Unofficial Translation

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Consolidation Act on Tobacco Products, etc.[1)]

Act No. 608 of 07 June 2016 on Tobacco Products, etc. with amendments pursuant to § 1 of Act No. 86 of 30 January 2019, is hereby promulgated.

Chapter 1

Area of application and definitions

§ 1. This act applies to tobacco products and herb-based smoking products produced or marketed in Denmark.

§ 2. The following terms and definitions are understood in this act:

1) Tobacco: Leaves and other natural, pre-processed or unprocessed parts of tobacco plants, including expanded and reconstituted tobacco.
2) Tobacco products: Products that can be used and that entirely or partly consist of tobacco, regardless of whether the tobacco is genetically modified.
3) Cigarette: A roll of tobacco that can be consumed through a combustion process, and that is more specifically defined in article 3, subsection 1, of Council Directive 2011/64/EU.
4) Rolling tobacco: Tobacco that can be used for the production of cigarettes by consumers or retail outlets.
5) Smokeless tobacco product: A tobacco product that is not consumed through a combustion process, including chewing tobacco, tobacco ingested nasally, and tobacco ingested orally.
6) Smoking tobacco: Tobacco products that are not smokeless tobacco products.
7) Tobacco ingested orally: All tobacco products intended for oral ingestion, except for goods intended to be inhaled or chewed, and that are entirely or partly comprised of tobacco in the form of powder or fine particles or any combination of these forms, particularly products in portion pouches or porous packets.
8) Chewing tobacco: A smokeless tobacco product that is exclusively intended to be chewed.
9) Additive: A substance other than tobacco that is added to a tobacco product, a unit pack or any outer packaging.
10) Emissions: Substances released when tobacco or an herb-based smoking product is used as intended, such as substances found in smoke, or substances released in conjunction with the use of smokeless tobacco products.
11) Distinctive flavor: A prominent fragrance or taste of other than tobacco that is the result of an additive or combination of additives, including fruits, spices, herbs, alcohol, sweets, menthol, or vanilla, and that is perceived as fragrance or tasted before or during consumption of the tobacco product.
12) Novel tobacco products: Tobacco products other than cigarettes, rolling tobacco, pipe tobacco, water pipe tobacco, cigars, cigarillos, chewing tobacco, tobacco ingested nasally, and tobacco ingested orally and marketed after 19 May 2014.
13) Herb-based smoking products: A product based on plants, herbs, or fruits that does not contain tobacco, and that can be consumed through a combustion process.
14) Unit packet: The smallest individual packaging of a tobacco product or an herb-based smoking product that is marketed.
15) Outer packaging: Any packaging apart from transparent material that a tobacco product or an herb-based smoking product is marketed in, and that surrounds one or more unit packs.
16) Health warning: A warning regarding a product's adverse effects on health or other undesirable consequences of consumption of the product, including text warnings, combinations of health warnings, general warnings, and information notices.
17) Manufacturer: Any natural person or legal entity that produces a tobacco product or an herb-based smoking product or has such goods or products manufactured or produced and marketed under one's name or trademark.

1) The Act contains provisions that implement parts of Directive 2014/40/EU of the European Parliament and of the Council of 03 April 2014 on the approximation of the laws, regulations and administrative provisions of the member states concerning the manufacture, presentation and sale of tobacco and related products and repealing Directive 2001/37/EC (Official Journal 2014, no. L 127, page 1) and provisions implementing arts of Commission Implementing Decision (EU) 2018/576 of 15 December 2017 on technical standards for security features applied to tobacco products, Official Journal 2018, no. L 96, page 57. The act adopts certain provisions from Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a tracing system for tobacco products, Official Journal 2018, no. L 96, page 7. According to article 288 of the Treaty on the Functioning of the European Union, a regulation shall immediately apply in each member state. Reiteration of these provisions in the act is therefore only justified for practical purposes and does not affect the immediate validity of the regulation in Denmark.

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18) Importer: The owner of or a natural person or legal entity with disposal over tobacco products or herb-based smoking products that have been introduced into the territory of the European Union.
19) Distributor: Any natural person or legal entity other than a manufacturer or importer that markets tobacco products or herb-based smoking products, with the exception of sales to consumers.
20) Retailer: Any natural person or legal entity that markets tobacco products or herb-based smoking products to consumers.
21) Marketing: To make tobacco products or herb-based smoking products available to consumers against or without payment. In the event of cross-border distance sales, the good or product is considered to be marketed in the country where the consumer is located.
22) Cross-border distance sales: Remote sales to consumers, where the consumer at the time of ordering the product from a retailer is located in an EU/EEA country other than the country where the retailer is established.
23) Unique identifier: The alphanumeric code that makes it possible to identify a single unit packet or aggregated packaging of tobacco products.
24) Economic operators: Any natural person or legal entity involved in trade in tobacco products, including for export, from the manufacturer to the last economic operator before the first retail outlet.

