Unofficial Translation

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Order on declarations of tobacco products and herbal products for smoking, and declarations of new categories of tobacco products etc.[1)]

Pursuant to § 3, clause 2, § 7, clause 4, § 11, clause 4, § 23, clause 2, § 26, clause 3, § 28, clause 3, § 40, clauses 1 and 2, § 43, clauses 4 and 5, and § 44, clauses 2 and 3, of Act no. 608 of the 7th of June 2016 on tobacco products etc. it is hereby decreed that:

Chapter 1

Area of application

§ 1. This Order contains regulations regarding declarations of tobacco products, annual reports, applications for the licensing of laboratories and the content of accreditation certificates, registration in the case of cross border distance selling, declarations of new categories of tobacco products, declarations, of herbal products for smoking and fees.

Chapter 2

Declaration of tobacco products

§ 2. Declarations of the ingredients of tobacco products and emission contents, cf. the Act's § 3, clause 1, shall contain the information set out in Appendix 1.

Clause 2. In the case of any change in the tobacco product in a way that affects the product declaration as per clause 1, a new declaration must be compiled in accordance with clause 1.

Clause 3. Marketing of new, or altered, tobacco products may only commence when a product declaration is submitted in accordance with clause 1.

§ 3. The product declaration, cf. § 2, clause 1, is submitted digitally via Central Entry Gate.

Clause 2. In order to use the system referred to in clause 1, an application must be made for an ID number (Report ID) the first time the system is used. The application for this is made via the system, and the ID number is generated by the system operator.

Clause 3. The manufacturer, or the importer, shall on request submit a document that identifies the relevant company and describes the activity areas in which the company is involved.

§ 4. Manufacturers and importers give every single product covered by the product declaration legislation a tobacco product ID (a TP-ID).

Clause 2. When, in relation to the product declaration, information is submitted for products that have the same composition, design and appearance, manufacturers and importers shall, as far as possible, use the same tobacco product-ID, especially if the details are supplied by different staff members of the same group of companies. This applies regardless of trade mark, product name and the number of markets in which the relevant items are being marketed, see however clause 3.

Clause 3. Where the manufacturer or importer cannot guarantee that the same tobacco product-ID is or will be used for products with the same composition and design, they must as far as possible, and as a minimum, submit the different tobacco product IDs that have been used for the products in question.

§ 5. On the submission of a product declaration via Central Entry Gate, the manufacturer and importer shall mark all those details they deem to be commercial secrets or otherwise confidential. On request, an explanation shall be provided as to why the details in question are regarded as commercial secrets or otherwise confidential.

Clause 2. In relation to the Commission's use of details from product declarations lodged in the system, the following information is seen in principle as not being a commercial secret or confidential:

1) The addition and amount of additives, apart from flavoring, in all tobacco products.
2) The addition and amount of ingredients, apart from additives used in volumes above 0.5 % of the tobacco product's combined unit weight, in all tobacco products.
3) The addition and amount of every single flavoring used in volumes above 0.1% of the tobacco product's combined unit weight in cigarettes and rolling tobacco.
4) The addition and amount of every single flavoring used in volumes above 0.5 % of the tobacco product's combined unit weight, in pipe tobacco, cigars, cigarillos, smoke-free tobacco products and all other tobacco products.
5) Studies and information submitted as per the Act's § 3, clause 1 no. 1, schedules d and e, and also no. 3, especially relating to toxicity and addictive properties. Where such studies relate to specific brands, explicit and implicit references to the relevant brand shall be removed, and the edited version made accessible.

Chapter 3

Declaration details

§ 6. Reporting of market analysis reports and studies, cf. the Act's § 7, clause 1, shall cover internal and external studies, to which, the manufacturer or importer has access, in the form of market analysis reports and studies of various consumer groups, including the preferences of young people and existing smokers where these refer to ingredients and emissions, and also, outlines of any relevant market research the manufacturer or importer carries out as part of the launch of new products.

§ 7. Reporting of sales volume details, cf. the Act's § 7, clause 2, shall cover the sales volume per brand and type, given in the number of cigarettes, cigars or cigarillos, or in kg., and per member state, with a start date of the 1st of January 2015.

§ 3. Product declarations, cf. § 6 and 7, are submitted digitally via Central Entry Gate.

Chapter 4

Licensing of laboratories for the measurement of emission contents

§ 9. Applications for authorization to check the measurements of emission content for tar, nicotine and carbon monoxide in cigarettes, cf. the Act's § 11, clause 1, are submitted digitally to the Danish Safety Technology Authority using a form available at the industry portal Virk.dk (www.virk.dk), or the Quick Counter or the One-Stop-Shop (www.businessindenmark.dk).

Clause 2. An accreditation certificate shall be attached to the application, which verifies that the laboratory in question is accredited as per DS/EN ISO/IEC 17025 for the sampling and assessment of test results as per ISO 8243 and for the measurement of emission content for tar in cigarettes as per ISO 4387, nicotine as per ISO 10315 and carbon monoxide as per ISO 8454.

§ 10. When the Danish Safety Technology Authority receives an application, cf. § 9, the Authority issues a receipt to the applying laboratory with details of the following:

1) The deadline for the notification of a decision on licensing.
2) That the applicant can regard licensing as notified, if the Danish Safety Technology Authority has not reached a decision within the deadline, cf. § 11, clause 3.
3) Appeal options

Kapitel 7

§ 11. The Danish Safety Technology Authority shall reach a decision on licensing no later than 60 days after receipt of the application and all necessary documentation, cf. however clause 2.

Clause 2. The deadline in clause 1 can be extended once only, if the complexity of the case warrants it. The Danish Safety Technology Authority shall, within the expiry of the deadline in clause 1, give the grounds for the extension to the applying laboratory and give the new deadline for when a decision will be reached.

