.
- § 35. The Danish Safety Technology Authority can, without payment and on foot of a receipt, take samples of tobacco products and herbal products for smoking from manufacturers, importers, distributors and retailers for checking purposes, as per § 32, clause 1.
- Clause 2. The Danish Safety Technology Authority can undertake, or arrange to have undertaken, a technical examination of tobacco products and herbal products for smoking that are taken as samples pursuant to clause 1.

Prohibition of marketing etc.

- § 36. The Safety Authority can forbid marketing of tobacco products, if
- 1) the products do not fulfil requirements in § 10, § 19, clause 1, or § 20, clause 1, and 2 or rules pursuant to § 8, clause 2, § 9, clause 2, § 19, clause 2, § 20, clause 3, or § 21,
- 2) where a product description has not been submitted, as per § 3, clause 1,
- 3) a report has not been prepared and submitted on additives, or supplementary details not submitted in this regard, as per § 5, stk. 1, or 2
- 4) no submissions have been made as per § 7, clause 1, or annual product declarations as per § 7, clause 2, or submissions or product declarations as per § 7, clauses 1 and 2 are not made in accordance with rules set pursuant to § 7, clause 4, or
- 5) new categories of tobacco products are marketed in this country without being declared as per § 26, clause 1.

- 6) § 37. The Danish Safety Technology Authority can forbid the marketing of herbal products for smoking if the products do not comply with § 30, clause 1, or § 31, clause 1, or rules pursuant to § 30, clause 2, or § 31, clause 2, or if a product description has not been submitted, as per § 28, clause 1.
- § 26. The Safety Authority can in the instances set out in § 36, nos. 1-3 and 5, or § 37, or where the Authority otherwise considers that the relevant products constitute a serious risk to public health, demand that manufacturers, importers, distributors and retailers of tobacco products and herbal products for smoking withdraw such goods and products from the market, or recall same from consumers.
- § 39. The Danish Safety Technology Authority is at liberty to inform the public of risks from tobacco products and herbal products for smoking when a ban or Order has been imposed as per §§ 36, 37 or 38.
- Clause 2. However, the Danish Safety Technology Authority does not publish information on operational or commercial factors to the extent that it is of significant commercial importance to the relevant person or company that such information is not published, unless such publication is necessary in order to protect public health or safety.

Digital communication

- § 40. The Minister for Business can set rules for written communication to and from the Danish Safety Technology Authority regarding factors covered by this Act, or rules set pursuant to this Act, to the effect that this 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 12

Right of appeal

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

Chapter 13

Costs and fees

- § 42. The Danish Safety Technology Authority defrays costs linked to hearings of the advisory panel, at EU level, mentioned in article 7, clause 4, in directive 2014/40/EU, for assessing whether a tobacco product is covered by the ban in § 14, clause 1.
- Clause 2. The Safety Authority can demand that the costs mentioned in clause 1 be reimbursed by the manufacturer or importer who wishes to market, or is marketing, the relevant tobacco product covered by the ban in § 14, clause 1, in this country.
- § 43. The Danish Safety Technology Authority demands fees to cover the Authority's costs in processing product declarations as per § 3, evaluations as per § 5, clause 2, licensing and checking of laboratories, cf. § 11, clause 1 and § 12, clause 1, and registrations, cf. § 23, clause 1, and also Safety Authority checks as per §§ 32-39, carried out amongst manufacturers and importers of tobacco products covered by the duty of declaration in § 3, clause 1.
- Clause 2. The fee is demanded from manufacturers and importers of tobacco products covered by the duty of declaration in § 3, clause 1. The fee is apportioned on the basis of the individual manufacturer's or importer's market share in the Danish market. Assessment of the individual manufacturer's or importer's market share is made on the basis of the tobacco duties reported to the TAXATION AUTHORITY, (SKAT).

- Clause 3. In order to assess the allocation of the fee, as per clause 1, the Danish Safety Technology Authority is at liberty to obtain information not in the public domain pertaining to the tobacco duty reported to the TAXATION AUTHORITY, (SKAT).
 - Clause 4. The Minister for Business can set more detailed rules on exceptions to fee demands, as per clause 2.
- Clause 5. The Minister for Business can set more detailed rules on fee amounts and demanding of fees, as per clause 1.
- § 44. The Danish Safety Technology Authority demands fees, as per § 26, clause 1, and for annual maintenance of product declarations, as well as notifications as per § 28, clause 1, and for annual maintenance of report submissions.
 - 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.

Penalties

- § 45. Unless a more severe penalty is warranted in accordance with other legislation, fines are imposed on those who
- 1) contravene § 4, clause 1, § 5, clause 1, § 10, § 13, § 14, clause 1, §§ 15-17, § 18, clauses 1, § 19, clause 1, § 20, clauses 1 and 2, § 28, clause 2, or § 30, clause 1,
- 2) fail to comply with the duty of declaration in § 26, clause 1,
- 3) fail to comply with the duty of registration in § 23, clause 1,
- 4) contravene a declared ban as per § §§36 or § 37
- 5) fail to comply with a directive, or duty to inform as per § 3, clause 1, § 5 clause 2 and 7, § 28, clause 1, § 32, clause 2, or § 38.
- Clause 2. In rules pursuant to § 8, clause 2, § 9, clause 1, § 21 or 30, clause 2, fines can be imposed for contravention of provisions in said rules.
- Clause 3. Companies etc. (legal persons) can face criminal liability charges as per the stipulations in Chapter 5 of the Criminal Law Act.

Chapter 15

Coming into force and transitional orders etc.

- § 46. The Act comes into force on the 9th of June 2016.
- Clause 2. For tobacco products ingested orally, and which are not intended for smoking or chewing, that are produced or imported before the 1st of January 2016, § 13 has effect from the 1st of July 2016.
- *Clause 3.* For herbal products for smoking produced before the 9th of June 2016, the Act has effect, from the 20th of May 2017.
- Clause 4. For cigarettes and rolling tobacco with a distinctive flavor/aroma that reach sales volumes of 3 percent or more in ELI before the 9th of June 2016, § 14, clause 1, and § 15 have effect from the 20th of May 2020.
- *Clause 5.* The Act on the production, presentation and sale of tobacco products, cf. consolidated legislation no. 1022 of 21st of October 2008 is rescinded, cf. however § 47, clause 1.
- Clause 6. Rules pursuant to the Act on the production, presentation and sale of tobacco products, cf. consolidated legislation no. 1022 of 21st of October 2008, remain in effect until they are replaced by or overruled by rules established as per this Act.
- § 47. Tobacco products produced before the 9th of June 2016 can, until the 20th of May 2017, be marketed, in accordance with hitherto applicable rules.
- Clause 2. For tobacco products marketed on the 9th of June 2016 that satisfy the requirements of this Act and rules pursuant to the Act, product declarations are made as per § 3, clause 1, no later than the 20th of November 2016.

- § 48. Those who before the 9th of June 2016 have commenced activities covered by § 23, clause 1, in accordance with the hitherto applicable rules who wish to continue these activities after this date shall, no later than the 9th of September 2016 ensure they are registered as per § 23, clause 1.
 - § 49. The Act does not apply in the Faroe Islands or Greenland.

Issued at Fredensborg Castle, this 7th of June 2016

Under Our Royal Hand and Seal MARGRETHE R.

/ Sophie Løhde

Unofficial Translation

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