Chapter 2

Reporting 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 Denmark shall for each tobacco product, broken down by trading name and type, report the following to the Danish Safety Technology Authority:

1) Information on all the ingredients in descending sequence by weight for each ingredient used in the production of the tobacco product, including
   a) a list of information on the name of the ingredient and included volume,
   b) a statement on why the ingredient in question is included in the tobacco product,
   c) information on the status of the ingredient, including indication of whether the ingredient is registered in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council, and its classification in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council,
   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 characteristics.
2) Information on the emissions content of the tobacco product.
3) Information on the measurement methods for emissions employed, with the exception of those mentioned in § 9, subsections 1 and 2.

Subsection 2. The Danish Ministry of Industry, Business and Financial Affairs sets more specific rules on the reports mentioned in subsection 1, including rules on what information must be reported, when reporting must take place and in what form, along with information regarding changes to tobacco products.

§ 4. Manufacturers and importers of cigarettes and rolling tobacco marketed in Denmark containing an additive included on the priority list mentioned in article 6, subsection 1, of Directive 2014/40/EU, must carry out comprehensive studies of the additive, cf. however, subsection 2.

Subsection 2. The Danish Health Authority sets more specific rules on the tests to be carried out in accordance with subsection 1 and rules stating that a manufacturer or importer covered by the obligation according to subsection 1 may, in certain cases, carry out investigations together with other manufacturers or importers, and may in certain cases be completely exempt from the obligation.

§ 5. Manufacturers and importers covered by § 4, subsection 1, must draw up and submit a report on the investigations carried out in accordance with § 4, subsection 1 to the Danish Safety Technology Authority and the European Commission by no later than 18 months after the additive in question was added to the priority list mentioned in § 4, subsection 1.

Subsection 2. The European Commission and the Danish Safety Technology Authority may each independently request that the manufacturer and importer submit additional information in conjunction with the report mentioned in subsection 1, and may set requirements for the report to be subject to evaluation by an independent scientific body.

Subsection 3. The Danish Ministry of Industry, Business and Financial Affairs sets more specific rules on the submission of reports in accordance with subsection 1 and on formal requirements.

Subsection 4. The Danish Health Authority establishes more specific rules on evaluation in accordance with subsection 2.

§ 6. The Danish Safety Technology Authority publishes and continuously updates on its website the information, declarations, and reports received in accordance with § 3, subsection 1, no. 1, letter a, and no. 2, § 5, subsection 1, and rules established in accordance with § 3, subsection 2, cf. § 3, subsection 1, no. 1, letter a, and no. 2, and § 5, subsection 3. This does not, however, apply to information on operating or business conditions to the extent that it is of considerable economic significance to the person or company to which the information pertains that this information not be disclosed.

§ 7. Manufacturers and importers of tobacco products that are marketed in Denmark shall for the tobacco products that they market submit market analyses and studies drawn up in conjunction with the launch of the tobacco products to the Danish Safety Technology Authority.

Subsection 2. Manufacturers and importers of tobacco products that are marketed in Denmark shall for the tobacco products that they market report information on sales volumes for the prior year to the Danish Safety Technology Authority by no later than 01 May of every year.

Subsection 3. In order to monitor market development for tobacco products, the Danish Health Authority can obtain the information reported in accordance with subsection 1 to the Danish Safety Technology Authority.

Subsection 4. The Danish Ministry of Industry, Business and Financial Affairs sets more specific rules for the information that must be reported to the Danish Safety Technology Authority in accordance with subsections 1 and 2.

Chapter 3

Limit values for emissions content in tobacco products and methods for measurement of emissions content

§ 8. The Danish Ministry of Health sets rules on the limit values for maximum content of tar, nicotine, and carbon monoxide in emissions from cigarettes marketed or produced in Denmark.

Subsection 2. The Danish Ministry of Health may set rules on limit values for emissions other than those mentioned in subsection 1 and for emissions from tobacco products other than cigarettes.