Clause 3. If the Danish Safety Technology Authority has not reached a decision within the expiry of all deadlines as per clauses 1 and 2, licensing can be deemed to be notified.

Clause 4. The Danish Safety Technology Authority supplies the Commission with a list of licensed laboratories. The Commission publishes this list.

Chapter 5

Duty of registration of cross border distance selling.

§ 12. Registration of the marketing of cross border distance selling, cf. the Act's § 23, clause 1, shall contain the following information:

1) The name or company name and permanent address of the business location from which the tobacco products will be sent.
2) The date for when the retail sales location began to offer tobacco products to consumers by distance selling using information society service systems, as defined in article 1, no. 2, of the European Parliament's and Council directive 98/34/EU on information procedures relating to technical standards and regulations, as well as regulations for information society services as amended by directive 98/48/EU.
3) The address of the website(s) used for the relevant purpose and all other relevant details necessary for identifying the website correctly.

Clause 2. Any changes to the details mentioned in clause 1 shall be reported to the Danish Safety Technology Authority.

§ 13. Registration, cf. clause 1, and reports of changes, cf. clause 2, shall be carried out digitally via the industry portal Virk.dk (www.virk.dk.) or the One-Stop-Shop (www.businessindenmark.dk).

Chapter 6

Declarations of new categories of tobacco products

§ 14. Declarations of new categories of tobacco products, cf. the Act's § 26, clause 1, shall contain the following:

1) A detailed declaration of the relevant new category of tobacco product.
2) A user guide.
3) Information as set out in the Act's § 3, clause 1.
4) Existing scientific studies of the toxicity, addictive characteristics, properties, and attractiveness of the new category of tobacco product, in particular regarding its ingredients and emissions.
5) Existing studies, outlines thereof, and market analysis reports regarding the preferences of various consumer groups, including young people and existing smokers.
6) Other available and relevant information, including a risk and advantage analysis of the product; its anticipated impact with regard to the number of people who stop consuming tobacco; its anticipated impact with regard to the number of people that take up tobacco consumption, and the anticipated views of consumers vis-à-vis the product.

Clause 2. The declaration will be deemed to have been received when the fee, as per § 19, clause 1, has been paid.

Clause 3. When the Danish Safety Technology Authority has reviewed the declaration, a confirmation of correct notification will be issued.

Kapitel 7

§ 15. Anmeldelsen, jf. § 14, stk. 1, foretages digitalt via www.sik.dk.

Herbal products for smoking

§ 16. Product declarations, f. the Act's § 28, clause 1, shall include a list of all the ingredients, and the amounts thereof, that are used in the production of such products, categorized according to brand name and type.

Clause 2. Those who market herbal products for smoking in this country are obliged to give notification of any changes to details as stated in clause 1.

Clause 3. The product declaration will be deemed to have been received when the fee, as per § 19, clause 1, has been paid

§ 17. The product declaration, cf. § 16, clause 1, and reports of changes, cf. § 16, clause 2, shall be carried out digitally via www.sik.

Chapter 8

Fees

§ 18. The Danish Safety Technology Authority demands fees from manufacturers and importers of tobacco products, cf. the Act's § 43, clause 1, cf. however clause 3. In 2016 the overall amount of fee to be distributed amongst manufacturers and importers, cf. the Act's § 43, clause 2, runs to 9.0 Mill.

Clause 2. The fees are collected twice yearly. Thus, a partial payment is collected as of 30. June each year, just as a final account balance and fee collection takes place on the 31st December every year.

Clause 3. Any fee amounts of DKK 100 or lower are not demanded.

Clause 4. If subsequent changes are made to the tobacco duty, used as the basis for assessment of the market share pertaining to manufacturers and importers and therefore the fee charged, any necessary adjustments thereof will be made in the year the TAXATION AUTHORITY makes its own adjustments

§ 19. Manufacturers and importers shall pay a fee of DKK 36,900 per. product for the declaration of a new category of tobacco product, as per § 14, clause 1, and product declarations for herbal products for smoking as per § 16, clause 1, and a fee of DKK 14,700 per product for the annual maintenance of each relevant declaration, cf. however clauses 2 and 3.

Clause 2. Products for which a product declaration or brand maintenance fee has already been paid by another manufacturer or importer are exempted from fee payment, as per clause 1. The exemption only applies for those periods when the other manufacturer or importer pays the fee.

Clause 3. In those instances, where a new category of tobacco product, following a period on the market, becomes subject to tobacco duty regulations and thereby the fees as per § 18, the relevant tobacco product is exempt from the brand maintenance fee.

§ 20. Gebyrer efter § 19, stk. 1, indbetales til Sikkerhedsstyrelsen på www.sik.dk.

Clause 2. The fee for product declaration, information submission, cf. § 19, clause 1, is paid in relation to the declaration or information submission.

Clause 3. The fee for the maintenance of the product declaration or information submission, cf. § 19, clause 1, is paid once a year and falls due for payment every year on the date that:

1) confirmation of a correct declaration was issued as per § 14, clause 3, or
2) product information submission occurred as per § 16, clause 1.

Chapter 9

Coming into force

§ 21. This Order comes into force the 9th of June 2016.

Ministry of Business and Growth, Denmark, the 7th of June 2016

TROELS LUND POULSEN

/ Lone Saaby

[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, p. 1, The Commission's implementation ruling (EU) 2015/2186 of 25th of November 2015 on the standard format for use in the product declaration and making details of tobacco products available, Official Journal of the European Union 2015, no. L 312, p. 5, and parts of The European Parliament's and Council directive 2006/123/EU of 12th of December 2006 on services in the internal market, Official Journal of the European Union 2006, no. L 376, p. 36.