Unofficial Translation

Legislation Bulletin

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Order on declaration of electronic cigarettes and refill containers etc..[1)]

Pursuant to § 5, clause 3, § 10, clause 2, § 12, clause 3, § 13, clause 2 and clause 3, 2. pt., § 30, clauses 1and 2, and § 32, clauses 2 and 3, of Act no. 426 of 18th of. May 2016 regarding electronic cigarettes etc. the following is hereby decreed:

Chapter 1

Area of application

§ 1. This Order contains regulations covering product declaration; systems for the collection of data on all assumed effects that are harmful to health; annual submission of data; registration of cross border distance selling and fees for electronic cigarettes and refill containers containing nicotine.

Chapter 2

Product Declaration

§ 2. Declarations of electronic cigarettes and refill containers containing nicotine, cf. the Act's § 5, clause 1, shall contain the information set out in Appendix 1.

Clause 2. The declaration will be deemed to have been received when the fee, as per § 12, 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.

§ 3. In the case of every significant alteration in previously declared electronic cigarettes or refill containers containing nicotine, a new declaration shall be made as per § 2.

Clause 2. In any assessment of whether a significant alteration of the electronic cigarette or refill container has occurred, cf. clause 1, emphasis is placed on any change in the volume or composition of liquids, changes in the electronic structure and function of the electronic cigarette etc.

§ 4. 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.

§ 5. Manufacturers and importers give every single product to be declared an e-cigarette ID (EC-ID).

Clause 2. When, in relation to the product description, information is submitted for products that have the same composition, design and appearance, manufacturers and importers shall, as far as possible, use the same e-cigarette 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 e-cigarette 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 e-cigarette IDs that have been used for the products in question.

§ 5. On the submission of a product description 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 descriptions lodged in the system, the following information is seen in principle as not being a commercial secret or confidential.

1) Ingredients used in volumes of over 0.1 % of the fully formulated liquid.

[1)] The Order implements parts of the European Parliament's and Council's directive 2014/40/EU of 3rd of April 2014 on mutual harmonisation of members 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, p. 1, and The Commission's implementation ruling (EU) 2015/2183 of 24. November 2015 on a common, format for use at, by, in the case of product declarations for electronic cigarettes and refill containers, Official Journal of the European Union, 2015, no. L 309, p. 15.

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2) Studies and data submitted as per § 2, clause.1, 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

System for the collection of data on any assumed harmful effects to health

§ 7. Manufacturers, importers and distributors of electronic cigarettes and refill containers containing nicotine shall ensure that the details in the system for the collection of information of all assumed harmful effects to health for relevant products, cf. the Act's § 10, clause 1, are up to date.

Clause 2. The system shall be documented in the form of a user manual or collection of documents that in a systematic and transparent way sets out the information described in clause 1. The documentation may be stored on paper or electronically.

Chapter 4

Annual product report

§ 8. The annual product description, cf. the Act's § 12, clause 1, shall, contain details of sales volume, consumer group preferences, sales channels and any available summaries of market surveys for the previous year.

Clause 2. Details of sales volume, cf. clause 1, shall be comprehensive and categorised according to brand name and product type.

Clause 3. Information on the various consumer groups' preferences, cf. clause 1, shall contain details of the preferences of young people, non-smokers and current primary consumer groups.

Clause 4. Summaries of any relevant market research carried out in relation to points made in clause 1 shall be in English, or an English translation of same must be available.

§ 9. Details, cf.§ 8, shall be submitted digitally via Central Entry Gate.

Chapter 5

Duty of registration of cross border distance selling.

§ 10. Registration of the marketing of cross border distance selling, cf. the Act's § 13, clause 1, shall contain the following information:

1) The name or company name and fixed address of the business location from which the electronic cigarettes or refill containers containing nicotine will be sent.
2) The date when the retail sales location began to offer electronic cigarettes and refill containers containing nicotine 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.

§ 11. Registration, cf. clause § 10, clause 1, and reports of changes, cf. § 10, clause 2, shall be done using a form on the industry portal Virk.dk (www.virk.dk) or The One-Stop-Shop (www.businessindenmark.dk).

Chapter 6

Fees

§ 12. Manufacturers and importers shall pay a fee of DKK 36,900 per. product for the declaration of a product, as per § 2, clause 1, and a fee of DKK 14,700 per product for the annual maintenance of each relevant declaration, cf. however clause 2.

Clause 2. The following are exempted from fees, as per clause 1:

1) Batteries.
2) Mouthpieces
3) Products that have already had their production declaration or brand maintenance paid for by another manufacturer or importer. The exemption only applies for those periods when the other manufacturer or importer pays the fee.

Clause 3. Once a year; the first time on the 1st of October 2016 , the Safety Authority carries out evaluation to see whether fee rates should be adjusted in order to ensure a balance between fee incomes and costs relating to the Authority's checking systems.

§ 13. Fees, as per § 12, clause 1, are paid to the Authority- styrelsen på www.sik.dk.

Clause 2. The product declaration fee, cf. § 12, clause 1, is paid at the time of the declaration.

Clause 3. The fee for the maintenance of the product declaration, cf. § 12, clause 1, is paid once a year and falls due for payment every years on the date confirmation of correct receipt of a declaration was issued, as per § 2, clause 3.

Chapter 7

Coming into force

§ 14. This order comes into force on the 7th of June 2016

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

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/ Lone Saab