§ 9. The Danish Ministry of Health sets rules on methods for measurement of emissions content of tar, nicotine, and carbon monoxide in cigarettes marketed or produced in Denmark.

Subsection 2. The Danish Ministry of Health may set rules on methods of measurement for emissions other than those mentioned in subsection 1, and from tobacco products other than cigarettes.

§ 10. The measurements mentioned in § 9 must be checked by laboratories approved by the Danish Safety Technology Authority in accordance with § 11.

Approval and inspection of laboratories for measurement of emissions content

§ 11. The Danish Safety Technology Authority may, upon application, approve laboratories to verify the measurements of emissions content of the tar, nicotine, and carbon monoxide in cigarettes marketed or produced in Denmark, cf. § 9.

Subsection 2. In order to be granted approval in accordance with subsection 1, the laboratory must be accredited by DANAK, the Danish Accreditation Foundation, or by an equivalent accreditation body that is a signatory of relevant EA multilateral agreements on mutual recognition to perform the tasks in accordance with subsection 1 and must be established in Denmark or another EU/EEA country.

Subsection 3. A laboratory seeking approval or that is approved according to subsection 1 may not be owned or indirectly controlled by the tobacco industry.

Subsection 4. The Danish Ministry of Industry, Business and Financial Affairs may set more specific rules on the processing of applications for approval in accordance with subsection 1 and the content of the accreditation according to subsection 2.

§ 12. The Safety Technology Authority conducts inspections to verify that the laboratories approved in accordance with § 11, subsection 1, fulfill the requirements in § 11, subsections 2 and 3.

Subsection 2. For the purpose of carrying out verification checks in accordance with subsection 1, the Danish Safety Technology Authority may require laboratories approved in accordance with § 11, subsection 1, to provide documentation that the requirements in § 11, subsections 2 and 3 are met.

Chapter 4

Prohibition on marketing certain tobacco products, etc.

§ 13. Tobacco ingested orally may not be marketed in Denmark.

§ 14. Cigarettes and rolling tobacco with a distinctive flavor may not be marketed in Denmark.

Subsection 2. The Danish Health Authority may set more specific rules on the prohibition in subsection 1, including rules on whether a given cigarette or type of rolling tobacco is covered by the prohibition in subsection 1, and on limit values for the content of cigarettes and rolling tobacco of additives or combinations of additives that provide a distinctive flavor.

§ 15. Cigarettes and rolling tobacco that contain flavoring substances in their components, such as filters, paper, packaging, capsules or any technical feature that makes it possible to modify the aroma or taste of the tobacco products in question or their smoke intensity may not be marketed in Denmark.

§ 16. Cigarettes and rolling tobacco, consisting of filter, paper or capsules containing tobacco or nicotine may not be marketed in Denmark.

§ 17. Tobacco products that contain the following additives may not be marketed in Denmark:

1) Vitamins or other additives that give the impression that a tobacco product presents a health benefit or constitutes a limited health risk.
2) Caffeine, taurine, or other additives and stimulant compounds.
3) Additives that have coloring properties for emissions.
4) Additives that have carcinogenic, mutagenic, or reproduction toxicity properties in non-combusted form.

Subsection 2. Smoking tobacco may not be marketed in Denmark if the tobacco product contains the additives mentioned in subsection 1 or additives that facilitate inhalation or nicotine uptake.

§ 18. Tobacco products that contain additives in volumes that upon consumption significantly or measurably increase the toxic or addictive effect or carcinogenic, mutagenic, or reproduction toxicity properties may not be marketed in Denmark.

Subsection 2. The Danish Health Authority may set more specific rules on the prohibition in subsection 1, including rules on whether a specific tobacco product is covered by the prohibition, and on limit values for the content in tobacco products of the additives mentioned in subsection 1.

Chapter 5

Health warnings on tobacco products, etc.

§ 19. Any party marketing a tobacco product in Denmark must ensure that each unit pack and any outer packaging features health warnings in Danish.

Subsection 2. The Danish Ministry of Health sets rules on

1) the quantity and type of health warnings that the individual category of tobacco products must bear,
2) the form, wording, layout, placement, and size of the health warnings, and
3) prohibition against partly of entirely concealing or breaking the health warnings when the tobacco product is marketed.

Chapter 6

Labeling and packaging of tobacco products, etc.

§ 20. Any party that markets a tobacco product in Denmark must ensure that each unit pack and any outer packaging does not contain elements or traits that

1) promote a tobacco product or encourage the use of it by giving a false impression of the product's characteristics, effects, risks, or emissions,
2) give the impression that a specific tobacco product is less harmful than others or are intended to reduce the impact of certain harmful constituents in the smoke,
3) give the impression that a specific tobacco product has vitalizing, energetic, healing, rejuvenating, natural, organic properties, or other positive properties or other positive effects on health or lifestyle,
4) refer to taste, aroma, flavorings or other additives or state that the product does not contain such,
5) cause the product to resemble a food product or a cosmetic product, or
6) give the impression that a specific tobacco product has improved biodegradability or other environmental benefits.

Subsection 2. Any party marketing a tobacco product in Denmark must ensure that a unit pack and any outer packaging is not labelled with information on the tobacco product's content of nicotine, tar, and carbon monoxide.

Subsection 3. The Danish Health Authority may establish more specific rules on requirements for labelling, cf. subsections 1 and 2.

§ 21. The Danish Health Authority sets more specific rules on requirements for size, form, functionality, and constituents with regard to unit packs of cigarettes and rolling tobacco.

§ 22. Any party marketing tobacco products in Denmark must ensure that each unit pack and any outer packaging does not contain coupons that offer rebates, free distribution, two-for-one offers or other similar offers.

§ 22 a. Any party marketing tobacco products in Denmark must ensure that each unit pack of tobacco products bears a unique identifier issued by the Danish ID issuers, cf. § 31 a.

Subsection 2. For tobacco products produced outside the EU, the requirements for unique identifiers only apply for products that are intended for or marketed in Denmark.

Subsection 3. Unique identifiers must be printed or applied in such a way that they cannot be removed or erased, and they must not be concealed or broken.

Subsection 4. Through a link to the unique identifier, the following information must be electronically available:

1) The actual route of shipment from the manufacturing site to the first retail outlet, including all storage facilities used, shipment date, destination, shipment location and recipient,
2) the identity of all buyers from production to the first retail outlet and
3) invoice, order number and payment information concerning all buyers from production to the first retail outlet.

Subsection 5. Tobacco product manufacturers must make equipment necessary for the registration of tobacco products purchased, sold, stored, transported or otherwise handled available for all economic operators involved in the trade of tobacco products. The equipment must be able to read and transfer the registered data electronically to a data storage facility that must be physically located within the territory of the European Union.

Subsection 6. An economic operator involved in trade in tobacco products may not change or delete data registered in the data storage facilities.

Subsection 7. An external auditor conducts inspections with suppliers of data storage facilities. The external auditor is paid by the tobacco product manufacturer and must upon proposal from the tobacco product manufacturer be approved by the European Commission.

Subsection 8. The European Commission, the Danish Safety Technology Authority and the external auditor must have full access to the data storage facilities. In duly justified cases, the European Commission or the Danish Safety Technology Authority may provide manufacturers or importers access to the stored data.

Subsection 9. The external auditor must submit an annual report to the Danish Safety Technology Authority and the European Commission.

§ 22 b. Any party marketing tobacco products in Denmark must ensure that each unit pack of tobacco products has a secure tax stamp applied.

Subsection 2. The Danish Ministry of Taxation may set more specific rules on the technical standards for the secure tax stamps on tobacco products.

Chapter 7

Cross-border distance sales

Duty to register tobacco products, etc.

§ 23. Any party seeking to market tobacco products to consumers in Denmark or in another EU/EEA country by means of cross-border distance sales must, before marketing starts, register with the Danish Safety Technology Authority. Marketing can only be started once the Danish Safety Technology Authority has confirmed that registration has taken place.

Subsection 2. The Danish Ministry of Industry, Business and Financial Affairs sets more specific rules on

1) the information that must accompany a registration in accordance with subsection 1,
2) duty to notify the Danish Safety Technology Authority if changes are made to this information, and
3) the Authority's processing of the registration.

§ 24. Retailers of tobacco products registered in accordance with § 23, subsection 1 must operate an age verification system.

Subsection 2. The Danish Ministry of Health sets more specific rules on the age verification system mentioned in subsection 1, including on the specific requirements for the system, and on the retailer's duty to provide the Danish Safety technology Authority information on the content and use of the system.

§ 25. The Danish Safety Technology Authority publishes and continuously updates on its website a list of retailers registered in accordance with § 23, subsection 1.

Chapter 8

Registration of novel tobacco products

§ 26. Novel tobacco products may only be marketed in Denmark if they are registered with the Danish Safety Technology Authority.

Subsection 2. The registration referred to in subsection 1 must be submitted by any manufacturer or importer that wishes to market a novel tobacco product, by no later than 6 months prior to the intended marketing.

Subsection 3. The Danish Ministry of Industry, Business and Financial Affairs sets rules on

1) the information and declarations that must accompany a notification in accordance with subsection 1,
2) duty to notify the Danish Safety Technology Authority if changes are made to this information, and
3) The Danish Safety Technology Authority's processing of the notification.

§ 27. The Danish Health Authority may establish rules on which of this Act's provisions apply for novel tobacco products, depending on whether it is smokeless tobacco or smoking tobacco.

Chapter 9

Marketing of herb-based smoking products

Reporting of information

§ 28. Manufacturers and importers marketing plant-based smoking products in Denmark must report information on product composition to the Danish Safety Technology Authority.

Subsection 2. The reporting in accordance with subsection 1 must take place before any new or modified herb-based smoking product is brought onto the market.

Subsection 3. The Danish Ministry of Industry, Business and Financial Affairs sets more specific rules on

1) the information that must be reported to the Danish Safety Technology Authority in accordance with subsection 1,
2) duty to notify the Danish Safety Technology Authority if changes are made to this information, and
3) The Danish Safety Technology Authority's processing of the reported information.

§ 29. The Danish Safety Technology Authority publishes and continuously updates on its website the information received in accordance with § 28, subsection 1, and rules established in accordance with § 28, subsection 3, no. 1, though not information on operating or business conditions, to the extent that it is of considerable economic significance for the person or company to which these disclosures pertain that this information not be made public.

Health warning and labelling

§ 30. Any party marketing an herb-based smoking product in Denmark must ensure that each unit pack and any outer packaging presents a health warning in Danish.

Subsection 2. The Danish Ministry of Health sets rules on the wording, placement, and size of the health warning.

§ 31. Any party marketing an herb-based smoking product in Denmark must ensure that unit packs and any outer packaging do not present indications that the product is free of additives, flavoring agents, nicotine, tar, or carbon monoxide or contains elements or features that

1) promote an herb-based smoking product or encourages its use by giving a false impression of the product's characteristics, effects, risks, or emissions,
2) give the impression that a specific herb-based smoking product is less harmful than others or is intended to reduce the impact of certain harmful elements in the smoke,
3) give the impression that a specific herb-based smoking product has vitalizing, energetic, healing, rejuvenating, natural or organic properties or other positive properties or other positive health or lifestyle effects, or
4) cause the product to resemble a food product or a cosmetic product.

Subsection 2. The Danish Health Authority may set more specific rules on the requirements mentioned in subsection 1 for the labelling of herb-based smoking products.

Chapter 9 a

Selection of ID issuers, issuing of unique identifiers and secure tax stamps

Unique identifiers

§ 31 a. The Danish Safety Technology Authority appoints an ID issuer that shall issue unique identifiers for tobacco products marketed in Denmark.

Subsection 2. The ID issuer can issue unique identifiers for tobacco products produced in Denmark and marketed in another EU country without requirements for national ID issuance and shall issue unique identifiers for tobacco products produced in Denmark and exported out of the EU.

Subsection 3. The ID issuer can require remuneration for operating expenses related to the issuance of unique identifiers, cf., however, subsection 4.

Subsection 4. The remuneration that the ID issuer sets and requires from the economic operators can only relate to the issue of unique identifiers. The remuneration must be non-discriminatory and reasonably proportionate to the number of unique identifiers issued to economic operators, depending on method of delivery.

Subsection 5. Decisions made by the ID issuer can be brought before the Danish Safety Technology Authority.

Secure tax stamps

§ 31 b. For tobacco products that are subject to an excise tax in accordance with the Act on Tobacco Excises Taxes, the Danish taxation/customs authorities issue secure tax stamps for unit packs of tobacco products that serve as both a tax stamp

according to the Act on Tobacco Excises Taxes and a secure tax stamp.

Subsection 2. For tobacco products that are subject to excise tax in accordance with the Act on Tobacco Excises Taxes or the Consumption Tax Act, but do not carry a secure tax stamp pursuant to the Act on Tobacco Excise Taxes, the Danish taxation/customs authorities issue secure tax stamps, without excise for unit packs, that serve as secure tax stamps.

Subsection 3. For the tobacco products not subject to excise, the Danish Customs/Tax Agency issues secure tax stamps without excise for unit packs that act as a secure tax stamp.

Chapter 10

Inspection activities of the Danish Safety Technology Authority and Danish taxation/customs authorities

§ 32. The Danish Safety Technology Authority conducts inspections to check compliance with the requirements in this act and in rules established in accordance with this act.

Subsection 2. The Danish Safety Technology Authority conducts inspections to check that unit packs of tobacco products bear unique identifiers and to check that the identifiers are printed or applied in accordance with § 22 a, subsection 3. The Danish Safety Technology Authority also conducts inspections of data integrity, cf. § 22 a, subsection 6 and 9. Furthermore, the Danish Safety Technology Authority conducts inspections to check that the ID issuer and supplier of devices to prevent tampering, and any subcontractors, are independent of the tobacco industry.

Subsection 3. The Danish Safety Technology Authority may require submission of all information from the ID issuer and suppliers of devices to prevent tampering and of any subcontractors necessary for the inspection in accordance with subsection 2.

Subsection 4. The Danish Safety Technology Authority may carry out basic search enquiries regarding all data stored in a primary data repository necessary for the inspection in accordance with subsection 2.

Subsection 5. The Danish Safety Technology Authority may require manufacturers, importers, distributors, and retailers of tobacco goods and herb-based smoking products to submit all information necessary for the inspection in accordance with subsection 1.

§ 32 a. The Danish taxation/customs authorities conduct inspections to check that unit packs of tobacco products have secure tax stamps applied, cf. § 31 b, subsections 1 and 2.

Subsection 2. The Danish taxation/customs authorities may require manufacturers, importers, distributors, and retailers of tobacco products and plant-based products to submit all information necessary for the inspection in accordance with subsection 1.

§ 33. The Danish Safety Technology Authority may, for purposes of inspection, cf. § 32, subsection 1, carry out registry integration of information from its own register and publicly available information collected from other public authorities.

Subsection 2. The Danish Safety Technology Authority may obtain information not publicly available from public authorities for the purpose of registry integration for inspection purposes, to the extent this is of essential importance for the inspection in accordance with § 32, subsections 1 and 2.

§ 34. To provide information for the purpose of carrying out the inspection in accordance with § 32, subsections 1 and 2, representatives from the Danish Safety Technology Authority have any time for, upon presentation of valid identification and without court order, access to the public and private property and facilities of manufacturers, importers, distributors, and retailers of tobacco products and herb-based smoking products. If necessary the police shall provide assistance to the Danish Safety Technology Authority for this purpose.

§ 35. The Danish Safety Technology Authority may, without payment and against a receipt, select tobacco products and herb-based smoking products from manufacturers, importers, distributors, and retailers of tobacco products and herb-based smoking products to be used in the inspection in accordance with § 32, subsections 1 and 2.

Subsection 2. The Danish Safety Technology Authority may carry out or have carried out a technical examination of tobacco products and herb-based smoking products selected in accordance with subsection 1.

Prohibition on marketing, etc.

§ 36. The Danish Safety Technology Authority may prohibit the marketing of tobacco products if

1) the product does not meet the requirements in § 10, § 19, subsection 1, or § 20, subsections 1 and 2, § 22 a, or in rules set in accordance with § 8, subsection 2, § 9, subsection 2, § 19, subsection 2, § 20, subsection 3, or § 21,
2) if reporting has not been conducted in accordance with § 3, subsection 1,
3) if a report on additives has not been drawn up and submitted or if supplemental information on these has not been provided in accordance with § 5, subsections 1 or 2,
4) if no submissions have been made in accordance with § 7, subsection 1, or if annual reports in accordance with § 7, subsection 2, or submissions or reports in accordance with § 7, subsection 4, have not been made, or
5) novel tobacco products are marketed in Denmark without being registered in accordance with § 26, subsection 1.

§ 37. The Danish Safety Authority may prohibit the marketing of herb-based smoking products if the products do not meet the requirements in § 30, subsection 1, or § 31, subsection 1, or rules established in accordance with § 30 subsection 2, or § 31, subsection 2, or if reporting has not been carried out per § 28, subsection 1.

§ 38. The Danish Safety Technology Authority may, in the instances presented in § 36, nos. 1-3 and 5, or § 37, or if the Danish Safety Technology Authority otherwise determines that the products constitute a serious risk to human health, order manufacturers, importers, distributors, and retailers of tobacco products and herb-based smoking products to withdraw such goods and products from the market or recall them from consumers.

§ 39. The Danish Safety Technology Authority may inform the public of the risk of tobacco products and herb-based smoking products when an order or injunction has been issued in accordance with § 36, 37, or 38.

Subsection 2. The Danish Safety Technology Authority does not, however, publish information on operating or business conditions, to the extent that it is of significant economic importance for the person or company to which the disclosures pertain that this information not be made public, unless publication is necessary to protect the health or safety of consumers.

§ 39 a. In accordance with Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical

standards for the establishment and operation of a tracing system for tobacco products, the Danish Safety Technology Authority may, in duly justified cases, deactivate an economic operator's

1) identification code, cf. article 15, subsection 4,
2) facility identification code, cf. article 17, subsection 4, or
3) machine identification code, cf. article 19, subsection 4.

Subsection 2. In the event of deactivation in accordance with subsection 1, either the economic operator, the operator of the first retail outlet, of the manufacturers and importers shall be notified of the deactivation.

Chapter 11

Digital communication

§ 40. The Danish Ministry of Industry, Business, and Financial Affairs may establish rules that written communication to and from the Danish Safety Technology Authority on conditions covered by this act or by rules established in accordance with this act must be carried out digitally.

Subsection 2. The Danish Ministry of Industry, Business, and Financial Affairs may establish more specific rules on digital communications, including on the use of specific IT systems, specific digital formats, and digital signatures, etc.

Subsection 3. A digital communication is considered to have arrived once it is accessible to the addressee of the communication.

Chapter 12

Appeals process

§ 41. The Danish Safety Technology Authority's decisions taken in accordance with this Act or rules established in accordance with this act cannot be brought before any other administrative authority.

Chapter 13

Costs and fees

§ 42. The Danish Safety Technology Authority pays costs for hearing of the independent advisory panel on the EU level mentioned in article 7, subsection 4, of Directive 2014/40/EU, for the purpose of determining whether a tobacco product is covered by the prohibition in § 44, subsection 1.

Subsection 2. The Danish Safety Technology Authority may require the costs referred to in subsection 1, to be refunded by the manufacturer or importer who wishes to market or markets the tobacco product in question covered by the prohibition in § 14, subsection 1, in Denmark.

§ 43. The Danish Safety Technology Authority collects fees to cover the Danish Safety Technology Authority's costs upon receipt of reports in accordance with § 3 evaluations in accordance with § 5, subsection 2, approval and inspection of laboratories, cf. § 11, subsection 1, and § 12, subsection 1, and registrations, cf. § 23, subsection 1, and the Danish Safety Technology Authority's inspection in accordance with §§ 32-39.

Subsection 2. The fee is collected by manufacturers and importers of tobacco products covered by the duty to report in § 3, subsection 1. The fee is allocated on the basis of the individual manufacturer's or importer's market share of the Danish market. The assessment of the individual manufacturer's or importer's market share is carried out on the basis of the tobacco excise reported to the Danish Taxation Agency.

Subsection 3. For the purpose of allocating the fee in accordance with subsection 1, the Danish Safety Technology Authority may obtain information not publicly available on the tobacco excise reported to the Danish Tax Agency.

Subsection 4. The Danish Ministry of Industry, Business, and Financial Affairs may establish more specific rules on exceptions from allocation of fines in accordance with subsection 2.

Subsection 5. The Danish Ministry of Industry, Business and Financial Affairs may set specific rules on the size and collection of fees in accordance with subsection 1.

§ 44. The Danish Safety Technology Authority collects a fee for notification in accordance with § 26, subsection 1, and for annual maintenance of the notification, and for reporting in accordance with § 28, subsection 1, and for annual maintenance of the reporting.

Subsection 2. The Danish Ministry of Industry, Business and Financial Affairs may set rules on exemptions from the collection of the fees mentioned in subsection 1.

Subsection 3. The Danish Ministry of Industry, Business and Financial Affairs may set specific rules on the size and collection of fees in accordance with subsection 1.

Chapter 14

Penalties

§ 45. Unless a higher penalty is imposed according to other legislation, fines shall be imposed on any party that

1) violates § 4, subsection 1, § 5, subsection 1, § 10, § 13, § 14, subsection 1, §§ 15-17, § 18, subsection 1, § 19, subsection 1, § 20, subsections 1 and 2, § 22 a, § 28, subsection 2, or § 30, subsection 1,
2) fails to comply with the duty to notify in § 26, subsection 1,
3) fails to comply with the duty to register in § 23, subsection 1,
4) violates an injunction issued according to §§ 36 or 37,
5) fails to comply with an injunction or an obligation to disclose based on § 3 subsection 1, § 5 subsection 2, § 7 § 28, subsection 1, § 32, subsections 3-5, or § 38,
6) violates the provisions on the obligations of economic operators, cf. articles 5, 10, 11, and 13, article 21, nos. 5 and 6, or articles 22, 23, or 32-34 in Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a tracing system for tobacco products,
7) violates the provisions on the obligations of manufacturers and importers, cf. articles 6-8, article 12, no. 2, article 18, article 21, nos. 1, 2, and 4, or Article 26, nos. 1-5, in Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a tracing system for tobacco products,
8) violates the provisions on the obligations of economic operators and operators of the first retail outlet, cf. article 14 or article 16, no. 2, in Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a tracing system for tobacco products,
9) violates the provisions on economic operators, apart from the obligations of manufacturers and importers, cf. article 12, no. 3, or article 29, no. 4, in Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a tracing system for tobacco products, or

10) violates the provision in article 36 of Commission Implementing Regulation (EU) 2018/574 of 15 December 2017 on technical standards for the establishment and operation of a tracing system for tobacco products regarding the use of secure means of communications and interoperability.

Subsection 2. In rules established in accordance with § 8, subsection 2, § 9, subsection 2, § 21 or § 30, subsection 2, a fine may be established for violation of the provisions in the rules.

Subsection 3. Companies etc. (legal entities) may be subject to criminal liability according to the rules in chapter 5 of the Penal Code.

Chapter 15

Entry into force and transitional provisions etc.

§ 46. This Act enters into force on 09 June 2016.

Subsection 2. For tobacco products ingested orally, and that are not intended to be smoked or chewed, that are produced or imported before 01 January 2016, § 13 is effective from 01 July 2016.

Subsection 3. For herb-based smoking products produced before 09 June 2016, the act is effective from 20 May 2017.

Subsection 4. For cigarettes and rolling tobacco with a distinctive flavor reaching a sales volume of 3% or more in the EU prior to 09 June 2016, § 14, subsection 1, and § 15 are effective as of 20 May 2020.

Subsection 5. The Act on the Manufacture, Presentation, and Sale of Tobacco Products, cf. Consolidation Act No. 1022 of 21 October 2008, is repealed, cf. however § 47, subsection 1.

Subsection 6. Rules set in accordance with the Act on the Manufacture, Presentation, and Sale of Tobacco Products, cf. Consolidation Act No. 1022 of 21 October 2008, remain in force until they are replaced by or repealed by rules established in accordance with this act.

§ 47. Tobacco products produced prior to 09 June 2016 can be marketed until 20 May 2017 in accordance with the previously applicable rules.

Subsection 2. For tobacco products marketed from 09 June 2016 that comply with the requirements of this Act and in rules established by the act, reporting is carried out in accordance with § 3, subsection 1, by no later than 20 November 2016.

§ 48. Any party that prior to 09 June 2016 has initiated activities covered by § 23, subsection 1, in accordance with the rules applicable to date and that wishes to continue these activities after this date shall by no later than 09 September 2016 register in accordance with § 23, subsection. 1.

§ 49. This act does not apply to the Faroe Islands or Greenland.

Act No. 86 of 30 January 2019 (Selection of ID issuers and issue of secure tax stamps and more stringent sanctions in the sale of tobacco to persons under 18 years of age) contains the following provision on entry into force:

§ 3

Subsection 1. § 1 of the act enters into force on 01 February 2019, cf. however, subsections 3 and 4.

Subsection 2. (Omitted)

Subsection 3. § 1, no. 3, of the act enters into force on 20 May 2019 for cigarettes and rolling tobacco produced in the EU or imported into the EU from 20 May 2019. For cigarettes and rolling tobacco that is produced in the EU or imported into the EU before 20 May 2019, § 1, no. 3, enters into force on 20 May 2020.

Subsection 4. § 1, no. 3, of the act enters into force on 20 May 2024 for tobacco products other than cigarettes and rolling tobacco that are produced in the EU or imported into the EU from 20 May 2024. For tobacco products other than cigarettes and rolling tobacco that are produced in the EU or imported into the EU before 20 May 2024, § 1, no. 3, enters into force on 20 May 2026.

Danish Ministry of Health, 26 August 2019

MAGNUS HEUNICKE

/ Anja Gade Andersen